S. Hrg. 103–601

FEDERAL REGULATION OF MEDICAL RADIATION USES

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

MAY 6, 1993

Printed for the use of the Committee on Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

68–495 cc WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-044575-2

S. Hrg. 103–601

FEDERAL REGULATION OF MEDICAL RADIATION USES

HEARING

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

MAY 6, 1993

Printed for the use of the Committee on Governmental Affairs

U.S. GOVERNMENT PRINTING OFFICE

68–495 cc WASHINGTON : 1994

For sale by the U.S. Government Printing Office
Superintendent of Documents, Congressional Sales Office, Washington, DC 20402
ISBN 0-16-044575-2

COMMITTEE ON GOVERNMENTAL AFFAIRS

JOHN GLENN, Ohio, *Chairman*

SAM NUNN, Georgia
CARL LEVIN, Michigan
JIM SASSER, Tennessee
DAVID PRYOR, Arkansas
JOSEPH I. LIEBERMAN, Connecticut
DANIEL K. AKAKA, Hawaii
BYRON L. DORGAN, North Dakota

WILLIAM V. ROTH, JR., Delaware
TED STEVENS, Alaska
WILLIAM S. COHEN, Maine
THAD COCHRAN, Mississippi
JOHN McCAIN, Arizona

Leonard Weiss, *Staff Director*
Robert Alvarez, *Professional Staff Member*
Christopher R. Kline, *Professional Staff Member*
Franklin G. Polk, *Minority Staff Director and Chief Counsel*
Michal Sue Prosser, *Chief Clerk*

CONTENTS

WITNESSES

THURSDAY, MAY 6, 1993

ALPHABETICAL LIST OF WITNESSES

APPENDIX

FEDERAL REGULATION OF MEDICAL RADIATION USES

THURSDAY, MAY 6, 1993

U.S. SENATE,
COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Committee met, pursuant to notice, at 9:38 a.m., in room SD–342, Dirksen Senate Office Building. Hon. John Glenn, Chairman of the Committee, presiding.

Present: Senators Glenn and Lieberman.

OPENING STATEMENT OF CHAIRMAN GLENN

Chairman GLENN. The hearing will be in order.

For a number of years, the Governmental Affairs Committee has maintained an interest in the subject of medical radiation. Our interest in this issue goes back a long way; and I am glad we are back on this subject again, because there is a strong need for continued Congressional oversight.

There is little question that medical uses of radiation provide significant benefits and have led to important medical discoveries. Every year, many people lead better and more healthy lives because of this valuable medical tool.

However, it has been known for decades that medical radiation misuse also poses risks of injury, latent disease and death, not only to the patient but to the health care and research professional as well as the community at large.

A recent accident that took place at a clinic in Indiana, Pennsylvania late last year is a case in point. A patient died after a highly radioactive source was accidentally left inside her body. The source subsequently exposed unwitting workers and residents to radiation doses that significantly exceed the annual limit allowed for workers in the U.S. The radiation source also posed a potential environmental risk because it was almost disposed of in a private landfill.

Over the past several years, the uses of ionizing radiation in medicine have experienced major growth. Various studies now indicate—or, estimate—that over 170 million diagnostic radiation procedures and some 20 million radiation therapy procedures are given each year in the United States. The estimated annual cost for these procedures is about $12.3 billion.

With the recent dramatic growth in medical radiation use over recent years, major questions have been raised as to whether Federal and State regulation provides an adequate margin of protection of public health and the rights of those who may be put at

risk. It is abundantly clear that if people become ill, they or their families should not relinquish the basic right to know if unnecessary harm has been done to them. Unfortunately, the Nuclear Regulatory Commission and the Food and Drug Administration have not taken action to assure that this basic right is guaranteed.

The Committee has been reviewing the role of Federal and State agencies that regulate medical radiation uses for a long time, and this review goes way back; it goes back into the seventies. In the seventies, we had hearings, and I proposed legislation and a bill that would have coordinated some of these activities and brought a little more sense to them. At that time, President Carter sort of preempted us, which was fine with me, by issuing an Executive order, which did the same thing basically I was going to do with the bill. After the change of administration, President Reagan cancelled that Executive order. So that is where we now sit.

We have had a Coordinating Council on Ionizing Radiation, but I think many would question whether their activities have been as forceful and effective as they should have been.

So we have been reviewing these regulations for a long time. The review was initiated after several disturbing disclosures were made in the news media about patient deaths, injuries and overexposures. Particularly the hearing today was triggered by a series of articles beginning in December of last year, published by the Cleveland *Plain Dealer*. I think *Plain Dealer* reporters Ted Wendling and Dave Davis, I think have done an excellent job, and their pointing out some of these matters to us is why we are here today. We are glad to have Ted with us this morning over at the press table.

I am pleased that the NRC has taken their reporting seriously and is starting to address some of the problems identified by the *Plain Dealer*.

During this period, the Committee has been contacted by several people who have written about serious problems they experienced from radiation procedures. The Committee is in no position to determine the merits of these problems; however, I am submitting copies of these letters to the NRC and the Food and Drug Administration for their determination of whether any misadministrations took place. I expect the two agencies to report to the Committee about these disturbing letters.

Assuring the safe and effective use of radiation in medicine involves a complicated web of relationships between the patient, medical professionals, equipment manufacturers, health care and research facilities, and various State and Federal regulatory programs. With a few important exceptions, a great deal of medical radiation regulation relies on the voluntary reporting of problems. And as we know, not everybody is forthcoming enough to make that system work.

Unfortunately, despite past scrutiny and recommendations by this Committee and others, medical radiation regulation is scattered, fragmented, and very inconsistent. Several Federal agencies in all 50 States have regulatory responsibility, but not the programs to follow up on that responsibility. States have varying and different programs which lack conformity with each other. One-third of the population of the United States lives in States—includ-

ing my home State of Ohio, I am sorry to say—that do not require people who operate radiation devices to be trained and certified. It was pointed out in the *Plain Dealer* articles that people with felony convictions for medical radiation violations in one State can move over to another State and serve as radiation protection officials in other States, because they are not likely to be discovered. In the reporting, there were two cases exactly like that.

Let me just give some short examples to illustrate how complex this is. There are 27 States that license radiographers; 21 States license radiation therapy technologists; 14 States license nuclear medicine technologists; three additional States have legislation permitting regulation of radiographers; five States have legislation authorizing regulation of radiation therapy technologists; four States have enabling legislation authorizing regulation of nuclear medicine technologists. All States continue to license dental hygienists. Of the 50 States permitting dental assistants to perform radiographs, one State licenses, 29 States certify, and two States register dental assistants. Now, that indicates how complex it is and how the regulation goes all over the lot.

I would like to acknowledge the efforts of Senator Lieberman, who is with us here this morning, in ensuring that the NRC fully and thoroughly investigated allegations of safety and wrongdoing by NRC licensees—for example, Senator Lieberman's diligence in oversight of the NRC and the work of the NRC's Office of Inspector General, which this Committee created. The OIG review resulted in a reinspection and validation of a number of allegations raised by Connecticut citizen Mr. Arnold Gunderson, which originally were missed by a faulty NRC inspection.

After today's testimony, I will review the situation, and I may consider the need for legislation to address some of these problems, because obviously, something must be done. I don't know whether it will be the same legislation I introduced back in the Carter years, whether something new is necessary, or whether this administration will go ahead and take action on their own, or whether NRC and FDA can in their testimony this morning give us some ideas about what direction we should go. They are the people who should be on the firing line, so I would welcome their suggestions, and we'll have some questions along that line after we hear testimony.

A number of people have died from overuse of radiation. I think there were 28 deaths in my home State of Ohio back through the years that can be directly traced to some of these misadministration of radiation. So while we are interested in seeing what happened and why people were not notified, we are even more interested in seeing how we can prevent this in the future and how we can tighten up this system so that the people of this country are adequately protected, and that's the purpose of today's hearing.

PREPARED STATEMENT OF SENATOR GLENN

Over the past several years, the Governmental Affairs Committee has maintained an interest in the subject of medical radiation. There is little question that medical uses of radiation provide significant benefits and have led to important medical discoveries. Every year, many people lead better and more healthy lives because of this valuable medical tool.

However, it has been known for decades that medical radiation misuse also poses risks of injury, latent disease and death, not only to the patient, but to the health care and research professional as well as the community at large. A recent accident that took place at a clinic in Indiana, Pennsylvania late last year is a case in point. A patient died after a highly radioactive source was accidently left inside her body. The source subsequently exposed unwitting workers and residents to radiation doses that significantly exceed the annual limit allowed for workers in the U.S. The radioactive source also posed a potential environmental risk because it was almost disposed of in a private landfill.

Over the past several years the uses of ionizing radiation in medicine have experienced major growth. Various studies indicate that over 170 million diagnostic radiation procedures and some 20 million radiation therapy procedures are given each year in the U.S. The estimated annual cost for these procedures is about $12.3 billion.

With the recent dramatic growth in medical radiation use over recent years, major questions have been raised as to whether Federal and state regulation provides an adequate margin of protection of public health and the rights of those who may be put at risk. It's abundantly clear that if people become ill, they or their families should not relinquish the basic right to know if unnecessary harm has been done to them. Unfortunately, the Nuclear Regulatory Commission and the Food and Drug Administration have not assured that this basic right is guaranteed.

The Committee on Governmental Affairs has been reviewing the role of Federal and state agencies that regulate medical radiation uses. This review was initiated after several disturbing disclosures were made in the news media about patient deaths, injuries and overexposures—particularly a series of articles beginning in December of last year published by the *Cleveland Plain Dealer*. The *Plain Dealer* reporters, Ted Wendling and Dave Davis, have done a commendable job. I am pleased that the NRC has taken their reporting seriously and is starting to address some of the problems identified by the *Plain Dealer*.

During this period, the Committee has been contacted by several people who have written about serious problems they experienced from radiation procedures. The Committee is in no position to determine the merits of these problems. However, I am submitting copies of these letters to the Nuclear Regulatory Commission and the Food and Drug Administration for their determination if any misadministrations took place. I expect the two agencies to report to the Committee about these disturbing letters.

Assuring the safe and effective use of radiation in medicine involves a complicated web of relationships between the patient, medical professionals, equipment manufacturers, health care and research facilities, and various state and Federal regulatory programs. With a few important exceptions, a great deal of medical radiation regulation relies on the voluntary reporting of problems. And as we know, not everybody is forthcoming.

Unfortunately, despite past scrutiny and recommendations by this Committee and others, medical radiation regulation is scattered, fragmented and inconsistent. Several Federal agencies and all 50 states have regulatory responsibility. States have varying and different programs which lack conformity with each other. One third of the population of the U.S. lives in states, including my home state of Ohio, that do not require people who operate radiation devices to be trained and certified. People with felony convictions for medical radiation violations in one state, can serve as radiation protection officials in other states.

I would like to acknowledge the efforts of Senator Lieberman in ensuring that that the NRC fully and thoroughly investigated allegations of safety and wrongdoing by NRC licensees. For example, Senator Lieberman's diligence in oversight of the NRC and the work of the NRC's Office of Inspector General which this committee created. The OIG review resulted in a re-inspection and validation of a number of allegations raised by Mr. Arnold Gunderson which originally were missed due to a faulty NRC inspection.

After hearing today's testimony, I will review this situation and I may consider the need for legislation to address some of these problems.

I welcome today's witnesses and thank them for appearing for this important hearing.

Senator Lieberman?

OPENING STATEMENT OF SENATOR LIEBERMAN

Senator LIEBERMAN. Thank you very much, Mr. Chairman.

I want to express my appreciation to you for conducting this hearing this morning on the Federal regulation of the medical uses of radiation, which is, as your statement has indicated, a very important issue affecting the health and the health care of millions of Americans.

I understand that this hearing will look at the regulation of the medical uses of radiation by the Nuclear Regulatory Commission, the Food and Drug Administration, and the various States.

One major issue that I hope the witnesses will address is how well these various regulatory bodies are coordinating their efforts; are there any gaps, or inconsistencies, or duplications in the current regulations? If so, how can these gaps be filled, and how can these duplications be eliminated?

Mr. Chairman, I am particularly interested in this matter from my perspective as chair of the Subcommittee on Clean Air and Nuclear Regulation of the Committee on Environment and Public Works. In that capacity, I have recently been examining a related matter, which is the NRC's enforcement practices and policies for nuclear power reactors and for nuclear materials licensees. As you have indicated in your statement, with respect to one of those issues that I have been following, this Committee today is distributing two reports prepared by the NRC's Office of Inspector General which address allegations by a Connecticut resident, Arnold Gunderson, concerning the actions of the NRC staff.

The first of these reports concerns allegations by Mr. Gunderson that the NRC staff conducted a faulty inspection of his original allegations regarding the practices of a nuclear materials licensee, a private company licensed by the Government, called Nuclear Energy Services, or NES. The NRC's first investigation, the staff investigation of Mr. Gunderson's allegations, found no violations.

Mr. Gunderson then contacted my office, presenting us with allegations that the original inspection was faulty, and we passed those on to the NRC. The NRC Inspector General independently began an investigation of the NRC staff's original inspection. Then, the NRC staff, to its credit, reinvestigated Mr. Gunderson's original allegations and found seven violations.

The second report which this Committee is releasing today concerns allegations also made by Mr. Gunderson that the NRC staff in one particular region, Region III, did not maintain an appropriate arm's-length relationship with personnel from Nuclear Energy Services, this private company, licensee. The report highlighted several practices in Region III, such as the sharing of expenses for meals and informal referrals of business, to the private company, NES, by the NRC personnel that gave the appearance that the NRC staff in Region III was not maintaining a proper regulatory relationship with the personnel of this private company.

Mr. Chairman, I have requested that the NRC's Inspector General report on the NRC's actions to correct the deficiencies that led to the faulty inspection of Mr. Gunderson's original applications, and I am also working through my subcommittee to monitor the NRC's response to the Inspector General's second report, to make sure that the Commission establishes clear policies and procedures for its personnel at the regional level and nationally, to maintain an appropriate arm's-length relationship with its licensees.

In response to the NRC's handling of the original Gunderson allegations and other whistleblower issues that have been brought to my attention as chairman of this subcommittee, I have requested the NRC's Inspector General to conduct a comprehensive review of the way in which the Commission is handling whistleblower complaints. The IG will in fact be looking at questions such as whether NRC personnel are too trusting of statements made to their own inspectors, made to themselves, by some of the licensees; whether the NRC adequately protects the confidentiality of whistleblowers who make allegations to the NRC, and whether the NRC discourages whistleblowers by taking too long to investigate their allegations.

I do all this and ask for this investigation not so much in the spirit of accusation with the Commission, but in the spirit of cooperation and attempting to work together to enable the Commission to fully perform the considerable responsibilities which we have given them by law, and to keep vital the whistleblower function, which is one of our best allies, I suppose, our frontline defense against misuse of the peaceful uses of nuclear energy, including those that you will be investigating today.

Mr. Chairman, I realize that the NRC's handling of these whistleblower complaints is not the focus of this hearing, which is on the regulation of the uses of radiation for medical purposes, but I see it as a related matter, and since the Committee is issuing those two reports, I wanted to indicate here for the record two things. One is that I hope to continue to follow these problems from the Subcommittee on Clean Air and Nuclear Regulation, and second, that I certainly do look forward to working with you, Mr. Chairman, in responding to the specific problem of the medical uses of nuclear energy and the extent to which we should better regulate them.

Mr. Chairman, that concludes my statement. I apologize to you and the witnesses that the lottery has worked against my interest here, and I must preside in the Senate at 10:00, but I look forward to reading the testimony of the witnesses later in the day.

Thank you.

Chairman GLENN. Thank you very much.

Our first panel this morning will be the Nuclear Regulatory Commission—Ivan Selin, Chairman; Kenneth C. Rogers, James Curtiss, Forrest Remick, and Gail de Planque.

Mr. Chairman, if you'd lead off for us, we'd appreciate it very much.

I would say to all of our witnesses this morning that if you have lengthy statements, we would appreciate an abridgement thereof. Your entire statements will be included in the record as though delivered; if you prefer to give the whole statement, that's fine, also. We'll leave it up to you.

Mr. Selin, we are happy to have you with us.

TESTIMONY OF IVAN SELIN,[1] CHAIRMAN, U.S. NUCLEAR REGULATORY COMMISSION, ACCOMPANIED BY KENNETH C. ROGERS, JAMES R. CURTISS, FORREST J. REMICK, AND E. GAIL DE PLANQUE, COMMISSIONERS

Mr. SELIN. Thank you very much, Mr. Chairman. Our written statement, of course, is not lengthy, but I will summarize.

It is a pleasure for the Commission to be here. First of all, I'd like to say that we certainly identify and accept the thrust of your opening remarks. I'll address some of the specific points you raised, and since I am not sure Senator Lieberman will be around at the end of my statement, I would like to say that as far as his remarks about the allegers in specific and the use of the IG in general, we completely identify and agree with these points.

The IG is one of the many mechanisms that we have in place now that we did not have in place 15 years ago, when the event to which you referred took place. I believe that one of the tests of the openness and the performance of our Commission will be just how well we do reply and react to allegations and information in general, and specifically to IG reports. So I agree completely with your remarks, Senator.

Our testimony today will focus on radiotherapy, since this is the area where the risks are the greatest, as you, Mr. Chairman, have pointed out. In fact, even in radiotherapy, the NRC has only a small slice of the pie. According to the rough estimates available, there were about half a million new cancer cases in 1992 which were treated using some form of radiation therapy. That is roughly consistent with the figure used of 20 million procedures, since there are old and new cases, and many of the procedures take from 20 to 40 applications. But roughly is the best we can do with the quality of the statistics that are available to us—and that's one of the problems that we address in the written testimony.

Sealed radiation sources made of byproduct material, which are the subject of NRC regulation under the Atomic Energy Act, were used in no more than 25 percent of these radiotherapy treatments. Radiation produced by electronic devices not regulated by the NRC, such as linear accelerators, was used in the other 75 percent of the cases.

In order to give the patients the best chance to survive, the radiotherapy treatments normally deliver high doses of radiation, close to the patient's limit of tolerance. Even when correctly delivered, a therapy dose of radiation may well have serious side effects and may on occasion result in the death of the patient.

The NRC does not regulate the appropriateness nor the effectiveness of the prescribed treatment. Our objective is to make sure that the patient receives the dose of radiation prescribed by the physician, as well as to protect health care workers and members of the public in this process.

The safety effect of misadministration appears to be rather small compared to the intrinsic risks involved in using radiotherapy accurately, but nevertheless that's our job, and we should be held to the standards, Mr. Chairman, that you laid out to make sure that that risk is kept at the lowest possible point.

---

[1] The prepared statement of Mr. Selin appears on page 59.

The NRC directly regulates the medical use of byproduct material in 21 States, a number of Territories, and in all Federal facilities. There are approximately 2,000 NRC licenses authorizing the medical use of byproduct material.

Under the Atomic Energy Act, the NRC is authorized to enter into agreements transferring our regulatory authority to a State. Twenty-nine such agreement States exist, and they have 4,500 medical use licenses.

Last year, our Office of State Programs, which oversees the agreement State program, was moved from the Commission level to go within the staff, in order to foster a more consistent, well-coordinated program between NRC and the agreement States. Nevertheless, there still exists considerable variability among the States and between the agreement State and NRC medical use programs. For example, reporting of misadministrations and other medical events by agreement States is so uneven at this point that it is difficult to determine if the misadministration rates reported are accurate or not.

Variations in jurisdiction over different sources of radiation—a point to which you referred in your opening statement, Mr. Chairman—also give rise to a range of problems. Jurisdiction is shared by the Federal Government and the States, and at the Federal level, by the Food and Drug Administration and the NRC, and I am forced to point out that any questions about notification of patients at the Federal level are really our responsibility; it is not the FDA's responsibility to do that. So the responsibility that you outlined in your statement falls clearly on our shoulders, at least at the Federal level. But more generally, I think the jurisdiction problems between the Federal level, mostly represented by the NRC, and the States are much more serious than intra-Federal-level questions between us and the FDA.

The vast majority of medical radiation sources, such as naturally-occurring and cyclotron-produced radioisotopes, diagnostic x-rays, and electronic radiation-producing therapy devices, are not subject to NRC regulation. Because regulation outside the byproduct material area is entirely at the States' own discretion, there is variability from State to State. Programs operated by the States range from minimal to programs comparable to, or in some cases even more extensive than that which we require.

In the example, Mr. Chairman, that you brought up in Ohio, actually, the next level is even more interesting—the technicians or the radiotherapists that you referred to are in fact certified at a rather high level of training to use the relatively simple Cobalt–60 devices, which we regulate, but to use the linear accelerator, an infinitely more complex device, they are subject only to the relatively low level of regulation that you pointed out. So it is not just from State to State, but from device to device that there is significant variation in a way which does not look to the outsider as being a particularly rational way.

Even the regulation of those medical devices that do use byproduct material does require special attention because of the complicated nature of the interface between the FDA and the NRC. The FDA regulates product manufacture and distribution while the NRC regulates radiation safety associated with the actual use of

the products. A simple way to paraphrase it is that the FDA's authority is exercised at the product model, or at the wholesale level, while the NRC and the agreement States work at the retail level. We regulate not only the model, but each instance of each model or device, directly on the basis of the individual licenses. So they might have a comment, say, on the Ford Pinto, whereas we would look at each vehicle in use to see if it is properly used.

The scope and level of detail required for NRC review obviously go far beyond that required by the FDA. We are able to provide this more detailed and focused review because while FDA has oversight responsibility for the entire universe of medical devices—some 20,000 devices—NRC and the agreement States are concerned only with the 300 types of devices that contain byproduct material.

We are in the early stages of an effort to establish a memorandum of understanding between the two agencies that will address the FDA/NRC interface, concentrating on medical devices, and I am quite sure that that effort will be successful.

Another area in which problems arise is the field of health statistics. While we have information about the number of reported misadministrations, there is evidence of underreporting. Misadministration reporting by agreement States is inconsistent, and we are not confident about projections of the total number of administrations. Without more reliable data on the total number of administrations, that is, on administrations of isotopes where the doctors' orders were in fact carried out, we cannot accurately determine misadministration rates nor misadministration trends.

Turning to operations, one of the points that you covered in your statement, Mr. Chairman, NRC's regulatory program consists of three fundamental elements. First is the licensing process, second is the inspection of current licensees, and third are the enforcement actions taken against violators of NRC regulations.

Overall, we are reasonably comfortable with the licensing process, although even there, a recent Inspector General report has shown that some formalization of procedures would be useful.

With respect to inspections, a different focus may be needed. Our current approach has been criticized as focusing too much on detailed compliance with NRC requirements and not enough on overall radiation safety performance. Compliance is important; we shouldn't have regulations if we don't expect people to live up to them, but compliance is not enough. We really have to look at the bottom line and see how well the programs are doing, and that should be the ultimate focus of our inspections, I believe.

Turning to enforcement, a point that Senator Lieberman brought up in a different context, this is really quite a complicated question. An enforcement policy is intended to do two things. It is intended to discourage repeat violations by the people who are found to have violated our regulations, and it is intended to deter other licensees from committing similar violations.

In the vast majority of cases, at least in the medical cases, NRC enforcement sanctions have been effective in gaining lasting corrective action. We have seen relatively few repeat violations for several years after a civil penalty is levied. However, we do not know whether the policy has been effective in deterring problems at

other licensees' facilities, and this is a question that we need to investigate.

Senator Lieberman's remarks about the enforcement process are right on the nose. He has been handling the allegations that have come to his office in a meticulous and proper way, and I agree with his careful summary of the IG cases. We too are awaiting the IG whistleblower report, due in June, that he mentioned, and we are awaiting it with great interest. We have a number of things we wish to do, and they depend on the IG report.

The series of stories in the Cleveland *Plain Dealer* to which you referred, and which we agree were a very valuable piece of reporting, expressed a number of concerns, including problems in patient follow-up. As a result, the NRC staff conducted a detailed review of therapeutic misadministrations at NRC license facilities over the past 3 years. This review indicated that the patients were notified of misadministrations only 72 percent of the time. Although it is true that the NRC permits not notifying patients in those special cases when a physician determines that it would be harmful to the patient, this exclusion does not appear to be the cause of most of the cases of non-notification.

Furthermore, of the patients notified, the 72 percent of the patients who were notified, only 56 percent of them were given a written report—contrary to explicit and longstanding NRC requirements. The staff is currently reviewing those cases in which the patients were not provided with a written notification to determine if enforcement action is called for.

I have gone through a rather long litany, and the written statement has many others, of places where we see that the program is subject to review and perhaps improvement. But on the positive side, we do believe that some recent steps have been taken which will increase the effectiveness of our program.

Among the various steps that I could cite, I'd like to single out the comprehensive rulemaking on quality management requirements in preventing and reporting misadministration, which I'll call the "QM rule" in further discussion, which became effective a little over a year ago. This is a performance-based rule that tells the licensees what they have to do, not how they have to do it, so it can be applied to a wide variety of programs, taking into account specific variations from case to case. It is also designed to have the greatest effect on those licensees that have weaker safety programs, since what it calls for is basically what the better programs already do today.

In time, when the rules' reporting features are implemented, not only for the NRC licensees, but in all the agreement States, it should provide us with much more reliable data on misadministration frequencies and causes than we have now.

In sum, Mr. Chairman, we believe the situation is about as follows. The NRC has what we consider to be a reasonably good regulatory program for the medical use of byproduct material, at least compared to the regulatory programs for other medical devices. Areas for improvement in the design of the program have been identified, especially in our relations with the agreement States, in our interface with the Food and Drug Administration, in the gaps

we see in radiation health care data, and in our responses to the rapid changes in medical technology.

We have also identified some weaknesses in execution, especially in the area of patient notification and follow-up, and perhaps in a tendency to inspect for compliance rather than directly for safety. We believe that we have steps underway, especially a shift toward performance-based rules and a regulatory regime which focuses more effort on the weaker licensees, a set of steps which if carried to their logical conclusion will remedy most of these problems.

The fact remains, however, that no matter what level of resources we in the agreement States devote to improving the regulatory program for medical therapy, the effect will be confined to no more than 25 percent of the radiation therapy treatment in the country, while the other 75 percent is subject only to discretionary and perhaps inconsistent regulation at the State level.

We question whether it makes sense to apply so much effort to 25 percent of the problem. It is a little bit like building a fort with a big wall in the front, a couple of small walls on the sides, and a river on the fourth side. So we have been giving some thought to ways to address the issues of coverage. Among the options that come to mind, we have thought of three. The first is to limit NRC's regulatory purview just to the approval of sealed sources and devices containing byproduct material, and leave it to the States to regulate the medical use of these sources. The second possibility would be for us to continue to write standards and guidelines and provide the technical support, but turn over to the States all the responsibility for inspection and enforcement. The third approach would go the other way; it would extend the type of regulation we do today for byproduct sources to all therapeutic radiation sources, not just for the byproduct material, but in particular to the linear accelerators. Such extension would, of course, require legislation.

Once we have completed our review and discussed it with the affected agencies, we will of course report promptly back to the Committee, we will give you our recommendations, and then we will leave it to the Congress to decide what to do with these questions.

Mr. Chairman, this completes our statement. We will be pleased to answer any questions that you and members of the Committee may have for us.

Chairman GLENN. Do other commissioners have comments they wish to make at this time?

[No response.]

Chairman GLENN. OK, fine.

I referred earlier to the deaths that occurred back home in Ohio at Riverside Hospital in 1975–76, where some 400 patients were overexposed, and I think about 28 deaths occurred, 10 directly from it, and 18 where the radiation was a contributing factor.

According to a memo to the Commission in February of this year from the Office of General Counsel, the NRC staff stopped the investigation on the basis that, "there would be no useful purpose in following up." And then: "Neither the then Chairman who made the commitment to the Congress regarding patient follow-up, nor any of the Commissioners, was advised of this decision."

What steps are you taking as far as dealing with the staff over there to determine if any other deaths occurred from overexpo-

sure—this is just one that came up—any other deaths from overexposure since 1980, when the NRC medical misadministration reporting rule was adopted; and next, to assure that deaths in the future will be reported as well?

Mr. SELIN. Mr. Chairman, that is a question that we put to ourselves quite strongly. In fact, you are really too gracious; the facts are even less complimentary than you put it, because the then chairman, Chairman Rowden, had in fact promised to Congressman Koch that all of the follow-up would be done, and that was not properly communicated to the region; neither the region nor the people who were working with the region were aware of that commitment.

But that was a watershed event. It was a terrible and a very unfortunate event, and we all would have preferred it not to happen, but at least the Commission drew, I think, some very powerful lessons from that that led to a revolutionary change in the way we went about the administration of the radiation therapy program.

First of all, there were a number of changes made to 10 CFR Part 35, the part of the Federal regulations that control the program. There was a policy statement issued in 1979, which I still think is quite valid. As you pointed out, in 1980, a misadministration reporting requirement was added; we didn't even have the concept of misadministration reporting nor a clear definition of misadministration. There were major revisions made to Part 35 in 1987, and then the quality management program that we talked about.

The second thing that was done in the time that came after that was to change the way in which follow-up would be done. At that time, the same people who were doing the licensing and were doing the inspections and enforcement were in fact interpreting the situation after the fact. In part through the IG legislation that your Committee has sponsored, and in part through a number of items, the whole approach of the NRC to the review of these cases has changed completely.

We now have a formal Office of Investigation, quite apart from the people who have done the work, that looks at the health and safety implications of these acts; we have the IG in the ultimate case, to look at the situation themselves; and then there is a set of intermediate steps that can go to the point of an independent investigative team which is composed of senior people outside the region, certainly outside the situation, to look at the facts. This is the mechanism that we used in the Indiana, Pennsylvania case. In that situation, also an unfortunate situation, the incident was much less serious than the 1975–76 incident to which you refer. Nevertheless, we traced down 92 different people who might have been subject to radiation; each one of them got a letter from the NRC, explaining what their radiation exposure might have been and what they should do about it.

The third area had specifically to do with patient notification. We did not have clear procedures at that time about the obligations to patients. We have had clear procedures, but not a very good practice for following up to make sure that they were carried out. Now, we have, I believe, all of these in place at this point.

Chairman GLENN. How do you establish these agreements with the States? Who initiates that agreement? Does the State have to come in and request that, or do you go out to the State and say, "We think you ought to have this"? How come we only have 29 States that have agreements?

Mr. SELIN. Formally, the State has to request an agreement. Informally, we try to hold forth a very inviting aspect. We like these agreements——

Chairman GLENN. So they have to ask you——

Mr. SELIN. Yes, Senator. The Governor has to formally request an agreement—but that usually comes at the end, not at the beginning, of a long negotiating and discussion process.

Chairman GLENN. So do some of these States have their own regulations within the State that are satisfactory?

Mr. SELIN. No, sir.

Chairman GLENN. In other words, if my wife or my kids were someplace right now to get some sort of treatment or therapy, and they are in one of these 21 States that do not have any regulation worked out through you, are they just at the mercy of whomever happens to be there?

Mr. SELIN. No; it is actually quite the contrary. The 21 States have quite uniform regulation because we run these programs ourselves. The agreement State programs are unique in Federal-State intercourse, as far as I know.

Chairman GLENN. So the other 21, then, you operate, you run them; is that correct?

Mr. SELIN. Yes, sir. We do the inspections, we license the people, we do the enforcement.

Chairman GLENN. The 29, though, where we have had some problems are ones where they have just chosen to make their own——

Mr. SELIN. Well, we have signed an agreement with those 29 States. I have to tell you that we do not know if we have more problems in the 29 States or the 21 States; that's one of the things that we are trying to find out. It is very hard for us to put on a comparable basis a bottom-line evaluation of the health programs in the different States.

These are not delegations of the Federal program. The State says that they will install a program which is adequate, which is compatible in certain aspects to our program. We terminate our program, and they start theirs, and then we continue in overview to make sure their program remains adequate and compatible.

Chairman GLENN. Why do these States want their own programs?

Mr. SELIN. Well, there are three reasons. The first question is why do we want them to have the program, you might say. And the reason is because there are 25 percent, roughly speaking, of these radiotherapy cases that we regulate and 75 percent that we do not. We are desirous—and I think you are desirous—that there be a more uniform set of regulations over radiotherapy regardless of what type of device it comes from. The States are already responsible for the naturally-occurring and artificially-generated radiation, and so there is the possibility of a more holistic approach that says all radiation, in fact all health supervision, in those

States will stay at the State level. This is highly desirable to us, provided that they carry out the byproduct program as well as we think we might carry it out. In fact, we even hope that it will bring up the rest of their programs alongside that.

It is desirable for the States in three ways. First, it keeps there from being an arbitrary distinction between one type of source and another type of source. It allows them at least the possibility of a uniform regulation.

The second, quite frankly, is their fees are lower. The licensees pay lower fees to the State than they do to the Federal Government. The reason is that the States charge licensees for all of the things the State does, but they share in the overhead of running the program for free. We do not charge the States an allotment for our technical support and our scientific work, so there is a benefit to the State in that respect.

And then the third is really a question, I believe, of sovereignty more than anything else.

Chairman GLENN. Let me ask you this. It is my understanding that only 19 out of the 29 States that you have agreements with have demonstrated compatibility with NRC's regulatory program. Now, given that situation, how do you know if there have been additional deaths, or medical misadministrations even if there is no follow-up?

Mr. SELIN. Well, there is plenty of follow-up. The key thing is are the programs adequate. Compatible is a very specialized function. The Atomic Energy Act says the programs must be adequate and compatible. The "adequate" is the key point—are they providing a program which provides adequate health and safety. I will provide information on the extent of compatibility and adequacy of the 29 Agreement State programs.[1]

The fact is that we aren't sure. I mean, what we do is we review their programs. We review the inputs of their programs—do they have enough people, do they run enough inspections. And that part, we are very comfortable about. But in our oversight of the agreement State programs, we don't look at their results. We don't ask are the morbidity or the fatality rates in States significantly different in agreement States from what they are in our case. We don't think they are, because we look at their programs very carefully, but we aren't sure, and that is one of the things that we will do.

The compatibility is limited to those items which really should be national level. They have more to do with standardization than they do with direct health and safety. There are certain regulations that they must adopt verbatim. They tend to be definitions, they tend to be radiation limits, and they tend to be reporting requirements. So the fact that a State is not compatible will affect our ability to run the National program, but it may not have much impact on whether the State's program is responsible or not.

But on the other hand, in the long run, we cannot allow States to run programs that are not compatible.

---

[1] See pages (274–282).

Chairman GLENN. Does your agreement require certain levels of training and inspection and qualification of people—to pass a board test, or something like that——

Mr. SELIN. Yes.

Chairman GLENN. Are those agreed to? How do you pass that kind of test?

Mr. SELIN. Well, the agreement says that they will meet our standards——

Chairman GLENN. And do you check on that?

Mr. SELIN. Yes, sir, we check on that. Now, the better question is what happens if they don't meet these standards, and the answer is we work an awful long time to try to bring them up to those standards before we come to the conclusion that the States will not——

Chairman GLENN. Is there any requirement under these agreements that only people who pass these tests can administer treatments, then?

Mr. SELIN. I'm sorry—are you talking about the physicians?

Chairman GLENN. Yes—and/or technicians; either one, not only doctors, but anybody who is authorized out there to give me a treatment if I go in. Let's say I have cancer, and I'm going in to get therapy. How do I know the person knows what he's doing?

Mr. SELIN. I misunderstood your question. I thought you were talking about the State personnel. I'm sorry. I misanswered the previous question.

Chairman GLENN. Well, I guess I'm talking about personnel across the board. If I'm getting a treatment how do I know that qualified people are giving it?

Mr. SELIN. Well, the fact is that the overwhelming number, probably 90 percent, of the people who are delivering any type of service are people who are certified by third parties, by joint committees on accreditation of hospitals, or physicians' boards. Most of the people who are qualified are qualified by the professional groups.

We have standards for people who claim to be qualified who have not gone through these groups, or for facilities that are not hospitals, that we carry out, and the States carry out these standards, and we look quite carefully at how they carry out the standards.

I'd say the biggest weakness is in the radiation safety officer, because that's a job which is not defined in other professional societies. It is something that is very specific to our regulations and the State regulations, and that's the area in which we have to look a lot harder.

I don't think it is true that the quality of the people who are carrying out our programs are noticeably different in the agreement States than they are in the places that we regulate directly.

Chairman GLENN. OK. You said you deal with licensing, inspection and enforcement.

Mr. SELIN. Yes, sir.

Chairman GLENN. How many people do you find who aren't qualified, who are doing something they shouldn't be doing?

Mr. SELIN. Well, those are two separate questions. We rarely find people who are not qualified, but we do find people who are qualified who nevertheless are cutting corners, doing things that they shouldn't do.

Chairman GLENN. What happens in that case?

Mr. SELIN. It depends on three things—how serious the case is; the long-term impact of what they are doing; and whether it was inadvertent or whether they were really trying to fool us.

I would say quite frankly that in looking over the 10 most spectacular cases of the last 10 years, the biggest questions have come about differing professional judgments as to whether people were doing things on an inadvertent basis, or they were really trying to fool us. Therefore, the principal conclusion that we have drawn from this is that we have to make our guidance much clearer as to what tests we will apply and how tough we will be in follow-up on people who don't seem to be carrying out their promises to us.

Chairman GLENN. I recall when we looked at Three-Mile Island on which we had detailed follow-up including hearings one after another in this very room. And yet we didn't lose anybody directly out of Three-Mile Island. But here, we have radiation of a similar kind, of course, but less concentrated in its overall danger to a large population.

Mr. SELIN. Mr. Chairman, if I might say something, there are on the order of 30 to 40 therapeutic misadministrations a year in the 21 States that we monitor directly. We have not in the past been tough enough on the agreement States in making sure that they collect this therapeutic misadministration information, so we can't speak with the same confidence.

But let's say just for the sake of argument that there were comparable numbers, so we are talking about roughly 70, 80, 90 therapeutic misadministrations a year, of which about 10 percent have serious consequences——

Chairman GLENN. But how do we know that? How do we know those figures are correct?

Mr. SELIN. Well, I am reasonably comfortable about the misadministrations in our area—we might miss one or two, but I'm sure that there aren't major changes. It is a very serious violation, a criminal violation, to change the records and lie about whether there is a misadministration or not. And we do do an audit of our licensees' records to see if they are reporting what they have in the records.

So to be reasonably confident, they would have to do one of three things. They would, number one, have to make sure that their records don't show a misadministration—which I think is not impossible, but unlikely. The second, which I am more concerned about, is that they would get a physician to say, "They did what we told them to do; maybe we didn't tell them to do the right thing"—in which case, by definition, it is not a misadministration, and we have a couple of cases of that.

And the third would be where they have the information in the records, don't report it to us, and hope we don't find it in an audit.

There is no risk-free operation in any of these areas, but the risks of doing something like that are much greater than the risks of shifting people, say, from a Cobalt device to a linear accelerator, where the rules for reporting misadministration have been unclear until 2 years ago.

So what we are concerned about is not so much the likelihood that there will be a frontal assault on our regulations, but that peo-

ple will just get around the regulations at the corners, which is a much greater source of concern to me and to the Commission.

Chairman GLENN. I know that some of the anecdotal material I use here today is back before your watch, all of you who are with us here this morning. Mr. Rogers, I think you came on in 1987; Ms. de Planque in 1991; Chairman Selin in 1991, and Mr. Curtiss in 1988—is that correct?

Mr. SELIN. Yes.

Chairman GLENN. OK, so some of these things occurred before your watch—but I ask these questions here to find out what has been done to correct these situations that did occur before.

Based on the Committee's investigation, in addition to being repeatedly opposed to the medical misadministration reporting rule, in 1984 the NRC staff made changes in the rule that affected patient notification and recordkeeping requirements without the knowledge of the Commission. Now, what kinds of safeguards do you think are necessary to assure that the staff can be held accountable for decisions made by the Commission?

Mr. SELIN. Well, among others, the knowledge that we are going to have to appear before you periodically has certainly sharpened our focus on making sure that we do hear from the staff. I am quite sure that the situations which have been reported in 1976 and 1984 and as recently as 1986, of the staff, going on unnoticed will not be repeated. It is absolutely clear to the staff that the Commission has a great interest in these topics. Particularly in the notification and misadministration definition topics, the organization that supervises that staff, the Office of Nuclear Material Safety and Safeguards, has been reorganized to bring the medical program to a higher level. The outside follow-up on what goes on, whether it is the Inspector General or our own reports, has just greatly increased the amount of information and the interest of the Commission in what the staff does.

I will give you two examples of things that are quite opposite from the situation that you refer to. One has to do with the use of the medical consultant. Before, the guidelines on using a medical consultant were very foggy and murky. The guidelines now—just recently, since Indiana, Pennsylvania, I have to admit—say very simply if there is a medical therapeutic misadministration, we use a medical consultant—no ifs, ands, or buts, no trying to estimate dose rates or damage or what-have-you.

And the second issue has to do with the question of patient follow-up. As pointed out in the statistics I brought up, that were brought up by the Cleveland *Plain Dealer*, the performance was just not consistent with our standards. Right now, we are investigating every medical therapeutic misadministration to see if the patient has been followed up. It is unequivocally understood by the staff that we will concentrate on the few high-dosage iodine misadministrations and then the medical therapeutic misadministrations, and absent an overwhelming concern for harm to the patient, which our own advisory committee estimates is maybe one to 3 percent of the cases, the patient will be notified in writing, and furthermore there will be a short-term follow-up to see if the deterministic effects have been assessed or not.

Chairman GLENN. We have a recent NRC/OIG report on the Indiana, Pennsylvania accident, where NRC inspectors failed to review records which showed that technicians were not trained to operate the device in a portable mode, and as a result, mistakes were made.

How do you explain that lapse? This is a recent incident.

Mr. SELIN. Actually, they have come up with more than that. The portable mode was probably not the cause of the accident. But what we did find is that they were using the device at a number of facilities that had not been included in the license; we found that the analyst, the inspector who allowed the license to be extended, got incomplete guidance from NMSS—more particularly, she didn't have a particular person to deal with, and it was not clear to her from whom she needed to get guidance and how to do it—and most particularly, it was quite clear, the most important part, the most serious failing, was that the RSO, the radiation safety officer, didn't do his job from all that we can see. There were people at these satellite clinics who had not gotten any effective supervision or training from him.

It is clear that the first two things will not happen again—the point of contact, the guidance, the inspectors, the sensitivity of the inspectors on the licensing is very clear now, and I have no doubt that the licensing part has been straightened out, and that we'll have no problems with that.

But as far as the inspection part, that's harder to say. We can say we will work harder, and will look more carefully for these things, and we will, but I cannot guarantee to you that there will not be other inspection lapses.

Chairman GLENN. In 1990, the NRC Office of Inspector General, OIG, found that NRC headquarters staff, again, without the knowledge of the Commission, provided improper assistance to medical groups by helping them prepare a petition for rulemaking that would weaken the current regulation. Now, if we had a nuclear power lobby coming in, I'm sure people would be out the door before nightfall if they were writing regulations in-house over there for the industry to submit to you. What has the NRC done to assure that this problem will not be repeated?

Mr. SELIN. That same IG report had another section which is also quite damning. It said that essentially, in spite of the fact that your intuition and your sense of what is right and what is wrong, said these are the wrong things to do, we had no regulation which these people violated, and it was another sign of the——

Chairman GLENN. Except common sense.

Mr. SELIN. Exactly, Senator.

Chairman GLENN. The staff doesn't, in my office or yours or anybody else's, go off half-cocked on their own and make decisions to weaken regulations or help the industry or whomever is out there to weaken regulations. And they would be out of my office before nightfall in my office if they did.

So I presume you have done something to make sure that they are not doing that now without bringing it to the Commission's attention.

Mr. SELIN. We have done three things. We started at the top. We fixed the internal guidance to make it absolutely clear that these

two types of things cannot be permitted to happen—either the staff marketing a petition to outside groups, or the staff dealing with outside groups in areas that would lead to a conflict.

The second thing is that the EDO issues not only once, but annually, a statement calling people's attention to this point. And the third is the specific people who were involved in this—it was discussed with them about what they should and should not do. But we cannot retrospectively do more than that, because they did not violate our written requirements. And as much as that goes against common sense, we can't have *ex poste facto* justice. So we have fixed the requirements; it is clear to the people that they did wrong, and that particular thing will not happen again.

But it is a broader example of the fact that in these highly complex and technical areas—which are very small, and the medical one is not the only one—we have been going for too long, until about 4 years ago, on common sense rather than formalizing the regulations to make it clear in the letter that what you have so aptly characterized as common sense will be expected.

Chairman GLENN. What is your requirement now for notification?

Mr. SELIN. Patient notification?

Chairman GLENN. Yes, where there has been some misadministration. As an example, for more than 8 years, the NRC failed to require the University of Cincinnati Medical Center to notify a patient and her daughter—the daughter had been improperly exposed—that a misadministration occurred. It was only after this Committee initiated an investigation at the NRC in January of this year, 1993, that they sent a letter to the hospital notifying them of their obligation.

Are there other cases like this, and why are we taking so long? What's the problem?

Mr. SELIN. The big problem there wasn't the notification. It was the reluctance of the staff, as you put it in a previous question, to recognize that this was in fact a misadministration. Once it was decided that it was a misadministration—which took far too long to get to that point—the notification was fairly prompt.

I believe that that case is really not a notification problem, but one of a number of cases that you have cited and that your staff has cited in the past where the fact that the regulations and the definition of misadministration were murky allowed for too broad a set of arguments as to whether specific instances were misadministrations or not. Now, the regulations are much clearer, and our interpretation is much tougher about what is a misadministration and what isn't.

As far as the patient notification is concerned, in the Riverside case that you cited earlier, the staff was just very confused as to why they were supposed to do this follow-up. They thought that the only purpose of the follow-up was to get enough information to improve our regulation and inspection procedures, and they were insufficiently sensitive to the patient rights aspects of the piece.

I assure you, sir, that that is no longer the case and that the notifications will be, and in fact are already much more thorough than they were then.

Chairman GLENN. OK. Your agreement States, which are responsible for regulating about 4,500 medical licensees, more than twice the number regulated directly by the NRC, are supposed to have programs that are compatible with the NRC. However, as I understand it, only 19 have demonstrated they are compatible.

How do you know if any of these agreement States are requiring that patients be notified if accidents occur?

Mr. SELIN. Well, it is true that they have to have compatible programs, but we have changed our rules on notification, and they have 3 years to catch up. So at this point, the States—and I am confident that not 19, but all 29—have in place a notification procedure that is based on the notification procedure which has in fact been superseded by our quality management rule.

So, starting in 1991—that was the first year that we unequivocally required that agreement States use our definition of misadministration and notify the patients. We have been making this topic a point of emphasis in our meetings with the agreement States and in our reviews of their programs. Before last year, it was not a major topic. We have plenty of reason to believe that the States were far more laggard than we were in notifying the patients before 1991. We think that they have made a lot of progress in 1992, but we aren't yet sure.

The second thing is that when our QM rule becomes binding for the States, which is 1995, then the definitions will be clear, and the notification will be clear. But there will be a period between now and then when the States' process of notifying patients will be uneven compared to the process in our 21 States—not because they don't meet the compatibility rules, but because there is a natural inertia when we change the groundrules for how long it takes for the States to follow.

Chairman GLENN. Let me go back to the University of Cincinnati. In 1986 the NRC officially declared the University of Cincinnati incident a misadministration. Why did it take until January of 1993 to formally notify the University of Cincinnati?

Mr. SELIN. Well, we declared it a misadministration, but the university did not agree on that, and there was a fairly long, drawn-out discussion of what should happen by the time that that was done unequivocally; then there was a second discussion about whether it made sense to notify somebody so far after the case about it being a misadministration. And then finally, in part because of your Committee and in part because of the perseverance of a member of the NRC staff, the Commission finally said enough of this—no more ifs, ands or buts—notify the patient's descendent, and let's get on with the situation.

Chairman GLENN. That took 7 years.

Mr. SELIN. That's true. What am I supposed to say? We didn't do it right, and we wouldn't do it again. That's all I can say to that.

Chairman GLENN. Well, my concern is are there other cases out there that haven't come to light yet, where we are hanging back on the notification of somebody who may be in some danger, and they might be able to do something about their health. If it takes 7 years before we notify them, people will have died a long time ago.

Mr. SELIN. We found in the last 3 years that only 72 percent of the misadministrations had been notified to the patients at the time of the Cleveland *Plain Dealer* article. So the answer to your question unfortunately is there probably are some out there that haven't been notified yet—a lot fewer now than a year ago, and a lot fewer next year than now. We had not paid sufficient attention to the notification procedures to make sure that was followed up. The attention is being put, but there is a delay between the time the attention is spent and the time the actions have been taken.

Chairman GLENN. Let me move on to a different area. According to the Committee's investigation, the NRC staff again halted probes by the NRC's Office of Investigations that found that physicians may have falsified their license applications. The first situation involved several situations where phantom applications were provided including floor plans for facilities to contain nuclear materials that never existed. Apparently, even after the NRC's Region III disagreed, the NRC headquarters staff advised that this did not constitute a violation—did not constitute a violation—and the case had to be dropped by the Office of Investigation.

In the second instance, a physician for over 10 years was operating under a license where another physician, who was the only one authorized to possess nuclear materials, was unaware he was even on the license. Yet the NRC staff again halted an investigation by the NRC's Office of Investigations on the grounds that there was no apparent violation.

On the face of these facts, it would seem that at the minimum, the NRC's Office of Investigation should have been allowed to proceed to determine whether these circumstances were willful violations; but under the current system, the NRC's Office of Nuclear Material Safety and Safeguards can simply overrule the NRC Region and the OI office on the basis of just a judgment call.

What kind of guidance and safeguards should the NRC have in place to deal with this obviously troubling situation? Have you corrected this?

Mr. SELIN. Yes, sir. We have taken steps. I think time will tell whether we have corrected it or not. But the key point is to separate out the investigation and review of the investigation from the control of the people who were involved in the situation in the first place. It is not so much whether the staff can supervise OI or not; it's the question at what level the staff will supervise the Office of Investigations. For too long, the medical area was thought of as something that was so arcane and so complicated that nobody at the general management level really could understand it well enough to get involved in these cases and see them out. I believe that we all understand that that is not true and that that will not continue.

The cases that you cite are really quite complicated cases, because we don't have an open and shut case to prove the statements that you have made. They are more, as you said earlier, common sense points. The fact that in one of those cases in particular, the physician who was down as the supervising physician asked that his name be withdrawn from the license. He didn't give us any reason for withdrawing the name, but the supposition that he was embarrassed by being considered a supervisor, when perhaps he didn't

think he was going the supervision, is certainly a supposition that comes up.

That doesn't come out of the investigation; that comes out of high-level people sitting down and saying, "This doesn't pass the 'red face' test. We've got to do something different from what we are doing." And the managerial changes have been made to make sure that the people who can interact in the case you brought up with OI are not the same people at the same level whose actions are indirectly being questioned by the OI investigation. The idea that the investigator should be independent and should be reporting to supervisors well above those who are implicitly involved in the subject being investigated is a well-established principle, but it wasn't carried out in practice as it should have been.

Chairman GLENN. In July of 1992, the NRC Office of Inspector General reported that NRC Region I staff failed to identify safety problems at a company in Connecticut that were brought to their attention by a former employee. In April of this year, just recently, the NRC OIG issued a second report which found that the NRC Region III staff were improperly recommending this same company to licensees in Ohio who were having regulatory problems with the NRC.

First, were any enforcement actions taken against this company, and second, what is the NRC doing to assure that Commission employees don't engage in potential conflict of interest practices?

Mr. SELIN. The first situation was much less serious than the second situation. I looked at the first one in some detail, and it is true—everything Mr. Gunderson said was absolutely right; he performed quite a service. But the question was whether the licensee was operating on his own license in a particular kind of case where most times, the licensees operate on their customers' licenses. We looked at the safety implications, and there was again a lesson to be learned about being much clearer about what information is to be available. The inspector was relatively inexperienced and did not use information that was available from another region. But it was a situation which, given the information at the time, was not unreasonable.

The second situation, if you'll allow me to continue, is much more troublesome because, to be frank, it's not just a question of who was paying for the lunches, but why were these people having lunch together in the first place. I mean, it was the familiarization and the fraternization that was more worrisome than whether somebody was picking up a check for $20 or not. We are very concerned about this situation. We are sharpening our regulations, but in this case there is no question that the actions happened as described by the IG, people knew and should have known that they should not have done these actions. There is a review going on at the management level. The EDO has put two people in charge of this review who are not directly or indirectly involved in the supervision of the situation at hand. But that is a very worrisome situation—both the fraternization with the licensee and then a well-meaning but very dangerous practice of recommending people to licensees to help them solve problems.

Most of these material licensees are very small organizations. A lot of them have radiography only as a sideline; if their program

runs into trouble, and they don't know where to turn to for help, it is natural for them to turn to us and say, "OK, you're right, we have a problem. How can we fix it?" But to say it is natural and to say it is appropriate are not the same thing.

We are putting in a formal procedure to keep lists of people who might be suggested—a large list that the licensee could take a look at. Whether there will be enforcement actions against the licensee, or what disciplinary actions might be taken against the NRC people is just a bit early to report. But when those decisions are made, we will of course report them to you, Senator.

Chairman GLENN. Another specific example, and I'd like to know how you are handling this. In early April, the Northwest Ohio Regional Sewer District filed a lawsuit against Advanced Medical Systems, AMS, Inc., a Cleveland-based manufacturer of cancer treatment equipment. The Sewer District claims that the company has disposed of Cobalt–60 sources which have contaminated the southerly sewage treatment plant, and they are asking for assistance in paying for the cleanup.

Congressman Stokes, Senator Metzenbaum and I have asked both the GAO and the NRC to investigate this situation and look at it. When did the NRC first become aware of this situation?

Mr. SELIN. We became aware of this situation only inadvertently. I fear that my answer may lead to another set of questions, but I will bravely go ahead, regardless.

At a meeting in Newburgh Heights when we were talking to the citizens of Newburgh Heights about the Chemetron site, we undertook to take a broad survey not just of the site, but to have an aerial survey taken of the area to see if there were other hot spots, other sources of radiation. That aerial survey turned up contamination from the sewer lines connecting the site evidently passing through the concentrating part of the sewer system. Investigation of that radiation turned out that there was Cobalt–60, as you pointed out, at the site. There was never any Cobalt–60 at the Chemetron site, so clear, the Cobalt–60 did not come from the Chemetron site——

Chairman GLENN. When was this survey?

Mr. SELIN. Two years ago. The aerial survey was 2 years ago, and it was last year—I'll get the date for you, more specifically a chronology of events—it was last year that the radiation was determined to be Cobalt–60 and where the contamination was.

INSERT FOR THE RECORD

Chronology of the Northeast Ohio Regional Sewer District

• During an April 1991 aerial gamma survey of the Cleveland, Ohio area several areas of elevated radiation were identified at the Northeast Ohio Regional Sewer District's Southerly facility. following this identification, Region III conducted radiological sampling at the site and determined that the site was contaminated with low levels of cobalt–60. (Direct radiation levels ranged from 30–60 microroentgen per hour with sampling concentrations ranging from 27–79 picocuries per gram of soil.)

• In order to obtain an understanding of the extent of the contamination, Region III contracted with Oak Ridge Institute for Science and Education (ORISE) to perform radiological characterization studies at the site. These studies were performed in September 1991 and March 1992 and confirmed the presence of cobalt–60 at levels that do not represent immediate health and safety risks at the site. Based upon this characterization, total cobalt–60 at the site was estimated to be approximately 200 millicuries.

• Concurrent with the ORISE site characterization studies, Region III initiated inspection efforts at the site to obtain information on the possible origin of the contaminant and to perform independent assessments of hazards of workers and radiation levels in facilities. Based upon those efforts, it appears that a likely origin of the cobalt–60 was from the Advanced Medical Systems (AMS) site in Cleveland. Both AMS and its predecessor, Picker Corporation, manufactured cobalt–60 sources for medical usage from the early 1970's to the mid-1980's. From the location of the contaminants at the site and the Sewer District's operational history, it appears that the contaminant most likely was deposited at the site sometime between the late 1970's to early 1980's. The Sewer District has initiated litigation claiming negligence on the part of AMS and also has petitioned the Commission pursuant to 10 CFR 2.206 to require AMS to assume all costs resulting from the off-site release of cobalt–60 from the AMS facility and to also decontaminate a sewer line from the AMS property.

• NRC representatives have met on numerous occasions with Sewer District representatives to discuss remediation plans for the site. The District has contracted with a consultant to assist them in performing additional site characterization activities, developing a remediation plan, and assessing potential personnel radiation exposures to District employees. The Sewer District has fenced off the contaminated areas and has provided adequate security and posting provisions for the contaminated areas.

• The NRC is in the process of reviewing the Sewer District's current plans which consist of emptying three contaminated settling ponds and placing the material in an isolated area on the Southerly property. It is essential that these ponds be emptied in order for the Sewer District to continue operations. The NRC will have onsite presence during this operation and future site activities to assure safety of the workers and also to perform independent measurements so that an accurate assessment of total activity at the site may be obtained. ORISE will assist the NRC in some of these activities. The NRC will be reviewing all future characterization and remediation plans proposed by the Sewer District.

We did a survey of all the licensees in the area, and the only one that was conceivable as being a source of Cobalt–60 was AMS. They had been doing a manufacturing process involving Cobalt–60 that terminated in 1987.

Then the problem gets interesting from there on in. We don't know whether the manufacturer, AMS, was in fact putting more Cobalt–60 into the water than their regulations allowed them to put in; so there is a question of fact. But even if they were within our regulation, the amount of Cobalt that they put in, when concentrated in the sewer system, could have led to these concentrations.

It is pretty clear that the Sewer District has some cleanup to do, and it is pretty clear that they were acting in an appropriate fashion.

So in answer to your question, the first thing we are doing is trying to help solve the problem, and that is to work with the Sewer District, providing technical advice and support on how to decontaminate those ponds that have to be decontaminated. The second thing that we are doing is looking at the generic basis and asking if you are going to have emissions that go into concentrating sewer systems instead of being dispersed into fluids the way we thought when the regulation was passed, are these emission levels too high. But the key question—it is not our question; it is really between the Sewer District and the manufacturer—is what is the liability of the manufacturer. There is a doctrine that says just because you are within Federal regulations doesn't mean you have no tort responsibility for what goes on. So that is basically a tort case between the Sewer District and the manufacturer.

Chairman GLENN. Is this a problem in other cases?

Mr. SELIN. Probably.

Chairman GLENN. I don't know whether you checked on this, or how you check it, or does anybody check on it, but it seems to me that when people have something they want to dispose of, they quite often flush it down the drain, and it winds up someplace in the sewer system. How do you check that, or do you just trust people's good sense not to do that—and it probably occurs more than we know.

Mr. SELIN. It is worse, Mr. Chairman. They were within our standards. Our standards did not foresee a sewer system at the end. If a radioisotope is soluble, if it dissolves or it will disperse, we set standards assuming that there will be a certain amount of dispersal, and that the concentrations will not cause any problem.

But if you have a sewer system doing what it is supposed to do, what it does is it concentrates the sludge and has an effect which is just the opposite of dispersal. I should assure you that these concentrations are not at what we consider to be dangerous levels, but there is clearly a lack of coordination between our standards assuming dispersal and the knowledge that there are sewer systems which lead to concentration rather than dispersal.

Prospectively, we are changing the standards to fix this situation, but retrospectively, we don't know of other places, but I wouldn't be surprised if there are other places. But this is where people are within our regulations. This is in addition to the cases where there would be illegal disposal of radioactive material.

Chairman GLENN. We could go on and on talking about the details of all these things and anecdotal examples. Let me get to the bottom line. In 1980, President Carter established the Radiation Policy Council, whose purpose was to coordinate the formulation and implementation of Federal policy relating to radiation protection. The council was comprised of representatives of 13 Federal agencies. It was also to advise on policy formulation, monitor implementation of radiation protection policies, resolve jurisdictional disputes, serve as a liaison with the States and Congress, and serve as a public forum.

Now, it was not in place long enough to really know whether it would have worked or not worked, and I don't know whether it would have or not. What President Carter did was basically what I had proposed here, and he sort of preempted that, and that was fine; I was glad to see it in place. President Reagan came in and abolished the council by Executive order soon after he was inaugurated.

Now, I don't know where we go from here, but I'm interested in answers. I know there has to be more close monitoring and coordination than in the past. That is obvious from all the information we have talked about this morning, the *Plain Dealer* articles, and the illustrations you have given and commented on.

I don't know whether a similar council to examine medical uses of radiation is in order, or what will work. We have radioisotopes that are produced in reactors, and those are regulated by you at the NRC.

Then you have radioisotopes produced in accelerators. It is my understanding there are some 2,000 accelerators now in this country. Is that a valid figure, about 2,000?

Mr. SELIN. I don't know how many there are, but I know how many procedures there are, and there are about——

Chairman GLENN. But there are a lot of them, and they have come into more common use; about 2,000 of them.

Mr. SELIN. Yes, sir.

Chairman GLENN. Now, these aren't regulated at all, as I understand it, by anybody.

Mr. SELIN. Not by us, no.

Chairman GLENN. By whom?

Mr. SELIN. The State department of health or State department of radiation. And of course, as I'm sure you are aware, there is the Conference of Radiation Control Program Directors which writes a standards document, but it is completely voluntary. Fifteen States have adopted those standards. They are comparable to our standards, but they don't have the Federal inspection and follow-up; they are just standards for——

Chairman GLENN. Well, I know we haven't had FDA up here yet, but FDA has very tight regulations now for things like sun lamps, tanning beds, television sets, and even airport surveillance, and things like that, but we have no regulation for accelerators. This just doesn't make any sense. We are supposed to have some international standards, but as I understand it, the international standards are not binding; they are advisory.

So I would appreciate your comments on what you think we need to do, or you need to do, or somebody needs to do. Would a council provide—and I am the last one in Washington who wants to set up another commission, council, advisory group, committee-type thing; that's the Washington solution to a problem—form a committee, and draft a quick press release so people will think you've done something. But I want to get to the bottom of how we regulate radiation. Should it be a Federal law, with Federal standards that have to be adhered to, that the States can't have any variation from? Should we turn it over, as you said was one of your options? Should the NRC and other Federal agencies set the standards in all their wisdom, and then leave it up to the States on how they comply? And we are getting complaints now—every time we do that, the States want money-complaints as to how we require them to do things and don't provide the money to do it. That's another problem.

What is your best advice—all of you here. I'd like your individual opinions—and I am asking for your opinions, not something preconceived. You all have different views on some of these things, and I want your personal opinion on what is best to get this whole thing under control so we aren't endangering the people of our States and our Nation.

Mr. SELIN. Fine. First of all, we are flattered that you are asking our advice on this. My own view is you have to start from the most specific and then work out. We have identified that there are serious questions with respect to radiation therapy, so we would like to see answers developed that deal specifically with radiation therapy—not with x-ray machines, not with dentist diagnostics, et cetera. So we would start at that level. We don't believe that something as broad as the council you are talking about is necessary, nor would it do much good at that detailed level.

We also don't think the main problem is between us and FDA; it has to do with the inconsistent regulation from the Federal level and the States and from agreement States to non-agreement States.

I think we understand the options. We need to do some homework and get back to you on which of these we would recommend. I personally feel that the one thing I would not recommend is the current situation; I consider that to be quite illogical, where a huge amount of resources is poured into, really, only a small part of the problem. It would not surprise me that part of the growth in linear accelerators is just because they are separately regulated, although they have technical advantages as well.

So at the level of therapeutic radiation, I think it is within the capability of us and the States, with the support of the Congress, to figure out what the best approach is there and where to go from there.

On the broader question of the control or regulation of all ionizing radiation, that's really quite a broad issue. We take the viewpoint that any of several approaches could work, and really, you know much better than we do which ones would work. But I would put the proviso that whatever does happen, the NRC has some specific responsibilities under the Atomic Energy Act, and we would be very uncomfortable if we didn't have the authority to carry out those responsibilities.

In other words, if, say, EPA, for instance, were given authority to mandate that we do certain things that kept us from carrying out our responsibilities, obviously, that would make us feel uncomfortable.

On the broader area of international standards, I think each of us has a different view. I think basically, the problems in the use of the devices—which is not a standards problem but an inspection and enforcement problem—are much worse than the standards problem. For instance, FDA does a reasonably good job in linear accelerators; the big weakness is not can you meet the FDA standards, but do you use them the way you are supposed to use them, do you maintain them the way you are supposed to maintain them, do you do the daily, weekly, and monthly calibrations—and that's far outside of their authority.

Chairman GLENN. Yet that's important.

Mr. SELIN. It is very important.

Chairman GLENN. Who should do it?

Mr. SELIN. Well, those are State responsibilities today, and they could either be——

Chairman GLENN. But don't they vary from one State to another, or are those the same for all States?

Mr. SELIN. No, sir; they vary from one State to another. Even where there is some standardization, it has only to do with the regulations, not the inspection. Even those States that have adopted the radiation officer standards are still monitoring themselves. There is no outside monitor.

Chairman GLENN. What you are telling me, then, is there is a big difference in how much you are protected, or whether you are safe or not, depending on which State you decide to get your treatment in; is that correct?

Mr. SELIN. It is plausible; it is probably true. And that's why my own view, and I think the Commission's view, is that whatever is done, we would be better off putting our resources into making some decision as to what level of Federal resources you and your colleagues wish to apply, and apply them more uniformly over all therapeutic radiation, and not concentrate so much on the sliver that we have.

In all respect, in spite of all the points you brought up—and I agree with every one of them—I still believe that we do a much better job than what's done on the edges when you get outside of byproduct regulation. For instance, there are no patient notification standards anywhere that have to do with misadministrations under linear accelerators. Your question to us is do we do a good job of carrying out the rules, and the answer is that sometimes we do, sometimes we don't. But in this other area, there are four times as many devices, presumably there are at least four times as many misadministrations, and there aren't any rules—at least, any national rules.

Chairman GLENN. That's what I'm getting at. Who should set the rules? There should be some rules so that we don't have people inadvertently being literally killed by some of these devices. It has already happened—not just from linear accelerators, but we know that deaths have occurred. Now, how do we protect against this? Who is the controlling factor—you, FDA, all of us, a council, or a what? I don't quite buy this idea that we should go along the way we are because we now have improved our act a little bit. I think maybe there is a whole new organization of some kind——

Mr. SELIN. I'm absolutely saying that we should not go along the way we are, but the Commission is not prepared to tell you what we should do. We are hoping that we will have established enough credibility with you that you will give us a little time to take a look at this. We do have some machinery set up to look systematically at these options, each of which would produce more standardization than we have today, at increasing cost to the public, and be allowed to come back to you with some recommendations when we have done our homework, instead of trying to do the recommendations without the study.

We are in agreement with your basic proposition, Senator.

Chairman GLENN. OK. When could we expect that advice?

Mr. SELIN. We would do a first cut by the end of the year to make sure we understand the options and that we're in the right ball park; and then, depending on how hard this study was, it might take another 6 months to a year to do properly. We want some outside help on this. We aren't really qualified to do this study internally.

I'm sure my colleagues have opinions on this topic as well, Mr. Chairman.

Chairman GLENN. Yes. I want to get everybody's opinion on this. Mr. Rogers, let's start with you—and I'd like these to be your own personal opinions. I know you haven't sat down and taken a vote on what you are going to say—or, I hope you haven't taken a vote—this morning. I'd like for these to be your own opinions.

Mr. ROGERS. No, we haven't voted—at least, not to my knowledge.

Chairman GLENN. You've been there longer than any of the rest of these people, so cut them out of the pattern and give me your personal advice.

Mr. ROGERS. I'd like to say that I really think the Chairman has said very well what is a reasonable approach here. I don't think we have considered all the possibilities. In my mind, there is a need for a standard approach nationally; that doesn't exist. It makes no sense to me at all that the same kind of radiation is regulated in totally different ways depending upon how it is created—whether it comes from a Cobalt source, or whether it comes from a linear accelerator makes absolutely no difference with respect to how it ought to be regulated from a health point of view, in my opinion.

Exactly what the best way to do that is, I really wouldn't want to make a recommendation at this point. I think it does need considerable study. But it is very clear that there is, in my view, an absurd situation in the United States that is not common in other places in the world where radiation is treated as radiation from a health point of view, and regulated uniformly.

I myself have not come to a conclusion as to whether States or Federal ways of regulating are best; I think the Chairman has expressed one very good argument for turning some of these things over to the States. My own personal experience over the years in dealing with State governments has been that there is a high variability in quality and competence in highly technical matters among the different States; they have very different financial and human resources, and very different abilities to deploy these resources, depending on the size of the State, its technical sophistication, and so on and so forth.

I myself would favor some kind of uniform standards established at the National level, but exactly how those would be administered, I'd say is something I personally am not prepared to make a recommendation on.

Chairman GLENN. Mr. Curtiss?

Mr. CURTISS. I share the Chairman's view when it comes to the regulatory jurisdiction over these activities. That is a fairly complex subject, and I think the Commission's view is that we ought to take a careful look at that question. There are several groups that have an interest in this—the Conference of Radiation Control Program Directors is the organization of State officials.

Picking up on your comment that a study in Washington can go on and on and be an excuse for not doing anything, I do think there are some things that can be done in the relatively near term. The Chairman mentioned the discussion with FDA on the memorandum of understanding. I do think we need to take a look at the agreement State program and make sure that that current program is functioning the way it ought to.

But over the course of the rest of this year, I think what you are hearing is that the Commission is dedicated to focusing on what the pros and cons are of the various options and bringing this issue to a head.

Chairman GLENN. Ms. de Planque?

Ms. DE PLANQUE. I'd like to make some general remarks in this area. First of all, I think it is extremely important to depend on international standards and internationally agreed-upon standards

when it comes to issues of radiation safety in general, and what is safe. There are several standard-making bodies, but basically this advice comes from the ICRP and is looked at in the United States by the NCRP, the National Council on Radiation Protection and Measurements. And I would agree with what some of the others have stated, Commissioner Rogers in particular, that I personally feel that radiation protection standards and what levels are safe should be set at a national level.

Now, these don't involve just the area of health that we have been talking about today, but they involve several complex areas—as you mentioned earlier, cleanup of a contaminated site, for example. So that setting what is safe covers many areas in addition to health.

What we are seeing is that in the health area as in some of these others, various government agencies are involved. In the past, we had the Federal Radiation Council that set some of these standards. We don't have that now. We have had other groups like the—CIRPPC is what it is called—which has not been effective as I think many of us would have liked. These bodies need the strong support of all the Federal agencies involved in order to make them work.

Once you get past the concept of setting standards for what is safe, be it for the worker, be it for the patient, be it for the public, then we get into the problem of implementation. And here, I agree with my colleagues, at least in the health area; we are looking at a number of things right now, and I think it takes a good deal of consideration to come up with a proposal that would be the best in terms of implementation, implementation then being things like notification, records, enforcement.

Here again, add economics and resources into the picture as well as exactly how you go about actually protecting the workers, the public and the patients.

Chairman GLENN. Well, the reason I get a little short-fused on some of this, with all due respect—and this goes back a long way—but this is a letter from the NRC to me when I was Chairman of the Subcommittee on Energy, Nuclear Proliferation and Federal Services. To indicate how long ago this was, March of 1979, my ranking minority member was Senator Jake Javits of New York. The letter was to me as Chairman of that Subcommittee, and I won't read the opening, but the second paragraph reads: "Following an investigation of the teletherapy overexposures at Riverside Methodist Hospital in Columbia, 1) NRC in agreement States notified all teletherapy licensees to check the calibration of their units; 2) NRC in agreement States made independent checks on the calibrations of licensed teletherapy units; 3) NRC published proposed and final rules requiring its medical licensees to a) calibrate each teletherapy unit annually, b) perform monthly spot-checks on those calibrations (NRC expects the agreement States to adopt similar requirements for their licensees)"—and then says these apply only to the ones in NRC agreement States, of course—"and in a not unrelated rulemaking procedure, NRC proposed that all medical licensees 1) keep records of all misadministrations of radiation material and 2) promptly report potentially dangerous misadministrations to the NRC, to the patient's referring physician,

and to the patient or the patient's responsible relatives. We have received approximately 150 comments, the vast majority opposed to the rulemaking, and are presently analyzing these comments for the Commission as part of the final rulemaking procedure."

Here we are in 1979, 14 years later, and we are analyzing the process here as to what we should do. That's the reason why I get so upset when something like this comes up. So I don't know where we go with it now.

Let me go further. The legislation I referred to——

Mr. SELIN. Could I say something, Senator?

Chairman GLENN. Just a moment, and I'll ask you to comment on this, too. This is just a little summary of what we proposed way back. It was Senate Bill 1938 in 1979. "The Federal Radiation Protection and Management Act of 1979 ensures adequate protection of workers, the general public, and the environment from harmful radiation exposure; to establish mechanisms for effective coordination among the various Federal agencies involved in radiation protection activities; to develop a coordinated radiation research program, and for other purposes." It was introduced on October 24, 1979 and referred back to this Committee, but because of Executive order action at that time, we never went ahead with it.

I would like to trot this out and send it over to you and see if you think it could be the basis for something—or maybe it could be the subject of another Executive order now. I don't know, but I want to do something, because I think we're all over the lot on this right now.

Mr. SELIN. Well, I just want to say three things. First of all, personally, I think the Commission is quite sympathetic with the general thrust of your comments. As far as the specific 1979 letter you read from, we fixed every one of those in terms of our standards and our rules. We have not done as complete a job, but we will in executing according to those. And there has been opposition every step of the way. For instance, the Office of Management and Budget refused to approve our quality management program, and we just overrode them. We said we are going to do this in spite of that. So there has been opposition, but on the other hand, it is possible to make progress.

There are two points I would like to make, sir. First, I completely agree with Commissioner de Planque's points about running off international and national standards—but standards aren't the problem here, whether we have a CIRPPC or a Federal radiation policy. We already know how to do a lot better than we are doing—we, the United States, including but not limited to the NRC. I'd say 90 percent of the problem is coordination and execution, not setting standards.

So the question that I brought up on behalf of the Commission in the testimony, which is what is the best way to integrate these different areas of radiation therapy, I think is the critical question. To the best of my knowledge, the NRC has never broached this issue with the Congress before. It was broached in a number of other places, including the newspaper articles. But we have taken this to heart. We think this is the right question, and we can do better. But we are polishing up the last 10 percent of improvement on 25 percent or fewer of the procedures, and we think it is time

to spread the aggravation to the other practitioners, not just to the people that we regulate.

Chairman GLENN. Well, how do we get all the aggrieved parties together so we can protect the people out there? That's the problem. And I realize you go back and forth with turf problems and things like that, but that's very little solace for someone out there who has gotten overexposure or isn't protected when they go to the hospital.

Mr. SELIN. Mr. Chairman, three-quarters of our orders, two-thirds of our enforcement actions agency-wide have to do with medical regulation. If it were a turf problem, I would gladly turn it over to somebody else. It is really what is the best way to protect the general public, and as we said, there are a number of ways to do it, all better than what we have now.

Chairman GLENN. All right. Thank you very much. I appreciate your testimony. Let me do one other thing. I would hope we could speed up the report between now and the end of the year. This has been studied since 1979 by various and sundry people, and I hope it isn't the end of the year before we can get your counsel and advice on this.

Mr. SELIN. We will undertake to give you a preliminary report probably in 3 months. Whether we have all the t's crossed and the i's dotted—I am sure you are right that it is really not a question of studying; it is a question of how much does the Federal Government want to see invested in one of hundreds of areas of health and safety, and that's really not our question to answer. So we'll do the best we can.

Chairman GLENN. That would be by August 6th. Can we get your report by August 6th?

Mr. SELIN. Mr. Chairman, your will is our command. Of course, you can.

Chairman GLENN. All right. I would like to get moving on this, because if it turns out that we need legislation to do anything, then I'd like to get it through this year. I don't want it to be next year. Once we do get beyond the August break this year, being a non-election year, it gets awfully tight to get things on the floor or even though committee, because we're up against appropriations and authorizations bills, and time gets tight over on the floor. So, I am serious. If you can do it, or even if you can beat August 6th, I'd appreciate it, because we'll have to get things going here if there is to be any legislation in this regard.

Mr. SELIN. What we can do is give you the first cut of the Commission's deliberations on this point. If it is pretty much open and shut, you may decide you have enough. But we need to talk to the affected parties. We cannot have the NRC coming to the Congress without talking to the States and the other agencies, telling you what we think you ought to do with them; that's just suicide.

Chairman GLENN. I understand. Thank you. I don't know what day of the week August 6th falls on, but let's make it Friday of that week; how's that?

Mr. SELIN. Yes, sir.

Chairman GLENN. We look forward to working with you.

Mr. SELIN. Thank you very much, Mr. Chairman.

Chairman GLENN. Thank you much.

Chairman GLENN. We'll hear next from Dr. Bruce Burlington, Director, Center for Devices and Radiological Health at the Food and Drug Administration. Dr. Burlington, we welcome your testimony this morning. Your entire statement will be included in the record if you choose to give an abridged version thereof. We understand you are accompanied today by Ronald M. Johnson, Director, Office of Compliance and Surveillance, Center for Devices and Radiological Health; Marvin Rosenstein, Director, Office of Health Physics, Center for Devices and Radiological Health; and Donald Hamilton, Radiation Policy Advisor, Office of Health Physics, Center for Devices and Radiological Health.

We welcome all of you this morning, and Dr. Burlington, if you would proceed, we would appreciate it.

TESTIMONY OF DR. D. BRUCE BURLINGTON,[1] DIRECTOR, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, FOOD AND DRUG ADMINISTRATION, ACCOMPANIED BY RONALD M. JOHNSON, DIRECTOR, OFFICE OF COMPLIANCE AND SURVEILLANCE, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH; MARVIN ROSENSTEIN, DIRECTOR, OFFICE OF HEALTH PHYSICS, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH, AND DONALD HAMILTON, RADIATION POLICY ADVISOR, OFFICE OF HEALTH PHYSICS, CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Dr. BURLINGTON. Thank you very much, Mr. Chairman.

We are pleased to be here this morning. Mr. Chairman and members of the Committee, I am here today to discuss the role of the Food and Drug Administration in helping to ensure that radiation-producing medical devices, particularly devices used in radiation therapy, are safe and effective.

Before I begin my testimony, I would like to announce that 2 days ago, acting in behalf of FDA, the U.S. Attorney in Houston carried out a mass seizure of Omnitron Model 2000 radiation therapy devices. Our inspection of this firm in December of 1992 revealed numerous violations of good manufacturing practices.

We acted promptly with the State of Texas to halt the shipments of products from this firm. We carefully considered how to prosecute this case, and in January we moved to seek seizure. This seizure is clear evidence of how seriously we are taking violations of medical device law. We will not tolerate the failure of manufacturers of critical products such as radiation therapy devices to risk the public's health by ignoring basic quality control as they go about making their products.

We are inspecting other radiation therapy device manufacturers, and we are clearly telling them all to report promptly adverse events to us.

As I begin my testimony, let me explain that I am new in the position as Center Director, having served only a little over 2 months. So I am accompanied today by staff who can provide institutional memory and a deeper perspective on our Center's program.

With respect to radiation-producing devices, FDA's job is to be sure that they are safe and effective, are properly manufactured,

[1] The prepared statement of Dr. Burlington appears on page 65.

and perform their intended function. Once these products are marketed, it is also our job to take action if they are found to pose unanticipated hazards.

Radiation therapy devices are the primary focus of this hearing because when radiation treatment is not delivered properly, the consequences can be very serious, or even fatal, as the cases you have brought to our attention illustrate.

Let me emphasize, though, that as a practicing physician, I understand radiation therapy is very useful in treating and sometimes even curing some cancers. It has real risks, but it also has real benefits, and the benefits far outweigh the risks in general.

Nonetheless, several highly-publicized incidences in which patients have been injured have occurred over the past few years. These have been caused both by device failures and more commonly, by user errors. I know these events have captured the attention of the Committee, and they are of great concern to us as well.

The jurisdiction over devices and their components of use extends across two Federal agencies as well as each State Government, as we have already heard this morning. Who does what with respect to controlling radiation products has been discussed, and I don't want to go into that in more detail. But let me point out that FDA's role under the statutory scheme is to see to it that radiation-emitting devices are designed, tested and manufactured to be safe and effective.

In other words, our primary job is to regulate radiation therapy equipment. We deal principally with the manufacturer of the device, both before the device is marketed and afterwards, if problems should arise. I will briefly summarize what we do to help assure the safety of radiation therapy devices. I will also point out where we would like to strengthen our regulation of these products. Then I will describe for you ways in which we are seeking to better assure the safety of patients who are undergoing radiation therapy.

We engage in three basic activities related to radiation therapy devices. First, before a manufacturer can market a new radiation therapy unit, we require that they submit data to us demonstrating that the device is safe and effective. This includes the computer software and accessories intended for use with the product. Second, we inspect firms who make devices, to be sure that manufacturing processes and quality control are in place to assure a well-manufactured product. And third, once the product is on the market, we monitor problems that may occur in use, and as necessary, we take action to correct them.

These corrective actions range from alerting physicians about potential hazards to requiring product recalls, or even seizures, as is appropriate. Problems are brought to our attention because manufacturers and now, more recently, users, are required by law to report to us when serious mishaps occur.

Since other agencies have at least partial jurisdiction over radiation therapy devices and also receive such reports, it is important that we coordinate our efforts with them.

As I analyze our programs in this area, it is clear to me that some have been more effective than others. I think we are doing a sound job of evaluating the safety and effectiveness of new radi-

ation therapy devices before permitting them to go on the market. Likewise, I think our inspection system is basically sound. We do want to get into plants more frequently, but we have in place the program for inspections and the authority to deal with problems in manufacturing.

My chief concern lies in our ability to be informed about problems with these devices as they arise in the real world of radiation therapy. We need more reports from manufacturers and users, promptly identifying serious incidents.

Finally, our communication with other Government agencies at the Federal and State level needs to be both rapid and comprehensive. Communication is a critical area. When we review a new product that a company wants to bring to market, we apply sound engineering and scientific analysis to the data on its design and performance—but new devices are often very complex systems, and unforeseen risks will always be with us. We can never be sure that life-threatening incidents won't occur once the product is in widespread use. Therefore, we must rely on quick and efficient reporting of adverse incidents in order to take action before even more serious or more frequent events happen.

With that in mind, Mr. Chairman, I would now like to turn to several actions that we have taken to improve our ability to find out about problems with radiation therapy devices at the earliest feasible stage.

We are requiring new user facility reporting of adverse events. These new regulations which, through notice and comment, are nearly ready as final rules will now require that medical facilities report device-related deaths, serious injuries or serious illnesses to us. Up to this time, device manufacturers have had to report what they knew, but we have actually had little information from the point of use. The new requirement will also increase the information content in reports.

We welcome the citizen reports you have received. This is the type of input we need to find problems quickly. We will, of course, analyze those reports and give you the results of that analysis.

At this point, I would also like to let you know that on June 3rd, FDA will announce its new "Med-Watch" program. This is a streamlined system that will enable radiation therapists and radiologists, as well as the entire array of other health professionals, to report adverse events for both drugs, biologics and devices to the agency directly and expeditiously. We think that this will substantially enhance reporting by practitioners.

As a second action, we will notify all dealers, importers, manufacturers, and distributors of radiation therapy devices about their obligation under the law to report to us, and about the criteria they must use in deciding when a problem is reportable.

Third, we are actively seeking a memorandum of understanding with the Nuclear Regulatory Commission, which will cover medical devices using NRC-licensed radiation sources. The memorandum will address prompt problem notification, coordination of investigations, and information exchange between the two agencies.

Formalization of our longstanding relationship should improve the speed and effectiveness with which our two agencies communicate about radiation therapy device problems.

Fourth, we will reassess our communicating with the State regulatory authorities. Although we have always worked with the Conference of Radiation Control Program Directors, and directly with the individual States in investigating cases in their jurisdictions, we want to be sure we are regularly relaying information to the States on problems occurring elsewhere.

Our fifth action goes beyond these improvements in our ability to receive and transmit information. Last year, we also stepped up industry-wide inspections of radiation therapy manufacturers. These inspections will include a check on whether manufacturers are reporting problems to us which they have in their files, as they are required to do.

In conclusion, Mr. Chairman, we share your concern about radiation therapy accidents, and we are taking steps attempting to resolve that concern. The actions I have described today should give us a better early warning system; they should also enhance communication among FDA, NRC, and the States.

Let me note we are not taking these actions in isolation. They are part of a larger, overall effort to improve the way FDA regulates all medical devices. Our Center is sharpening the criteria for new product evaluation. We are improving our surveillance system to detect and evaluate marketed device problems. We are seeking enhanced problem reporting, and we are taking swift and decisive action against those who violate the law.

Thank you, Mr. Chairman. That concludes my prepared remarks. We welcome any questions.

Chairman GLENN. Thank you very much.

Do any of the other gentlemen have any comments to make before we proceed with questions?

[No response.]

Chairman GLENN. All right. Thank you.

The FDA,, Dr. Burlington, defines "serious injury" as "an injury that is 1) life-threatening, 2) results in permanent impairment of a body function or permanent damage to body structure or 3) necessitates medical or surgical intervention."

But when a person is accidentally exposed to a dose of ionizing radiation, it doesn't have an immediate clinical effect, but it nonetheless can likely contribute to cancer later in life. Does this classify as a "serious injury"?

Dr. BURLINGTON. Mr. Chairman, that is a difficult way to work through the definitions. Fortunately, under the statutory scheme, we also have authority to require other significant events be reported to us even if they are not immediate, palpable injuries.

In looking at our user reporting regulation, we are trying to find a way to make sure that we get those over- and underexposures reported to us through this additional authority.

Chairman GLENN. Well, is that classified then as "serious injury" or not?

Dr. BURLINGTON. Serious injuries are, as you have noted, broadly classified by FDA to be cases that require intervention of some type, or result in permanent disability or death. Rather than saying that these are serious injuries, it makes sense to me for us to say these are significant additional events that we need to know about, and there is a probability that the patient may eventually

turn out to be injured, but that is not anything that is clear and present today.

The effect of that will be to make sure that we get the information so that we are in a position to analyze it.

Chairman GLENN. I understand the difference, and I won't press it, but it is a difficult situation, because one is a danger now as opposed to "may be," and we don't know what may be down the line. I would think there ought to be some way that that has to be considered, so we can make sure people are notified.

Dr. BURLINGTON. Absolutely, we agree, Mr. Chairman.

Chairman GLENN. You are reorganizing, I believe, the Center for Devices and Radiological Health; is that correct?

Dr. BURLINGTON. Sir, we have undertaken a reorganization within our Office of Compliance and Surveillance just recently, on a pilot basis, and we will be continuing that, so that we are organized within this office along lines of business.

We do not have in process an overall reorganization of the Center at this time.

Chairman GLENN. OK. I understood the Center for Devices and Radiological Health is being reorganized in part to improve postmarket surveillance and to develop patient notification programs. You are saying that isn't the case?

Dr. BURLINGTON. We are in the process of looking very hard at how to do a good job on that. Right now, we are organized in such a way that those programs are integrated through a matrix involving four different offices. And we need to make sure that we cover the functions, that we properly coordinate the information. Whether that will result in structural changes in organization, or whether it will make sure that we have cross-structure reporting is not yet decided.

Chairman GLENN. But whatever you do, I presume that this reorganization will also address medical devices that produce or utilize radiation.

Dr. BURLINGTON. Absolutely.

Chairman GLENN. OK. What aspects of patient notification will you also look at? How will this be coordinated with NRC's patient notification of misadministration? Will you coordinate with them if you are setting different standards, or reorganizing that group?

Dr. BURLINGTON. Let me address that in two parts. In terms of the question of what is an under- or overdose in terms of the administration of radiation, we intend to coordinate that very closely with the NRC so that we are using a uniform reporting standard for practitioners so that they don't have to have different rules for different Federal agencies and can understand that one level is the threshold at which they need to be reporting.

The separate question in terms of how we will coordinate patient notification, our statutory scheme provides us with authority to require patient notification where it is necessary and there are no alternative methods feasible to mitigate the effects of the adverse event. We have not routinely undertaken patient notification in the past. Clearly, over the last couple of decades, with the changes in practice of medicine, there is a changing expectation on the part of patients and the medical community about getting the information to patients. We have moved more toward patient notification. We

have done that in a number of cases where the patient needed the information in order to take action that would affect their risk of the adverse event. And we are carefully considering how we ought to apply that in the case of inappropriate administration of radiation.

We also have to be cognizant of the fact that we don't want patient notification to be a trip-wire or a signal that gives physicians pause and reduces reporting to us of events, because if every doctor thinks that I report to FDA, and I am immediately inviting a bunch of lawsuits, then we aren't going to get the reports we need to find out what is going on.

Chairman GLENN. Have misadministrations been followed on a regular basis by lawsuits?

Dr. BURLINGTON. I don't know the answer to that, Senator.

Chairman GLENN. Does anybody know?

Mr. JOHNSON. Frequently, it has, yes, Senator.

Chairman GLENN. Even though we don't know what the effect of it may be.

Mr. JOHNSON. That's true.

Chairman GLENN. FDA has established radiation control performance standards for television and diagnostic x-ray systems, lasers, microwave ovens, and even tanning beds. Why hasn't the agency established such standards for linear accelerators, which are far more dangerous?

Dr. BURLINGTON. Somewhat over a decade ago, we established notice of intent that we were going to do exactly that. We received resoundingly negative input, and in fact were advised——

Chairman GLENN. From whom?

Dr. BURLINGTON. From the community, principally practitioners.

Subsequent to that, we have become aware that today, products coming through for marketing approval are uniformly manufactured in accordance with the IEC, the International Electrotechnical Standards, because they are in an international marketplace. If one should come through that did not meet that standard, we would reinforce the standard by asking the same types of questions in the review process that the standard is designed to meet.

So we have de facto adopted that standard even though it is not a required performance standard.

Chairman GLENN. You are saying, then, that you in effect have adopted the international standards, and you want everybody to adhere to that. Do you check, then, to see whether they do adhere to those standards?

Dr. BURLINGTON. We look at the applications that they submit to us to ensure that they have committed to adhere to them. We have an inspection system that addresses the manufacturing principles. We also have a BIMO system that, in complement with our manufacturing system, is designed to assure that there is valid information submitted to us.

In terms of do we go and do an engineering quality assessment, engineering drawing level, no. We are not staffed at that level, and we don't have the capacity to deal with every application.

Chairman GLENN. Well, if you have a doctor out there using a linear accelerator to treat someone therapeutically, how do we know that that machine is within the international standards? Is

there any checkup on this? Are there requirements for measurements to be made or assessments to be made of individual pieces of equipment over a certain period of time?

Dr. BURLINGTON. As was addressed earlier in Mr. Selin's discussion and the colloquy, there is a network of regulations through State authorities in terms of the user point administration of radiotherapy; that principally, this is an activity regulated through the States—it does vary, depending on the type of radiation being delivered; it is different for linear accelerators or naturally-occurring sources than it is for byproduct sources. Obviously, for byproduct sources, the NRC has an active role in assuring that the medical device is performing appropriately on site. For the others, it is a State responsibility.

Chairman GLENN. Well, do you think that's the best way to leave it? Maybe you don't have the facilities right now, but do you think you should be doing follow-up? Because the improper or unauthorized use of these linear accelerators' safety bypass system in the research mode has led to a number of serious injuries. Do you know what the purpose of that safety bypass switch is?

Dr. BURLINGTON. No, sir, I don't know.

Chairman GLENN. Mr. Hamilton?

Mr. HAMILTON. Basically, in many of these linear accelerators, the machine is capable of not only doing patient work, but also research applications as well, and many times, what the manufacturer or the user would like to be able to do is to use that machine to determine whether there is improved methodology for treating patients.

So the machines have a bypass whereby you can actually get more energy out of the machine for particular research. We are aware of that. Again, one of the criteria we would want to see in the applications that would come in to us would be ways to prevent that bypass from being used, even accidentally, in treating a patient.

Chairman GLENN. There is no restriction on that now—you just leave it up to the individual doctor?

Mr. HAMILTON. Basically, it is left up to the user to use, again, with the labelling instructions that we do review to show that there is some way of not letting that thing accidentally happen.

Chairman GLENN. Are any of these machines designed so you could cut out the research mode when it is being used on patients? Is such a thing possible—because that is where the accidents have occurred, as I understand it.

Dr. BURLINGTON. Mr. Chairman, I don't know how it would be possible for a machine to distinguish between whether it was being turned on for patient use or for research.

Chairman GLENN. Well, it could be done any time it is being used for a medical therapeutic purpose, though—you'd throw the therapeutic switch, and that prevents anything else—I don't know. I haven't even seen one of the machines—and I am not making light of it at all, but there ought to be some way to do that, because that is where some accidents have happened with these machines.

Dr. BURLINGTON. Yes, sir. The operation of these machines is fundamentally the responsibility of the unit and the institution in which they are being operated. We rely on sound medical practice,

sound radiation safety practice on behalf of the professionals who are operating them and the institutions that are overseeing that, including the State licensing, to the extent that that is relevant, to make sure that——

Chairman GLENN. When you approve a machine like this to be sold, Doctor, do you require any warnings that the research mode on these machines not be used when the machine is being used for therapeutic purposes?

Dr. BURLINGTON. Let me again ask Mr. Hamilton to address the labelling issue.

Mr. HAMILTON. Again, we rely upon the user to determine how the machine is to be——

Chairman GLENN. No—do you give the user a warning that this could be dangerous if it is used that way? That's the question.

Mr. HAMILTON. Normally, you would find something like that in the operator's manual, yes, sir.

Chairman GLENN. Do you require that kind of warning in an operator's manual?

Mr. HAMILTON. I don't know honestly whether it is required or not, but it is something we know all the reviewers would be looking for as they would go through that submission.

Chairman GLENN. It might not be a bad idea since we have had problems in that area already.

When FDA is alerted to a serious problem with a medical device, what steps are taken by FDA to alert other users of the device of that problem?

Dr. BURLINGTON. The first thing we do when we get a report is take a look at it and analyze it and try to sort through whether we have a user problem or whether we have a device problem, and that leads us to a number of consequences in terms of developing further information.

In terms of our network of how we communicate to other involved parties, let me ask Mr. Johnson to address this.

Mr. JOHNSON. Generally, if we get a report, when we speak of users, we are usually thinking of the health care worker or the institution. When we find that there is a problem that is deriving from a defective device, our immediate concern is notifying, making sure that the other users—hospitals, physicians, whatever—are aware of those problems. That can take the form of what we call "safety alerts" that are issued by the company; safety alerts that are issued by us if it is a generic, across-the-board kinds of problem; or actually a recall notice that would involve both a notification and a correction if there is a defect to the device.

Chairman GLENN. We have a similar problem on fluoroscopy x-ray devices, similar to the linear accelerator. On the fluoroscopy x-ray device, they have so-called "turbo switches," which allow the user to drastically increase the dose to obtain a clearer image; but as the dose increases, so does the risk to the patient. I don't know whether you monitor things like that when you assess a machine. Do you put limits on it, or redline it, or once again, provide instructions so that it can't be misused? I guess the purpose of a turbo switch is to obtain a clearer image, but there should be certain limits there so that you can prevent misuse. Is that something you get into?

Dr. BURLINGTON. Mr. Chairman, you are correct. The purpose of these high-level energy switches is to allow a clearer image so that certain diagnostic applications, principally in cardiology, can get clearer images and can operate more efficiently. Because of concern about this issue and the patient exposure involved, on the 3rd of this month, we proposed regulations that would put limits on these switches in order to enhance patient safety when they are used.

Chairman GLENN. OK. We have a February 20, 1992 GAO report on FDA device inspections which found that, "FDA does not meet its minimum statutory obligation to inspect manufacturers of medium and high-risk devices at least once every 2 years." They continue, "GAO also found that the frequency of inspections has been declining in recent years"—I don't know whether that is a budget problem or what it is. "Further, foreign manufacturers must also be inspected by the FDA, but they have only been inspected about once every 8 years."

Do you agree with GAO's findings, and what is being done to address this situation?

Dr. BURLINGTON. Mr. Chairman, as I noted in my remarks, we are concerned; we want to be in those plants more often. We need to have the resources to get there. The administration, cognizant of the growing responsibilities of our Center, has asked in the President's budget for $20 million of additional funds. We need the bodies and those dollars in order to fully implement our program.

I'd like to ask Mr. Johnson to respond more fully to your question.

Chairman GLENN. Fine.

Mr. JOHNSON. Yes, I think those numbers probably are accurate. In the domestic area, to address that issue, what we have tried to do is identify some priorities for our field investigators so that they are at least getting to the most problematic of companies on a regular basis, reasonably regular basis. We think that has worked very well. We have developed a number of initiatives that look at corporate profiles, chronic violators, repeat offenders, if you will, multiple recalls. So I think that is making as good a use as possible.

We have found that the time it takes to make an inspection has significantly increase because the complexity of these devices is always increasing.

In the foreign area, we recognize that there is an obvious weakness in there—it is very costly, and it is very difficult for us to get there. But in this last year, we have doubled the number of inspections that we have asked our field offices to carry out, and we are being much more aggressive in enforcing the rules, using some very powerful authorities to bar products from coming into the country, and that has proven to be very beneficial as well.

Chairman GLENN. That same GAO report also found that FDA's inspections were not coordinated particularly with market introduction, which is the time when product design and manufacturing problems are most likely to appear. For example, during fiscal years 1987–90, one-third of domestic manufacturers with recalled devices had not received an inspection within 2 years of their products being recalled.

Is that a factor, do you think? Do we need to address that?

Dr. BURLINGTON. We think it is a factor, Mr. Chairman, and we are prepared to address it. We are moving to have a pre-market inspection program that will be applicable to the most risky devices that are approved under this mechanism.

Chairman GLENN. We understand that FDA and the NRC were planning on negotiating a memorandum of understanding to assist each other in regulating medical devices that employed radiation therapy technology. Has this been done?

Dr. BURLINGTON. We have begun discussions on such a memorandum. We have talked about the principles of hat we want to accomplish in it. Because it requires coordination among the various centers that use radiation in human diagnostic and therapeutic issues—that is, biologics, drugs, as well as devices—we are in the process of coordinating that.

We have not yet gotten that memorandum, but we have discussed it. I met yesterday with Dr. Selin, and we are committed to see this process through expeditiously.

Chairman GLENN. OK. Like how expeditiously? Can you give us a time frame or a date by which you expect to have this done?

Dr. BURLINGTON. I can make a commitment to you to work very hard on it. Given the complexity of the situation and the fact that it involves people who are in other areas of responsibility and other centers, I would hesitate to make a commitment for their actions.

Chairman GLENN. Well, this isn't all that complicated. I wonder if we could have that same August 6th date as a target date for getting the agreement?

Dr. BURLINGTON. We will certainly try.

Chairman GLENN. Because staff just passed me a note that says, "This has been ongoing since at least 1984." That gives us 9 years. It seems to me we ought to be able to get it here by August 6th, since we have been considering it for 9 years. We'll look for that as part of our August 6th reporting.

August 6th is a Friday, so that's fine. Staff tells me August 6th is also Hiroshima day.

You have already addressed Theratronics. Can you go into that a little bit? They have been a manufacturer of linear accelerators and other medical radiation devices. I think it would be fair to say that they have had a rather checkered history with regard to the performance and their compliance with your FDA regulations.

Is the Theratronics equipment that you and the U.S. Attorney seized in Houston—was that the company we were talking about, Theratronics?

Dr. BURLINGTON. No, sir. The company in Houston was Omnitron.

Chairman GLENN. Oh, OK.

Dr. BURLINGTON. But you are absolutely correct about the checkered history of Theratronics.

Chairman GLENN. OK. Let me address that. Theratronics has indicated that they do not plan to provide spare parts support any longer. What are you doing about that? This was investigated by the House, also, when Congressman Dingell got into this some time ago. What is the status of Theratronics now, and does FDA have the authority to insist that Theratronics meet its obligation to the hospitals that originally purchased the equipment for spare parts?

Dr. BURLINGTON. I would prefer to refer this question to the Director of our Office of Compliance and Surveillance, Mr. Johnson.

Chairman GLENN. Fine.

Mr. JOHNSON. We have had, as you know, a lot of problems with Theratronics products over the years. They are a Canadian firm, and they have a subsidiary here in the United States, and we have inspected both of those over the last several years rather extensively. We have barred all importations of products from Theratronics since 1991, with some expectations; those exceptions were for parts.

Chairman GLENN. Everything, the whole works.

Mr. JOHNSON. Everything. We have just completed inspection in February of the Canadian facility, and we are now going to permit entry of selected products, but not other products that they are continuing to do validation work on and have still to get their good manufacturing practices into shape.

They are in fact permitted to import parts for repair and service for all of their units at this point.

Chairman GLENN. But it's not that they are permitted. They have said they are not going to; they do not plan to provide spare parts. Can you require them to do that, because this leaves some of our hospitals and others high and dry.

Mr. JOHNSON. I don't think that we can compel them, but my understanding from what we know is that they are continuing notwithstanding their notification that service and parts may ultimately go away on some of their older units.

Chairman GLENN. I would think most contracts would have a requirement for spare parts within a certain time period, don't they—quite apart from this or any other type of equipment.

Mr. JOHNSON. Yes. The products that are subject of these parts needs are 30, 35 years old. Another source of service and parts are third party reconditioners and refurbishers. There are a number of them that I know specifically are very interested in Theratronics products and have an active business in that area.

Chairman GLENN. Are things like this a problem with foreign suppliers, not just from Canada, but from other places? We have medical equipment and all sorts of equipment sold all over the world now; do we have any more problem with foreign suppliers than we have here with our own people?

Mr. JOHNSON. From the standpoint of continuing to provide parts?

Chairman GLENN. Well, I mean just the general acceptability of the product, doing what it says it should do, parts, the whole thing.

Mr. JOHNSON. We think the bottom line measure is whether they comply with good manufacturing practices, and in our foreign inspection program, we find that compliance is a little less than it is in the domestic market, but not significantly worse, in other words. So we think the products that are coming in are comparable to domestic products, and Dr. Burlington mentioned in response to your question on the GAO report that we do in fact do an inspection of every product that is brought to market under the PMA process before it is permitted on the market, and we are going to begin to do that on even the 510(k) Class 3, or the most problematic devices.

Chairman GLENN. When you have foreign devices, let's say a big x-ray machine, and it's a new type, do you send people over to investigate it at the plant, or do you have a sample sent here for your analysis? What process do you use when approving a machine?

Dr. BURLINGTON. These are pretty big devices, by and large, and we don't generally get samples shipped in. We do onsite inspections, and that allows us not only to look at the product, but also to look at the manufacturing control processes.

Our inspection and good manufacturing practices is a systems approach where the company has to have the quality control systems in place in order to produce a quality product.

Chairman GLENN. Last year, Mr. Benson, then director of CDRH, indicated before Chairman Dingell's subcommittee that he has, "invited a review of our device evaluation and pre-market approval programs by the HHS IG." Additionally, he said that the agency's Office of Management, which oversees internal controls, and audits, conducted under FMFIA, will take, "an independent look at the way you do business."

What has been the outcome of those reviews, with specific reference to our topic here today of radiation control?

Dr. BURLINGTON. I have to apologize, Mr. Chairman, I don't know. We'll have to look into that, and we can get back to you.

Chairman GLENN. All right. If you could get back to us with that information for the record, we'd appreciate it.

The President's budget seeks increased funding for FDA device activities, by 24 percent; I believe it is scheduled for $153 million. Is that correct?

Dr. BURLINGTON. Certainly, he has sought an increase in funding. I will take your word for the dollar amount.

Chairman GLENN. OK. I think it is $153 million. Reportedly, this increase is for "monitoring and inspection coverage to improve market surveillance and to employ new enforcement authorities."

The question is if you receive this increase, if Congress approves it, how will it affect the regulation of the devices we are talking about here today? That's supposedly an increase of 24 percent. What will you use that money for?

Dr. BURLINGTON. We'll use that to implement principally the authorities given to us under the Safe Medical Devices Act of 1990 as amended in 1992, where we have a number of new authorities that are going to make a difference. We will also be ramping up our inspection program, as we have earlier alluded to, in addition to which we will have an increased capacity to review applications as they come through, both re-establishing timeliness of review of applications as they come through, and as well looking with enhanced scrutiny to make sure that they are meeting applicable standards.

Chairman GLENN. You have an Import Alert List that is maintained by FDA. When a product is placed on that list, it is effectively barred from being marketed in the United States, as I understand it; is that correct?

Dr. BURLINGTON. That is correct.

Chairman GLENN. Do you have any idea how many radiation devices are currently on the Import Alert List?

Mr. JOHNSON. I don't know the number.

Chairman GLENN. Is it a large number—or none?

Mr. JOHNSON. No—there clearly are. Theratronics is on that list, and Mitsibushi is on that list, some of the larger ones that we have recently had problems with. But there is a list that is maintained. I honestly don't know the number.

Chairman GLENN. I presume most of those products barred would be on specific pieces of equipment, not a bar against everything a manufacturer produces; is that correct?

Mr. JOHNSON. It frequently can be either or both, but generally it is a bar against things coming in from that particular facility.

Chairman GLENN. Do you have certain standards you apply when you check it out? What causes a radiation device to be placed on the list—that's my question.

Mr. JOHNSON. Well, principally, the same reason that any other medical device would get placed on the list, and that is usually a failure to comply with good manufacturing practices. If they are not manufacturing in a state of control their quality assurance program, that's usually the primary reason.

Chairman GLENN. What do you do to ensure that once a product is placed on the Import Alert List that similar devices which may already have entered the domestic market are located? Do you keep a record of those, or do you require the company to keep a record?

Mr. JOHNSON. Companies are required to keep distribution records, so if need be, we can go to the companies and determine where the products are. The threshold, however, for putting a company on an import alert, the statutory authorities are different. So, while we may bar a company from bringing in new product, the threshold may not have been met for us to go out and actively take some action against products that are already in the country. They may have been, for example, manufactured perfectly in compliance with good manufacturer practices, and our most recent evidence indicates that current operations are not in compliance. So there may not be any applicability to domestic products.

Chairman GLENN. In other words, the equipment is all right, but it is being misused—is that what you meant?

Mr. JOHNSON. No. I am talking about the systems and the controls in the actual manufacture of the device, to make sure that what is manufactured is what is intended to be manufactured, that it meets the specifications, that that is what it is supposed to do.

Chairman GLENN. There was a linear accelerator used in a Spanish incident. Is that on the list now?

Mr. JOHNSON. It is not on the list. That was an event that was reported to us by General Electric. The episode was the result of a service problem. We did work with General Electric to determine whether that kind of a problem might exist in any of their other facilities, and it was determined that that problem was not one that was generic to the product line. It was a unique circumstance in Spain, based upon service.

Chairman GLENN. The problem was there, but nothing occurred here. That was a very important one, I think, because some 20 people, I believe, were killed; is that correct?

Mr. JOHNSON. Absolutely. Yes, it was very serious. The problem was that they had an unqualified service person in Spain come in and service the unit, and in the servicing created a situation where

the machine could actually overdose. That kind of problem—the users in this country were notified of the event, but there really wasn't anything they could do because it had been improperly serviced.

Chairman GLENN. Are service people certified? That just points out the difficulty of this. How do you certify a repairman who can misadjust or maladjust a machine, and kill 20 people? How do you check up on that? Does that come under your regulation and follow-up? Somebody needs to be looking into this stuff. We had 28 people in Ohio, 20 in Spain.

Mr. ROSENSTEIN. The case in Spain was a service person who was not qualified to repair the device——

Chairman GLENN. I know, but who determines whether he is qualified or not? That's the point.

Mr. ROSENSTEIN. He was qualified to fix the Cobalt therapy systems, and the staff there imposed on him to correct the other one, and he should not have, so it was a misjudgment on his part to even attempt to do something that he was not certified to do.

Chairman GLENN. Well, let's say the same thing happens right here, in Kansas City. Do we have any regulations for controlling that kind of thing here? How do we qualify repair people?

Dr. BURLINGTON. We have FDA requirements for people who are basically reprocessing and refurbishing machines to put them back in new condition and put them back on the market. In terms of the service people for machines out on the market, that fundamentally is the responsibility of the institution in which that machine is operating and the States.

Chairman GLENN. Is that good enough?

Dr. BURLINGTON. It leaves gaps, as you pointed out, Mr. Chairman.

Chairman GLENN. We have so many Federal regulations these days that I'm hesitant to impose more. We just fought part of last week on the floor over the EPA bill that I was managing on the Senate floor, and part of the big debate last week was in this area of rules and regulations. And I get more complaints about rules and regulations from the Federal Government when I go back home and have town meetings than almost any other complaint that people have. So I am extremely sensitive to making more rules and regulations, but it seems to me there ought to be some way where machinery, maladjusted and misused by people with all good intentions, can kill folks and should be regulated. We have already had it at home in Ohio, and now we have 20 in Spain.

I would think that in your consideration and the NRC's consideration of what system we are going to have in this country with regard to use of radiation equipment, we have to consider some kind of follow-up. Whatever we set up as a control program, I think it has to include things like this—people maladjusting a machine, which I presume was not obvious to the operators of the machine, and wound up killing 20 people. I think that's something we have to consider, too. I don't know how we do that. Do you have any suggestions?

Dr. BURLINGTON. It is a very difficult issue, and you are absolutely correct; we get a lot of feedback as well that the American citizens, the companies that manufacture these products, think

they are heavily burdened by the current regulatory system. Imposing more requirements ought to be done on the basis of looking and saying that this is a rational way to deal with the problem.

We have identified a problem, and we concur that this is a real problem, and we share your concern about how to grapple with the right answer.

Chairman GLENN. Well, first, you want to make sure the machines are as foolproof as possible, and then that the people are trained, it seems to me, and then you don't want to make so many restrictions that you can't use the machines for the very good and beneficial purposes for which they are designed. So nothing is perfect. I had a background in aviation, and they used to joke that the only way to never have an aviation accident is to keep everything in the hangar and never get it out there and fly it. And that's a little bit like where we are with this. There is a balance here that has to be hit, but it seems to me that when people have already been killed, that's a warning that we have to take some precautionary measures.

You heard the discussion that I had with the NRC people a little while ago about the Radiation Policy Council that President Carter established, and I read off what I had proposed at one time. Is that the way we should go? What is your advice on this? I'd like each of you to address this as I did the previous panel. What do you think we ought to do? Do we need some overriding authority on this? When people have been killed, it is obviously a danger. This isn't, "Take an Advil and call me in the morning"; this is really serious. And it seems to me we have to have some kind of control, and I don't know exactly what it is. You are the experts. What do you propose?

Dr. BURLINGTON. Mr. Chairman, the agency and the Department to the best of my knowledge do not have a thought-through, considered opinion on this. We, like NRC, would be glad to grapple with the question and see what we can come up with.

Chairman GLENN. Can you coordinate with them and hit that August 6th date?

Dr. BURLINGTON. We can certainly seek to have input to their deliberations and to coordinate with them.

Chairman GLENN. If you would, I'd sure appreciate that, because if we are going to get something through this year, we have to have your advice and counsel. I don't want to just pass something up here from on high, as though we have all the magic answers. You are the people who are going to have to make whatever we pass work, so I want your advice on this, and any advice you can give us this morning would be appreciated.

Dr. BURLINGTON. We certainly will try. I must, of course, note that we are at a relatively low level within the Department. We have agency, Public Health Service, and then the Department administrative structure above us. To develop a coordinated position in that time frame is a commitment that, again, I would hesitate to make on my own authority, but we'll provide our input to our supervisors.

Chairman GLENN. Well, we sent the letter of invitation to the Secretary over there, and she sent it to your level, so I presume you speak for her. You can carry the word back that we expect the

answers by August 6th, along with NRC's answer, if you can possibly do that.

Dr. BURLINGTON. We will certainly carry that word back, Mr. Chairman.

Chairman GLENN. Thank you.

Mr. Johnson, what do you think—what do we need to do to correct this?

Mr. JOHNSON. I don't think I know the answer. I think you have pointed out some very, very good questions on a lot of disconnects. It is very frustrating for us, the one we were just talking about. It is very frustrating for us to try to assure that a device is properly designed and then properly manufactured and will in fact perform safely and effectively, only to have it tweaked by somebody who is unqualified, or used by someone who is unqualified. I think that clearly is a gap that needs to be filled.

The disconnect between the level of user regulation for linear accelerators versus Cobalt teletherapy is another obvious one that needs to be addressed. I think some of that may be appropriately addressed through legislation. I think a lot of it, because there is always going to be overlay, can be done through some kind of a coordinated effort—whether that is creation of a council on a temporary basis to get the house in order, but not live forever; or perhaps expansion and more formalization of the memorandum of understanding that we are developing with NRC to include some other parties. That might be another way to do it.

Chairman GLENN. Mr. Rosenstein?

Mr. ROSENSTEIN. Thank you. I am a representative from the Department to the CIRPPC group, the Committee for Interagency Radiation Protection and Policy Coordination. If you look at the charter, the committee is limited to a coordination role. It serves a useful purpose as a forum for discussion, but it does not supersede or replace any authorities that the member agencies have. Therefore, whatever authorities reside in the agencies are the authorities that count, and they work together whenever they can to come to agreement.

The issue of radiation therapy has not come before them, and in my opinion would not be an appropriate issue for them, since it is limited to a couple of agencies.

In my own personal view—and this is all personal opinion—I think the components for the regulation of these systems—and I speak specifically of radiation therapy devices—exists. It exists between the NRC, the FDA's roles, and the State roles. They are the parties that I think need to be brought together in some fashion. I don't know how you do that through legislation, but the pieces are there; they are just unsatisfactory.

So I would not look to the Radiation Policy Council or its current version of that unless there is some major change in the charter, and the committee or the council has authority to actually regulate these devices, which is not the case at the present time.

Chairman GLENN. Mr. Hamilton?

Mr. HAMILTON. I think that there are a number of authorities already present for the various agencies, both at the Federal and the State levels, to utilize. I think that with perhaps improved coordination and communication between those agencies, a number of the

problems that have brought us here today may have been solved beforehand, and we would not necessarily have been spending the time.

Chairman GLENN. Yes, but I am a cynic on that approach, because we have been waiting since 1979 for this coordination that we were told about in the letter that I quoted from. So I don't take much solace, nor do I think the people out there who may get overdosed are going to take much solace out of the fact that government has to get together and coordinate. I think we may have to push. I hope we don't. I hope this August 6th report gets some information on how we really can go at this and gives us some examples perhaps of what you are doing between now and August 6th to hopefully get control of this thing.

Right now, there are just too many gaps. Just from the few anecdotal things we have pointed out this morning and some of the comments, it is evident that something needs to be done to ensure that people are better-protected out there. And like I said before, I don't want to set up another committee or commission, and I don't want to put in legislation—unless I have to. But we want your advice on it. You are the ones who have to make it work.

Thank you very much. We may have additional questions for you, and we'd appreciate your early reply so we can include it in the record.

Dr. BURLINGTON. We'll make every attempt. Thank you, Mr. Chairman.

Chairman GLENN. Thank you very much, gentlemen.

Our last witness this morning is Aubrey Godwin, Chairman, Conference for Radiation Control Program Directors.

Mr. Godwin, we welcome you this morning and look forward to your testimony. I know you have been in the audience here all morning, and I'm sure you have heard all the comments, so maybe you can straighten out some of these things for us.

TESTIMONY OF AUBREY V. GODWIN,[1] CHAIRMAN, CONFERENCE FOR RADIATION CONTROL PROGRAM DIRECTORS

Mr. GODWIN. Thank you, Mr. Chairman. I appreciate you and the members of the Committee inviting the Conference to come and offer some testimony.

You have my written testimony already, and I thought I might go through and just hit some of the points that came up this morning.

Chairman GLENN. First, tell us what the Conference on Radiation Control does. What is the organization, and what is its background?

Mr. GODWIN. Each State that has a radiation control program, the director of it is a former Conference member. The associate members are people within the programs within the States. We also have what we call affiliate members, who are other groups including, in some cases, industry, in some cases, user groups, like universities, for example, and some Federal people also appear in that. But the actual voting members are the actual program directors for the radiation control programs in each State, which is typi-

[1] The prepared statement of Mr. Godwin appears on page 70.

cally in the health department, although in my particular case it is a minor cabinet level.

Chairman GLENN. Thank you.

Mr. GODWIN. Looking at some of the issues that came up this morning, first of all, there were some comments relative to dental assistants and their training. I think we need to recognize that the training program in some cases is normally part of their dental assisting training, and is not necessarily limited to radiation protection—and indeed in some cases, they can probably take the test for dental assisting and fail all the radiation protection requirements and still pass it. So you need to be aware of that.

Also, along the same line of training, with the exception of Wyoming, all States have some requirement that says a general statement of training for the users of ionizing radiation, i.e., they will say the facility or the operator is required to train its workers. And that's about as specific as it gets. So you do have that, and as we address this, the numbers you were giving are probably those States who certify additionally their qualifications; so there is certification and license, and it goes beyond that rather general statement.

Chairman GLENN. But that's up to the State.

Mr. GODWIN. That's up to the State. That is clearly-established by the State.

Chairman GLENN. There are no national standards that——

Mr. GODWIN. Well, now, FDA had some authorities given to them that they could put forward some advisory guidance that the States could use, and they were to get back to Congress and make recommendations as to whether to make it stronger than advisory. But I believe that is advisory; you might need to——

Chairman GLENN. Well, I don't know if we need to go to Congress—and I don't mean to interrupt your statement, but in something like this, I would think FDA would have full authority right now to go ahead and put out an advisory as to what they think——

Mr. GODWIN. Oh, yes, they can put out an advisory, and they put out a preliminary draft in the Federal Register, but I'm not aware of it being finally finalized. It may have been, but I am not aware.

Chairman GLENN. OK. Go ahead.

Mr. GODWIN. Another issue that came up was regarding individuals who may have a record of not being fully open, or perhaps even willfully violating regulations, or malpractice, if you would. Even though the States, as a part of their general medical licensing, chiropractic licensing and dental licensing, have the overall, if you would, licensing authority, in some States the radiation program, when they ask for a license to use radioactive material, they do undertake to go back into the record and obtain information from other States that they may be coming from, to see if they did have a record of problems. And in the former State that I worked with, Alabama, we would take a one- to 2-year prohibition perhaps on giving them a license until they had established that they would do things properly.

Chairman GLENN. But that is left up to the States, then; you can do it or not?

Mr. GODWIN. It is left up to the States. The NRC, I don't think, has adopted that regulation. They could adopt that regulation

themselves and pick up information from States. For example, if they were coming from an agreement State, they could ask about it, but I am not sure they are doing that at the present time. Again, that's related to the byproduct source and special nuclear material.

Chairman GLENN. The *Plain Dealer* cases that I referred to earlier, I think, are ones where they actually found two cases where people had been felony violators in one State and just went over to another State, got a job, and I think were in an official position in the second State. We don't have any way of checking up on that. Would your organization be one that could keep a central file on this sort of thing, or is that too voluminous?

Mr. GODWIN. Well, we are looking at a similar operation relative to industrial radiography. We discovered that you have to be very careful to avoid the blacklisting characterization and character assassination; you can pick up some interesting liabilities when you approach this. And the only thing we would be able to do, I suspect, would be to pass on information where an official order had been issued by some State, probably a court, and pass on a copy of the court order. Otherwise, you are going out for character assassination.

Along somewhat similar lines, compatibility issues came up. Compatibility generates a lot of discussion within States because, as always, the first question is, Do you mean "identical," or do you mean "compatible"? Can a State adopt something more stringent, then?

In relation to what came up this morning, you need to recognize that in some cases, a State is ruled not compatible when it really has nothing to do with health and safety. For example, my State is found to be noncompatible. The issues involved, however, one of them was a decommissioning bonding requirement, and the only facility involved was a university which has to make a statement rather than post a bond, and the statement says, "We will seek funding if we have to decommission."

The other issue involved was emergency planning, and we have no licenses that fall into that. So even though we are noncompatible, it effectively has no meaning as far as health and safety is concerned. Now, unfortunately, that is not true; there are several States that do have some issues that need to be looked at.

Another area that we might want to look at is in the nonagreement States, you may end up in a little worse situation with regard to particle accelerators, because in the agreement States, you do have a training program of some sort in existence. In a nonagreement State, you have no assurance that there is a training program of any type—in fact, in one State, there is no radiation program. So there is less likely an opportunity to review the use of a particle accelerator in a nonagreement State.

Now, turning to the particle accelerators for just a moment, part of the problem in the use of particle accelerators is that the FDA really licenses the device that has been installed in a room that is not, if you would, part of the manufacture of the device itself. So the bypass operation may take place as a result of the way it is built into the room. It has nothing to do with the circuit diagram of the piece of equipment that is installed, but has to do with the

way the safety equipment is connected to the doorways and things that lead into the room.

Because of that, my testimony indicates that we see some real need for the States to be closely involved in particularly looking at the user end of it. In fact, I think the States in general would support things that would keep the States involved in looking at the user end of it. We are very concerned that we don't lose that particular area. I think the States have a vital mission to play there, and I think most of the States would also want to continue the general licensing of the medical practice provisions, which is currently the practice in this country.

You touched upon the service personnel. To elaborate just a little on the situation you are going to find there, some States do regulate service personnel. Again, it is a State decision, as you heard earlier. Service personnel may consist of people from the original manufacturer; they may be a third-party supplier, or in some cases, they may be the facility's own in-house service personnel. So you then come into a real tangle of problems as to how to assure that each one of those groups gets appropriate training before they actually do the work. And I think that, looking at the scope of it, you can see it is a real tangle there that will have to be dealt with.

You also mentioned something earlier relative to the States coming in and saying they need funding, and I will address this as my personal thoughts rather than associate the Conference with it.

The approach that is being taken by NRC through their agreement State program has some merit in that they say, "Look, States, we don't give you a grant to be an agreement State, but you can charge fees." And quite often, as you heard, the fees are less than the NRC fees because of less overhead, less travel, and for various reasons—less salary, too, I might add.

If, in establishing some proposal, you establish a requirement that the States charge fees equal to some minimum floor value to be used for those purchases, you in effect have guaranteed the funding for the program without necessarily having a Federal program established, but allow it to be handled through the State legislature and be appropriated back to the program such that it would be cheaper to run it at a State level, thereby again reducing the overall cost at the Federal level.

Touching on those issues as a quick run-through, Mr. Chairman, I am prepared to answer your questions.

Chairman GLENN. Thank you very much, Mr. Godwin.

It is my understanding that of the 29 NRC agreement States, those States that have agreed under authority of the Atomic Energy Act to assume regulation of byproduct material, only 16 States have demonstrated their programs are fully compatible with the NRC. Do you view that situation as serious, and what should we do about it?

Mr. GODWIN. Well, I think you almost have to look at it on an individual, case-by-case basis. Some of them are serious, there is no doubt about it, and I won't try to duck that issue at all. But as I indicated in my earlier statement, in some cases, the items that are noncompatible really have no effect because they don't address anything that has taken place in the State. For a while, one State was noncompatible because they didn't have certain import regulations.

The States don't really control import, but they didn't have that particular general license, in effect. So you run into those kinds of things. Others are far more serious.

Chairman GLENN. You could take the other tack, though, and say that the public health and safety is impacted by the fact that nearly half the agreement States don't have adequate radiation protection programs, too.

Mr. GODWIN. I think you'll find that in most of the cases, although they were noncompatible, that a finding of adequacy to protect public health and safety did exist.

Chairman GLENN. Well, OK. I think unless you look at them, though, and try to get them into compliance, you don't know.

Mr. GODWIN. Yes. They need to be looked at, no doubt about it.

Chairman GLENN. You don't know whether someone is dangerous out there or not, unless you look at it.

Mr. GODWIN. You do have to look at it, that's absolutely true; I agree.

Chairman GLENN. OK. You mentioned this briefly, but according to the Department of Health and Human Services, 27 States regulate radiographers, 21 States license radiation therapy technologists, 14 States license nuclear medicine technologists, 32 States certify or register dental hygienists to give x-rays. Is this a logical way to protect the public health and safety? It is all over the lot. I don't know what we should do about it. How do we get this to become more standard? Who does it? Shall we leave it up to the States and set some Federal guidelines and let the States adhere to that, or what?

Mr. GODWIN. I tend to think that the Federal Government sets some general criteria and put it to the States to enforce it would be the more logical way to go about it. I don't think involving the Federal Government in day-to-day medical practice issues is the way for us to do; I think that is really a State issue.

Chairman GLENN. Well, how consistent are the licensing procedures? Let me just give an example. Do some States require that radiographers pass a test or take a course before they apply for a license?

Mr. GODWIN. Some States do, some don't. It is not consistent.

Chairman GLENN. Let me ask this. Is it possible in some other States for someone to just walk in off the street, apply for a radiographer's license, and get it?

Mr. GODWIN. I am not sure that they can get licensed, but there are some States where they can walk in and start doing work.

Chairman GLENN. Do all States require a license to be a radiographer?

Mr. GODWIN. No, sir.

Chairman GLENN. They do not?

Mr. GODWIN. They do not.

Chairman GLENN. So you don't need a license. I was putting an extra step in there. You don't even need a license.

Mr. GODWIN. Some States do not require a license; that's very clear.

Chairman GLENN. Are you aware of any instance when a patient has been harmed due to inadequate training on the part of a radiographer or a radiation technologist? Are there examples?

Mr. GODWIN. Well, other than the ones that have already been mentioned, I'm not aware of any. When I was in Alabama, there was a case where you'd have to decide whether it was inadequate training or whether it was malpractice. We did have a patient who was harmed by a technologist inappropriately doing some work, and you'd have to make that evaluation as to whether you believed that was malpractice or lack of training. She did not follow her directives, I'll say.

Chairman GLENN. What concerns me as much as anything else is that we just don't know. We don't know the status of machinery and people and training and their level of competency.

Is there a mechanism by which States can share data on medical uses of radiation? For example, does a database even exist that is accessible to both Federal and State regulators which lists medical devices, for instance, that have been recalled, or should be subjected to particular attention? Is this shared back and forth?

Mr. GODWIN. On the byproduct source and special nuclear material side, there is what we call a source and device catalog, in which approved devices appear, and if something happens that it gets disapproved, it will be pulled out of it. I was surprised to hear this morning relative to the FDA having seized all these devices in Texas. FDA does have a notification list. Unfortunately, they don't get it to all the States. Arizona is one that we don't get their recall lists; it is just one of the quirks of their system.

Chairman GLENN. Why do you not get their recall list?

Mr. GODWIN. As I understand, it is shipped to another agency. They have one agency in each State that gets all of their notices, and if that agency cooperates, it will send them out to everybody, and if it doesn't, you don't get them. And I don't know whom it goes to in Arizona yet; I am still trying to find out. I have only been there since September, and I am trying to find out where it goes so I can get the list.

Chairman GLENN. Dr. Burlington is still in the audience. Can you get him the information on whom it goes to in Arizona?

Dr. BURLINGTON. Yes, Senator.

Chairman GLENN. All right. You'll get it.

I think that's ridiculous, that they send it out, and a State organization would take something this important and not get it to the people who should use it.

Mr. GODWIN. Well, they don't recognize it as important quite often, unfortunately.

Chairman GLENN. Well, maybe you can enlighten them when you go back.

Mr. GODWIN. As soon as I find out, I'll get with them.

Chairman GLENN. Could you elaborate on your view of the consistency of Federal regulations with respect to medical devices? For example, in your written testimony, you state that "the two Federal laws directly affecting medical devices have not been implemented for radiation devices."

Mr. GODWIN. With regard to users.

Chairman GLENN. Yes. And you go on to say, "These laws do not adequately provide for State regulatory control."

How do we improve that situation?

Mr. GODWIN. If you look at the particular laws involved, of which one of them was the Medical Device Act Amendments of 1990, I believe, there is an application, and I read it as saying that they could require the user to have certain minimum training, or maybe even certain additional equipment. And to my knowledge, they have not required anyone to have that particular type of equipment.

The other one is the Mammography Quality Assurance Act, which is in the process of being implemented, and it will require specific user things whenever they implement it—October of 1994 is the current schedule.

Chairman GLENN. Do you think there is a need for Federal performance standards for linear accelerators?

Mr. GODWIN. I think we and the States need to know that they are built to certain specifications with surety—whether they want to do it by informally adopting international, or whether they want to go with a formal program, we need to know that that equipment meets these minimum design criteria, and we need to know what they are so that when we go through and look at the user and how he is going to use it, we know the starting point.

Chairman GLENN. Let's say you had a linear accelerator like the one in Spain. It has passed all the standards, FDA has approved it, it's a good piece of equipment, and they send it out. How do you make sure it isn't being misused?

Mr. GODWIN. This is where I think the State has a particular role to play, in that they should come in and look at how they are going to set that piece of equipment up, particularly if they are going to use it for something that I would call nonstandard, like research, where they are perhaps going to bypass something, to make sure they have the safeguards in place to prevent that situation from occurring as it did in Spain.

Chairman GLENN. But you think States can do that——

Mr. GODWIN. The States can do it—not all States do it, you understand.

Chairman GLENN. Well, should there be just a general requirement that States do it and then let them decide how they do it and how many people they put on it, and things like that?

Mr. GODWIN. There should be some way to get the States to do it, yes, or somebody needs to do it. I certainly agree with that.

Chairman GLENN. For what reason would States not do it—just money for inspections?

Mr. GODWIN. Resources are very tight, and you must recognize that the priorities given to this in the political arena—these decisions are made by elected officials, and medical issues are quite often not what he is running on; he is probably running on the idea that if he can keep high-level waste from coming across his county or jurisdiction, and he can get a lot of money to keep the trucks out that are carrying high-level waste—but he doesn't get any votes for the other.

Chairman GLENN. In Chairman Selin's written statement, he indicates that the NRC may take over device approval from the agreement States. Do you have any reaction to that?

Mr. GODWIN. I don't see that that will result in a whole lot of improvement where you have States that are operating under the

agreement program, where they have been reviewed and assured that they are doing things in a relatively comparable manner, because if you look at track records, you can find problems that the NRC has had in approving devices, and you can find problems that the States have had in approving devices. So I don't see a whole lot to be gained by that.

It works a little better on the user by having it at the State level in that he doesn't have to truck over to Washington or some regional Federal office to talk to people and show what he is doing. So there are some advantages to having it at the State level.

Chairman GLENN. There was a 1992 study in the *International Journal of Oncology* which says that linear accelerators are fast replacing radiation teletherapy devices. The study found that as of 1990, the number of Cobalt and accelerator devices were 504 and 1,893, respectively. In other words, the linear accelerators were over triple the Cobalt devices. The study also noted that the number of facilities to treat cancer with radiation are increasing faster than the number of new patients, almost.

With the exception of the FDA approval of manufacture and design, there is no Federal regulation governing accelerator use. States have advocated in the past that the NRC assume regulation of accelerators. What are your views on that?

Mr. GODWIN. I think that some agency would do well to assume that because of very high-dose output. I also think that you need to look very closely also at the turbo fluoro units, because they have a relatively high-dose output. So really, let's look across the board at all of it, rather than just strictly at the high things. Where you get a lot of retakes because of poor equipment, you in effect begin to build up in the population sense; maybe not on an individual basis, but in the population sense, you do build that dose.

Chairman GLENN. In your testimony, you mention there is no central repository of national health care statistics that can provide complete information about the number of procedures involving medical radiation uses. I agree that without such data, regulators cannot accurately know misadministration frequency and trends, but I also don't know quite how that should be set up. It is a voluminous procedure, with everything that's going on.

Should that be a Federal Government procedure requirement? How do you develop such a database?

Mr. GODWIN. That's one that you may have to do sampling; you may have to do something very limited. I don't have an offer on how to go about that. As you noted from my testimony, I talked about that. You need to compare what is the misadministration rate for chemical treatments versus x-ray. You may find it's a whole lot worse than chemical—you may find it's a whole lot better. I don't know which way it will go. But it is really very vital information to make an informed decision. But I don't have any advice on how we can go about doing that, I'm afraid, Mr. Chairman.

Chairman GLENN. The last question is the same one I asked previous witnesses. Give us your advice on this. It's obvious we have a lot of gaps and holes and maladministration these things and difficulties that have resulted in deaths. And I know we all want the States to have this and that and something else, and I don't want to impinge the Federal Government into States any more than we

have to. But how do we deal with this? People are either being seriously injured or dying. The Spanish incident is one; we had our own in Ohio that has been reported, as I indicated earlier this morning, and I don't know—there may be others.

How do we set up an adequate control to protect the people of this country in this area?

Mr. GODWIN. Well, as I indicated in my testimony, I think we need an agency, set up—either existing or somewhere else; I'm not sure exactly how you'd want to go about doing it, because there is a lot of political give and take on which way that would have to go—but you need someone who sets the overall criteria, standards, design, whatever that the States must as a minimum follow. I think the States need the capability to go beyond that where it is necessary for their local conditions. It needs to have the ability for the States to work as a partner with the Federal Government, particularly when you start looking at things like rural areas, where you have local populations; you've got to be very careful that you don't just completely eliminate care in some areas.

All of these are very vital issues that you need to address in setting up——

Chairman GLENN. Do you think the agencies in existence now are adequate to do the job if there were better coordination between them? In other words, I think about whether we need something to replace existing authorities or whether we just need coordination between existing authorities, if you get that difference.

Mr. GODWIN. Well, if you take FDA and NRC as the two entities we are primarily looking at, the NRC has the agreement State program which works pretty well in that it turns the authority over to the States, the States then continue to meet it—the States need some kicking along in some cases to make sure they maintain adequate regulations. Part has to do with resources, which I addressed earlier as a personal comment.

The FDA laws for the most part—with one exception that I am familiar with, which is the mammography law—do not allow a similar transfer of authority, so you end up having sort of a glitch there on how the States would go about enforcement. Now, the FDA has been very good to come out with contracts to let the States do inspections of their diagnostic x-ray equipment as a part of their program, and the States interact there, but they have nothing to do with the development of the regulations, they have nothing to do with how they get what is important and what is not important on the inspection. And it only looks at the equipment end of it; it does not look at exposure to the public, it does not look at operator exposure per se. So those are some of the limitations on the FDA.

Actually, there may be some need for legislative actions on one side or the other.

Chairman GLENN. Do we need to change some of the authorities—what I'm thinking about are some of the things that have come up here this morning—NRC regulates Cobalt, but not linear accelerators; FDA approves linear accelerators, but not their operation, not the standards for which they will be used.

Mr. GODWIN. Right—and we've got radium out there, too, that people are using, that needs to be looked at. Some of those on occasion leak and cause sniff contamination problems.

Chairman GLENN. Can a coordinating group such as Jimmy Carter had for a while in the Executive order bring some order out of this, or do we need legislation that will change some of the jurisdictions?

Mr. GODWIN. Since the group didn't exist long enough, it's hard to read whether that would work.

Chairman GLENN. Well, that's true.

Mr. GODWIN. I think you need to get together and get the groups working together and see what we can come up with as an overall picture, because all the people are going to be affected. You've really just got to have a group before you get to the legislative, or the other group; either one.

Chairman GLENN. We would appreciate your input to that, and I'd ask you to have it in by August 6th; how about that?

Mr. GODWIN. We'll work with them.

Chairman GLENN. Could you give us your advice on this? I am serious about that.

Mr. GODWIN. We'll work with those agencies. The Conference has always worked with those agencies.

Chairman GLENN. All right. We've set sort of an arbitrary time period for them to get the information in to us, and if you can work with them, or give us your independent opinion of it on August 6th. I would appreciate it.

Mr. GODWIN. The Conference will work with them—I may not be the one doing the work, but Conference will work with them.

Chairman GLENN. All right. We'd appreciate whomever wants to give us advice in that area from the Conference.

Thank you. You have all been very patient with us this morning. The hearing has gone about 3 hours, and we appreciate your input. Obviously, there is a lot of work to be done, and we want to get on with doing it, so we can get whatever needs to be done, done this year.

Thank you. The Committee stands in recess subject to call of the Chair.

[Whereupon, at 12:35 p.m., the Committee was adjourned.]

APPENDIX

PREPARED STATEMENT OF SENATOR ROTH

Mr. Chairman:

I certainly share your concern that Federal regulation must protect the consumer of health care services. Nowhere is this more important than in the case of medical uses of radiation because of the intrinsic danger represented by the high levels of exposure needed to kill cancer.

Certain principles are clear from the onset: Substantive violations should not be swept under the carpet as may have been the case in the past. Furthermore, responsible agencies should co-ordinate their efforts in order to improve efficiency and productivity.

Yet, I feel that a word of caution is needed. I would like to point out that medical uses of radiation are among the most sophisticated and effective technologies in modern medicine. Many thousands of lives have been extended and improved as a result of this technology. One can even make a good case for economic efficiency of these technologies; but it is not my intention to place dollar values on lives.

Rather, I hope to draw attention to the fact that responsible regulation must consider its impact on accessibility, its impact on cost, and its impact on the competitive pressures needed to make high technology medical services safely available to the largest possible number of Americans in need of them. Regulation must not be a blunt instrument that slights the pressing national problem of affordable health care.

I look forward to working with you to find the best ways to meet the expectation of all Americans for safety, access, and quality of health care.

Thank you, Mr. Chairman.

PREPARED STATEMENT OF IVAN SELIN, CHAIRMAN, UNITED STATES NUCLEAR ENERGY COMMISSION

Mr. Chairman, members of the Committee, it is a pleasure for us to be here today to discuss the Nuclear Regulatory Commission's national program for regulation of radiation medicine.

Two categories of radiation medicine use radioisotopes subject to NRC regulatory jurisdiction. One is nuclear medicine, which employs radioactive drugs. These drugs usually contain only very small quantities of radioactive materials, and are used primarily for the diagnosis and mapping of disease. Nuclear medicine also includes the use of radioactive drugs for therapy, especially for disease of the thyroid gland.

The other category of radiation medicine is radiation therapy. Larger quantities of radioactive material are used in therapy. According to the rough estimates available, about 1.1 million new cases of cancer appeared in 1992. Of these, more than 500,000, or almost half, were treated using some form of radiation therapy. Sealed radiation sources made of byproduct material (radioisotopes), which are regulated under the Atomic Energy Act, were used in no more than twenty-five percent of these radiotherapy treatments. Radiation produced by electronic devices not regulated under the Atomic Energy Act, such as linear accelerators, was used in the other seventy-five percent of these cases.

In order to achieve optimal cure and remission rates or to alleviate pain, radiotherapy treatments normally deliver high doses of radiation, often close to the patient's limit of tolerance. Even when correctly delivered, a therapy dose of radiation may well have serious side effects, and may on occasion result in death.

The objective of NRC's regulatory program is to assure that the patient receives the dose of radiation or radioactive material that is prescribed by the physician, as well as to protect health care workers and members of the public in the process.

NRC does not regulate the appropriateness or effectiveness of the prescribed treatment.

Much, although not all, of the focus of our current concerns is on therapeutic misadministrations—cases in which radiotherapy as delivered is different from that which is prescribed. The information we have indicates that the misadministration risk is very small in comparison with the intrinsic risk to the patient from radiotherapy treatment; one of the problems I'll discuss is that there is some uncertainty in our knowledge of the precise rate of misadministrations, but it is probably less than one in several thousand. Misadministrations may or may not cause adverse effects to patients. NRC requires that each therapeutic misadministration be assessed and the likely consequences communicated to the referring physician and the patient. This communication is another topic of our testimony.

Of course, all medical misadministrations are of importance to the NRC and we set as an objective the avoidance of misadministrations to the greatest extent practicable. Our testimony will focus on radiotherapy since this is the area where the consequences of potential errors are generally the greatest. However, many regulatory initiatives in radiotherapy also would apply to nuclear medicine where the consequences of errors, in most cases, are much less.

I. HISTORY OF NUCLEAR MEDICINE REGULATORY PROGRAM

Under the Atomic Energy Act (AEA) the NRC regulates the use of byproduct materials, *i.e.,* radioisotopes produced as a result of the nuclear fission process in a nuclear reactor. The NRC does not have authority to regulate radioisotopes produced by other means such as cyclotrons, nor does NRC regulate electronic devices which produce radiation, such as X-ray machines and linear accelerators.

The single most important use of byproduct material is probably for medical diagnosis and therapy. NRC directly regulates medical use of this material in 21 states, the District of Columbia, Puerto Rico, Virgin Islands, United States territories, and all Federal facilities through a system of regulations, licensing, inspection and enforcement. There are approximately 2,000 NRC licenses authorizing the medical use of byproduct material.

Under Section 274 of the AEA, the NRC is authorized to enter into agreements whereby a state assumes regulatory authority over most byproduct materials, including medical use. To enter into an agreement, the state must have a program which is adequate to protect the public health and safety, and which is compatible with NRC's regulatory program. Twenty-nine states have agreements with the NRC to regulate byproduct material. They have issued approximately 4,500 active licenses authorizing the medical use of byproduct material.

Over the years, and especially since the mid 1980s, the Commission has made a concerted effort to improve and strengthen the medical use program. The Atomic Energy Act of 1946 authorized the medical use program; the Atomic Energy Commission initiated steps to regulate radioactive drug safety at that time. The first medical use of byproduct material also occurred in 1946. In 1967, the AEC codified its medical regulations into a new 10 CFR Part 35 which covered both the medical use of radioactive drugs and the use of radiation from medical devices. Following a 1976 report of hundreds of patient overexposures at Riverside Methodist Hospital in Columbus, Ohio, NRC took actions to upgrade its regulation of radiation sources in medical use. As a direct result, NRC amended its regulations to require licensees to conduct annual calibrations and monthly spot-checks of teletherapy units.

In 1979 NRC issued its "Medical Use Policy Statement," which stated NRC's intent to regulate the radiation safety of patients while minimizing interference with the practice of medicine. In 1980, NRC published a final rule requiring reporting of misadministrations involving byproduct material. This rule also required that patients affected by misadministrations and their own referring physicians be notified of misadministrations. Exceptions to patient notification requirements are allowed only when the referring physician determines, based on medical judgement, that notification would be harmful to the patient.

In 1987 a major revision to Part 35 codified many of the radiation safety practices which had become standard in licensed medical use. In 1988 the NRC began developing a performance-based rule to improve medical quality assurance in using byproduct material. As part of the initiative to upgrade quality in the delivery of radiation medicine, NRC increased resources in order to inspect medical licensees more frequently.

We reached a milestone in the medical use program when we issued a new regulation known as the "Quality Management Program and Misadministrations" (QM) rule which became effective on January 27, 1992. This rule governs medical uses of radioactive material; it requires NRC's medical licensees to develop and imple-

ment programs to provide high confidence that radiation and radioactive materials will be administered as directed by an authorized physician. This rule also modified the definitions and reporting requirements for misadministrations. The rule is a performance-based standard rather than one which contains prescriptive requirements, and therefore it is more accommodating to medical innovation, technology development, and varying hospital control processes. This rule has a decidedly greater impact on licensees with weaker programs; it is intended to raise them towards the level of the better performers. The staff will reevaluate the program after three years of experience, to see if results are as intended.

II. AREAS OF NRC'S MEDICAL USE PROGRAM WHERE IMPROVEMENT IS NEEDED

The last several years have seen a number of reviews of NRC's medical use program. These reviews have identified several systemic or jurisdictional problem areas where improvement is clearly needed in our regulatory program for radiation medicine, in addition to a number of specific weaknesses in the execution of this regulatory program.

During the week of December 13, 1992 the *Cleveland Plain Dealer* published a series of newspaper articles which focused increased attention on the medical use of radiation. They raised several questions on the extent of NRC's and agreement states' knowledge of misadministrations and on the follow-up with patients subject to misadministrations. We have also found work by NRC's Office of Inspector General helpful in drawing attention to areas in our medical program in need of improvement.

The Commission had already initiated several efforts to reexamine our medical regulatory program before the *Plain Dealer* series. In part because of the *Plain Dealer* articles and in part due to a recent misadministration at Indiana, Pennsylvania, we have accelerated these efforts. They include:

- performing two independent reviews of NRC's medical use program, one being conducted by NRC senior management not currently associated with the medical program, and the other to be conducted by an outside group of qualified experts, such as the National Academy of Sciences;
- working with the food and Drug Administration (FDA) to clarify our respective responsibilities to ensure that generic problems with radiation devices are addressed; and
- redefining the focus of NRC's Advisory Committee on Medical Uses of Isotopes to reflect the change in the scope and type of advice sought by the Commission. The Committee, originally formed primarily to assist the NRC staff on medical technology issues, now often provides advice on policy and generic issues.

III. THE AGREEMENT STATE PROGRAM

Some generic problems arise in the agreement state program. Although the NRC reviews agreement state programs to be sure they are adequate in terms of health and safety protection, the degree to which state rules must be compatible with NRC rules continues to be an important issue between agreement states and the NRC. Currently, state compatability is required for generic standards, definitions, and some reporting requirements.

Last year, the Office of State Programs was assigned to the Executive Director for Operations for direct control. This has fostered a more consistent, well-coordinated program between NRC and the agreement states. This has improved coordination with other NRC offices in developing policies and guidance for implementation by both NRC and agreement states. Nevertheless, variability exists among the states and between the execution of agreement states' and NRC's medical use programs. For example, there is currently such uneven reporting of misadministrations and other medical events by agreement states that it is difficult to determine if the misadministration rates reported are accurate; the staff is working to obtain better and more timely information on misadministrations which occur in agreement states in order to develop a clearer understanding of the total number and rate of misadministrations. The agreement states should all have misadministration reporting requirements compatible with NRC's by January 1995, three years after the effective date of NRC's "QM" rule.

IV. JURISDICTIONAL ISSUES

A second set of problems arises from the variations in jurisdiction over different sources of radiation. Jurisdiction over various aspects of the use of ionizing radiation in medicine is exercised by the Federal Government and the states, and at the Federal level, by FDA and the NRC. Within this regulatory framework the NRC has jurisdiction only over medical use of byproduct material.

The vast majority of medical radiation sources, such as naturally occurring and cyclotron-produced radioisotopes, diagnostic X-rays, and electronic radiation-producing therapy devices, are not subject to regulation by NRC. FDA regulates to assure the safety of new devices and drugs, whether or not they use byproduct material, as they are placed in service. The states may regulate the use of nonbyproduct material devices and drugs FDA approves. States exercise widely varying degrees of regulatory control over radiation sources not subject to NRC jurisdiction, and programs operated by states vary widely.

Even the regulation of those medical devices that do use byproduct material requires special attention because of the complicated nature of the jurisdictional interface between FDA and the NRC. The FDA regulates the manufacture and distribution of radiopharmaceuticals, biologics and medical devices for safety and efficacy, while the NRC regulates radiation safety associated with the actual use of these products. The FDA's authority is exercised at the investigational, premarket review, and manufacturing site level, and in their post-market surveillance of the market, which includes user facilities only when serious problems are reported.

FDA's premarket safety evaluation of radiation devices and materials does not, by itself, assure the safe use of a specific device at a particular facility. For example, safe use also requires that adequate operating and emergency procedures be developed and implemented, and that personnel be adequately trained and supervised to assure that radiation safety requirements are met. Also, devices in service must be properly maintained.

In addition to receiving a premarketing approval from FDA, medical devices containing byproduct material must be approved for radiation safety by NRC or an agreement state prior to use through a certificate of registration. The scope and level of detail required for this approval go beyond that required by FDA; a request for NRC review must include detailed information about installation, service and maintenance requirements, operating and safety instructions, and any potential hazards. We are able to provide the more focused review necessary to assure radiation safety in service because, whereas FDA has oversight responsibility for the entire universe of medical devices, NRC and the agreement states are concerned only with about 300 types of devices that contain byproduct material.

We have identified three areas where the interface between FDA and NRC could be improved: 1) coordination of the FDA and NRC reviews of medical devices; 2) coordination of response to incidents involving device failures, such as occurred last year in Indiana, Pennsylvania; and 3) coordination on the regulation of manufacturing, compounding and use of radiopharmaceuticals and radiolabelled biologics. We are in the early stages of an effort to establish a Memorandum of Understanding between the two agencies that will address these three areas.

V. HEALTH STATISTICS

A third area in which problems arise is the field of health statistics. While we have information about the number of reported misadministrations, we are less confident about projections of the number of administrations. There is no central repository of national health care statistics which can provide complete information about the number of procedures involving the application of ionizing radiation. Without more reliable data on the total numbers of administrations we cannot accurately determine misadministration frequency and trends.

VI. COPING WITH TECHNOLOGICAL DEVELOPMENTS

A fourth problem area intrinsic to the regulation of radiation medicine is the challenge involved in keeping the regulatory program current with technological developments. Radiation medicine is a dynamic, high-technology field. New treatment modalities and equipment appear frequently. Many cobalt–60 teletherapy units, which were once the ultimate state-of-the-art, are being replaced by linear accelerators. Brachytherapy—the implantation of sealed sources in the patient's body—is moving toward faster acting high-dose-rate sources which present much different radiation safety concerns. The coming use of radiolabelled biologics for medical purposes, particularly monoclonal antibodies, will open up an entirely new area of medical applications with attendant radiological safety issues yet to be seen. This cutting-edge technology is now being approved by the FDA for widespread use. In addition, efforts aimed at health care cost reduction and consolidation of services also cause changes such as greater use of mobile nuclear medicine facilities. Emphasis on out-patient treatment has given rise to specialized clinics which may not have the review committees, credentialing or quality assurance procedures equivalent to those found in most hospitals.

NRC staff monitors these emerging technologies and trends in service delivery to identify and prioritize radiation safety issues. However, due to the highly dynamic nature of radiation medicine, the NRC staff is sometimes not able to evaluate fully, and address with appropriate regulations and guidance, all the safety concerns associated with a new technology application before its use. Even when we do address these concerns a minimum of two years is needed to promulgate new regulations, and another three years pass before agreement states are obligated to implement regulations for which compatibility is required. In the interim, NRC can issue guidance to address safety concerns in the form of NRC bulletins, information notices, or generic letters to licensees. In such cases, NRC expects agreement states to follow through by providing this guidance to their licensees.

VII. ASSESSMENT OF THE EXECUTION OF NRC PROGRAMS

NRC's regulatory program consists of three fundamental elements: 1) the licensing process, which approves facilities and users of byproduct material for medical purposes, based on ability to protect public health and safety; 2) inspections of current licensees, to determine compliance with NRC regulations; and 3) enforcement, to remedy deficiencies and act as a deterrent against future violations of NRC requirements.

We are reasonably comfortable with the licensing process, although a recent Inspector General report has shown that even here some formalization of procedures would be useful. However, a further shift in the focus of inspections may be required. For years inspectors were generally asked only to ascertain whether a licensee is in compliance with NRC requirements. This is done by direct observation of work activities, interviews with workers, and sometimes special demonstrations by workers of work practices regulated by the NRC. Additionally, information in licensee records is reviewed to assess performance since the last inspection and determine compliance with recordkeeping requirements. This approach has led to criticism that our inspectors focus too much on detailed compliance with NRC requirements, and not enough on overall radiation safety performance. In response, in recent years NRC inspectors have been asked to broaden their inspection oversight to search for safety problems, but more emphasis and further guidance in this area may be needed.

The fundamental purpose of the enforcement policy is, of course, to promote and protect the radiological health and safety of the public, including patients and health care workers. This is accomplished in two ways: by encouraging the prompt identification and lasting correction of deficiencies; and by deterring new violations from occurring. In the vast majority of cases NRC enforcement sanctions have been effective in gaining lasting corrective action. Our records indicate that in combination, the experience of appearing before NRC in an enforcement conference following an inspection identifying significant violations, receiving a civil penalty, and the associated adverse publicity, have resulted in relatively few repeat violations for several years after a civil penalty is levied. However, we do not know whether the policy has been effective in deterring problems at other licensees' facilities.

The staff is reviewing the size of the base civil penalties for various categories of facilities, and evaluating the feasibility of other potential sanctions, such as probation for medical licensees.

VIII. IMPACT OF TRAINING, EXPERIENCE AND HUMAN FACTORS

The last problem area we will discuss here concerning the regulation of radiation medicine is human factors. Radiation therapy often involves deliberate exposure of patients to high levels of radiation for beneficial purposes, and the consequences of mistakes can be grave. We cannot eradicate all human error, but we can look to see whether there are ways to reduce the error rate significantly. Achieving and maintaining a high level of safety in the use of byproduct material in medicine is highly dependent on having properly trained personnel who follow procedures and maintain equipment properly.

How to judge the adequacy of the training and experience of individuals responsible for the medical use of byproduct material has been and will continue to be a priority concern for the NRC. Currently, the NRC has specific requirements for training and experience of authorized physician users, radiation safety officers, and teletherapy physicists, and we are examining the need for training and experience requirements for other personnel involved in the medical use of byproduct material. However, we do not yet have in place a process for periodic reassessment of the knowledge and understanding of individuals responsible for radiation safety.

A specific case illustrates the importance of the issues surrounding human factors. In connection with the recent, tragic therapy misadministration and patient death

in Indiana, Pennsylvania in which a radioactive source was inadvertently left in a patient, the NRC sent an Incident Investigation Team to investigate the circumstances surrounding the incident. The team found that human error was the primary cause, while machine problems were also important.

The team did find a need for updated licensing and inspection guidance for high dose rate brachytherapy devices, such as the one involved in this event, to make more clear what safety requirements apply to the use of this type of device. In the interim, NRC published two bulletins specifying additional controls to be implemented by licensees using the technology involved in the incident, and revised the inspection guidance for these facilities. Ultimately, rulemaking may be needed to address some of the issues identified by this investigation.

IX. REPORTING TO PATIENTS AND PATIENT FOLLOW-UP

Following the *Plain Dealer* series, NRC staff conducted a review of therapeutic misadministrations at NRC-licensed facilities over the past three years. This review indicated that patients were notified of misadministrations only 72 percent of the time. Although NRC permits not notifying patients when a physician determines it would be harmful to the patient (in which case a responsible relative must be informed), this does not appear to be the cause in most of the cases we have reviewed. Furthermore, of the patients notified only 56 percent were given a written report, contrary to explicit and longstanding NRC requirements. NRC is preparing an information notice to alert the regulated community to these failures to comply with the regulations, and to remind them of their obligations under the notification and reporting requirements. In addition, future NRC inspections will focus on assuring that licensees comply with all the notification and reporting requirements in the event of a misadministration. The staff is currently reviewing the cases in which the patients were not provided with a written notification, to determine if enforcement action is warranted.

The *Plain Dealer* series also focused attention on the issue of patient follow-up after misadministrations. NRC's current policies and guidance on patient follow-up are being reexamined as a part of our ongoing program reviews. It is current agency practice to consider the NRC medical consultant's opinion of harm to the patient in the determination of appropriate enforcement actions, and of the probable consequences to the patient to be reported, if required as part of the periodic report on abnormal occurrences required by Section 208 of the Energy Reorganization Act of 1974. We are now reconsidering this issue from the perspective of the agency's obligation to the patient, who needs medical follow-up which continues long enough for any anticipated delayed deterministic effects to have appeared and been recognized.

X. LONGER RANGE REGULATORY OPTIONS

The previous discussion has focused on the effectiveness of our regulatory program from this agency's programmatic point of view. We must also look at the program from the patient's point of view. In this regard, we note that NRC's regulatory jurisdiction covers only approximately 25 percent of radiation therapy treatments. The remainder, which involve identical radiation from different types of sources, are covered under a range of state regulatory programs.

As long as the use of byproduct material in radiation medicine is subject to NRC licensing and regulation, we will do the very best job we can of regulating that component of radiation medicine. But at the same time it is fair to ask if there is any public policy justification for the continuation of the present approach to regulation of radiation use for medical purposes. It is also fair to ask if continuation of the existing scheme is the best way to use limited resources to achieve the goal of protection of the public. So we have been giving some thought to ways to address these issues. Among the options that come to mind and that appear to warrant evaluation—although this may not be an exhaustive list—are (1) limiting NRC's regulatory involvement to approval for use of sealed sources and devices containing byproduct material with the states then regulating their medical use, (2) NRC's continuing to write standards and guidelines with the states assuming all responsibility for inspection and enforcement, or (3) extension of NRC regulation to all radiation sources used for therapy, not just byproduct material. Such an extension would require legislation.

These and other approaches require careful development, evaluation and consideration by the NRC before the Commission would be in a position to make a decision on this matter, including any eventual recommendation to Congress for possible revisions to our statutory authority.

SUMMARY

In sum, Mr. Chairman, we believe the situation is as follows:

The NRC has what we consider to be a reasonably good regulatory program for the medical use of byproduct material. Areas for improvement have been identified—especially in our relations with the agreement states, in our interface with the FDA, in the gaps we see in radiation health care data, and in our responses to the rapid changes in medical technology. We have also identified some weaknesses in execution, especially in the area of patient notification and follow-up. We believe we have steps underway—especially a shift towards performance-based rules and a regulatory regime which focuses more effort on weaker licensees—which, if carried to their logical conclusion, will remedy most of these problems.

The fact remains, however, that no matter what level of resources is devoted to improving NRC's regulatory program for medical therapy, the effect will be confined to no more than about 25 percent of the radiation therapy treatment in the country, while the rest, beyond the Federal-level regulation of devices exerted by FDA, is subject only to discretionary and perhaps inconsistent regulation at the state level.

NRC's objective continues to be a vigorous program that fulfills all statutory responsibilities, one that provides adequate safety for patients, radiation workers and the general public; minimizes interference with the practice of medicine; and accommodates medical innovation and technology development. We will continue on this path. However, the Congress may eventually want to consider some legislation in the future which would bring more consistency to the regulation of radiation medicine as a whole. Such legislation should not be considered until the independent reviews of the medical use program initiated by NRC have been completed and other agencies such as the FDA and state regulatory authorities have been consulted.

Mr. Chairman, this completes our statement. We will be pleased to answer any questions that you and the Committee may have.

PREPARED STATEMENT OF D. BRUCE BURLINGTON, M.D.

Introduction

I am here today to discuss the Food and Drug Administration's regulatory program for medical radiation devices, principally the radiation therapy devices. As with all medical devices, the FDA program, administered through the Center for Devices and Radiological Health, encompasses the review of a device before it reaches the marketplace and a postmarket surveillance of the device. When we approve a device, the data submitted for our evaluation must demonstrate that the new device is safe and effective and that its potential benefits outweigh any potential risks.

We must do our utmost to make certain that medical devices used by physicians and consumers are safe and effective. We must all also understand that even with careful design, manufacturing controls and clinical investigations; devices can have unintended and unforseen effects during widespread use. Even with a quality control system that strives for "Zero" defects, we must accept that devices can fail and user error can occur. FDA's job is to address, in advance, the safety and effectiveness of devices, and to act quickly and decisively if an unanticipated failure or malfunction of the device occurs after it is marketed.

Our concerns today focus on radiation therapy devices. The benefits of radiation therapy treatment are great. The ACR estimates that nearly 20 million radiation therapy procedures are performed each year. The American College of Radiology (ACR) estimates that as a primary cancer treatment, radiation therapy has been partially responsible for increasing the overall cure rate for cancer to more than 50 percent. Between 50 and 60 percent of all cancer patients are treated with radiation at some point during their therapy. For some patients the use of radiation is the major or sole way to achieve cures. In patients who have cancer that has spread to bone or brain tissue, radiation therapy offers an irreplaceable treatment that improves their lives. It is frequently the principle measure to relieve pain.

All radiation therapy systems, such as medical linear acclerators, Cobalt–60 teletherapy units, computerized treatment planning systems, and the accessories used in the provision of radiation therapy treatment, are regulated by the FDA. I would like to discuss the legislation that the Congress has provided FDA and how FDA implements it. Then I will address a deficiency the FDA sees in receiving reports of adverse incidents and the actions that we are taking to improve the situation.

History of FDA Medical Radiation Device Regulation

The Food and Drug Administration has several legislative mandates for regulatory control of radiation therapy devices. These include:

- the Medical Device Amendments of 1976 to the Federal Food, Drug and Cosmetic Act (P.L. 94–295),
- the Safe Medical Devices Act of 1990 (P.L. 101–629) and its amendments.
- the Radiation Control for Health and Safety Act of 1968 (P.L. 90–602), and
- the Consumer-Patient Radiation Health and Safety Act of 1981 (P.L. 97–35).

These laws and their implementing regulations provide a system of premarketing clearance and manufacturing controls so that radiation therapy devices will be both safe and effective when used as labeled.

The Medical Device Amendments and the Safe Medical Devices Act provide the most extensive regulatory tools available to the FDA. While these authorities cover all types of medical devices, I will focus on radiation therapy equipment.

The Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act (the Act):

The Medical Device Amendments were enacted by Congress in 1976. This legislation requires device manufacturers to notify FDA of plans to market devices so our staff may undertake premarket review of the product. This review permits the FDA to determine the level of regulatory control necessary to assure that devices are suitable for their intended uses. Each device is classified according to the knowledge about the types of risks it raises and the level of regulatory controls needed to manage those risks.

FDA addresses manufacturing problems through regulatory authority derived from this Act with the Good Manufacturing Practices (GMP) regulation. The GMP regulation covers the methods, facilities, and controls used in manufacturing, packing, storing, and installing medical devices. It identifies the essential objectives that must be included in a quality assurance system. Such a quality assurance program will ensure that the marketed device meets specifications by reducing manufacturing process variation that can lower quality. The FDA field staff conduct both routine and directed inspections of radiation therapy device manufacturers to ensure compliance with GMPs.

The 1976 legislation also authorizes FDA to issue an order that requires manufacturers to notify certain health professionals that the device presents an unreasonable risk of harm to the public health. The manufacturer's notification obligation may be extended, either directly or through health professionals, to include all individuals at risk. Manufacturers may be required to recall the devices from the market or repair or replace this equipment, depending on the risk. One such example occurred in June 1991 when the Agency asked one of the largest Cobalt–60 teletherapy manufacturers to notify all users of their teletherapy units of certain device-related problems and that appropriate actions should be taken to correct the problems.

As a result of adverse incident reports and subsequent inspections, problems were uncovered with the software controlling one brand of radiation therapy accelerators. In April 1986, FDA directed all manufacturers of medical accelerators to conduct thorough verifications of their software programs and, where necessary, make appropriate modifications to minimize the risks of similar failures.

Similar to our inspection experience with all medical devices, 53 out of 71 (75 percent) registered manufacturers of radiation therapy devices have been inspected, including eight of the nine manufacturers of brachytherapy devices, in which the radiation source is in contact with the patient. This was the type of device involved in the Indiana, Pennsylvania incident, where a patient died as a result of a broken radiation source wire and multiple safeguard failures.

Our shortfall for medical device inspections is due to competing medical device workloads and priorities for the inspection staff. For example, in December 1992, FDA initiated new directed inspections of all firms engaged in the commercial distribution of linear accelerators and teletherapy systems used to treat patients and radiation therapy treatment planning systems. Proportionate to the number of devices regulated, this is approximately a two fold excess commitment of our inspection capacity.

The last authority under the Medical Device Amendments I would like to mention is the mandatory medical device reporting program. The legislation requires manufacturers to report to the FDA any death, serious injury, or malfunction which could lead to a death or serious injury. Each report received by the Agency is reviewed and necessary action is taken. Since the inception of the program in 1984, the Agency has received 57 reports concerning deaths and serious injuries associated with the use of radiation therapy devices. These reports refer to seven deaths and 236 injuries. The information in these reports has led to product recalls, notifications to health professionals, and improvements in product design. We are reminding all dealers, importers, manufacturers, and distributors of radiation therapy equipment

about reporting requirements and the criteria to use for reporting problems to the FDA.

Safe Medical Devices Act of 1990

With the enactment of the Safe Medical Devices Act of 1990, Congress provided several expansions of FDA's medical device authority, including the requirement for mandatory reporting by user facilities. User facilities (e.g., hospitals, nursing homes, and outpatient treatment sites) must file reports of deaths, serious injuries and serious illnesses associated with the use of medical devices with either the manufacturer of the implicated device or with the FDA. This will increase the opportunity to learn about problems early and to permit the Agency to take quicker action to avert major problems. The user facility reporting requirements became effective in November 1991, but reporting is below anticipated levels. Final regulations are under development. FDA personnel are developing a "universal reporting form" that can be used by those that we regulate or anyone that wants to report a device problem.

Other authorities that were expanded include: distributor reporting for all types of medical devices; authority for FDA to initiate recalls; and expanded postmarketing surveillance.

Radiation Control for Health and Safety Act of 1968

The first FDA law to specifically address medical radation was the Radiation Control for Health and Safety Act of 1968. This act provided for the regulation of all electronic products that produce radiation. Medical linear accelerators are an example of a radiation therapy device covered by regulations promulgated under this law. These electronic radiation devices are also subject to the Medical Device Amendments.

Manufacturers of electronic radiation products are required to submit a number of reports to FDA. Before marketing an electronic product, such as a linear accelerator, an initial report must be submitted. When a manufacturer learns of any accidental radiation occurrence or a radiation safety defect it is required to report that information to FDA. In addition, manufacturers are required to submit annual reports on the device. These reports contain information that is not required by the premarket notification requirements under the Medical Device Amendments, such as equipment maintenance schedules.

Consumer-Patient Radiation Health and Safety Act of 1981

Congress enacted the Consumer-Patient Radiation Health and Safety Act of 1981 to minimize unnecessary radiation exposures. The Act was a directive to provide guidance. It was also a mechanism to have a continuing supply of adequately educated medical radiation technologists with appropriate accreditation and certification.

The Health Services and Resources Administration in the Department of Health and Human Services has responsibility for the implementation of Section 981 of the Act. Section 981 provides for the promulgation of minimum standards for the accreditation of educational programs to train individuals to perform radio logic procedures and to assist the States in the certification of those persons.

FDA has responsibility for Section 982 of the Act. Section 982 directed various Federal Government agencies to work together to promulgate Federal radiation guidelines to minimize unnecessary radiation exposure from diagnostic procedures and therapeutic applications.

The FDA developed a series of training videotapes; published a primer on the operation of accelerators in radiation therapy; and began a regional workshop series to encourage quality assurance. In addition, the FDA initiated a quality assurance service at the University of Texas to check radiation therapy doses. This program is still operational today and is self-supporting.

Relationships between FDA, NRC, and States

Nuclear Regulatory Commission

In 1983, an exchange of letters between the CDRH Director and the NRC's Chief of Materials Licensing Branch confirmed an agreement for:

- the notification to premarket applicants concerning other Federal agency requirements;
- the exchange of documents and other information on developing policy guides and compliance publications; periodic meetings between staff; and
- the identification of key contact persons in each Agency.

The most frequent contact with NRC, concerning regulated products, is at the staff level. The Center's Office of Device Evaluation (ODE) routinely notifies manu-

facturers, at the premarket stage, of the need to meet other Federal requirements, before marketing new medical devices. The Center's Office of Compliance and Surveillance (OCS) has exchanged information with NRC in response to specific postmarket problems with devices or use of the devices and facilitated coordination of inspections and investigations by the two agencies. This relationship has allowed FDA access to information regarding device problems before being reported through other channels.

In December 1992, NRC notified FDA of the death of a patient in Indiana, Pennsylvania, resulting from a combination of a brachytherapy device malfunction and a series of user errors. The FDA joined the NRC team at the site of the incident and at the manufacturer's facility. The purpose was to coordinate Federal action in the investigation of the event and to determine corrective action. This combined team was able to complete the investigation quickly.

Representatives from the FDA and the NRC are working on a Memorandum of Understanding (MOU). This MOU would address medical radiation devices that utilize radioactive materials licensed by the NRC. The MOU would provide for prompt problem notification, coordination of investigations, and exchange of information between the two agencies.

States

The Conference of Radiation Control Program Directors (CRCPD) is a professional organization of State radiation control personnel which is supported, in part, by FDA and several other Federal agencies. FDA maintains a liaison with the CRCPD for the exchange of information on regulatory issues, technical items, training programs, resources, and incidents. FDA staff interacts with numerous CRCPD committees.

The Conference has guidelines for the evaluation and State licensing of the use of naturally occurring and accelerator produced radioactive sources not licensed by the NRC. The FDA and the NRC cooperate in maintaining a catalog of such sources for the Conference. The CRCPD has the responsibility to update and disseminate the Suggested State Regulations for Control of Radiation (SSRCR). The Suggested State Regulations represent a set of model regulations, for the control of electronic product radiation and radioactive materials published to assist the States in developing their individual programs while maintaining a degree of national uniformity. Various sections of the SSRCR specifically addresses radiation therapy devices.

It is vital that we work directly with appropriate State personnel at the site of the radiation incident. It is also important to cooperate with the State in which the manufacturer operates and where the device is registered. In a recent brachytherapy incident where the radiation source was left in contact with the patient's body, the Agency worked with the States of Louisiana and Texas, where the equipment was manufactured, as well as Pennsylvania, the site of the incident. This cooperation is standard procedure in such cases.

FDA Initiatives to Lessen the Likelihood of Adverse Incidents Involving Radiation Therapy Devices:

FDA's regulatory programs designed to ensure the safety of radiation therapy devices include three areas: premarket review of new products, inspection of manufacturing facilities, and postmarket surveillance to detect problems in existing devices. The types of incidents that have brought radiation therapy devices to the Committee's attention are largely unanticipated in the premarket review process. We must rely on quick, accurate postmarket reporting of incidents in order to evaluate them and limit the public health risk. Without these reports we lack the early warning signals needed to act before serious events occur. We want to identify potential sources of failure early enough to investigate and intercede. Many radiation incidents are either caused by or accompanied by human error, which are events outside our immediate regulatory control. However, better product information and training can reduce human error. With adequate information we can differentiate human error from device failure and know whether the corrective action should be directed to the operator or the device.

We have taken the following actions to improve our ability to identify problems as soon as possible:

- User facility reporting regulations, as required by the Safe Medical Devices Act of 1990, will issue later this year. User reporting regulations require medical facilities to report a device-related death, serious injury, or serious illness to either the manufacturer of the implicated device or to FDA. The information reported will help identify problems as quickly as possible.

- We are reminding dealers, importers, manufacturers and distributors of radiation therapy devices about reporting requirements and the criteria to use for reporting problems to FDA.
- We are discussing a Memorandum of Understanding with the Nuclear Regulatory Commission that will cover medical devices using NRC-licensed radiation sources. We expect the Memorandum to address prompt problem notification, coordination of investigations, and information exchange between the two agencies.
- We will re-assess how we communicate information we receive on problems with radiation therapy devices to the State regulatory authorities. Although we are already working directly with the individual States to investigate cases in their jurisdictions, we want to be sure we regularly relay information to the States about problems occurring elsewhere. This serves as an early-warning system to the States as they exercise their respective authorities and license users of various devices. We will also seek prompt notification from the States about problems reported to them so we may be more comprehensive in identifying problems.
- Finally, beyond these improvements in our ability to receive and transmit information about radiation problems, we are also conducting industry-wide inspections of radiation therapy device manufacturers. These comprehensive inspections will also help to determine whether the manufacturers comply with the requirements for reporting device failures or malfunctions. These actions are consistent with FDA's overall plan to improve the regulation of all medical devices. In the entire medical device arena, FDA is committed to enhanced premarket review and postmarket surveillance, and to prompt action against those who violate the law.

TESTIMONY OF AUBREY V. GODWIN

BEFORE THE U.S. SENATE COMMITTEE

ON GOVERNMENTAL AFFAIRS

APRIL 22, 1993

Good morning, and thank you Mr. Chairman and members of the Committee for inviting me here to testify on the regulation of medical ionizing radiation uses. I am testifying as Chairman of the Conference of Radiation Control Program Directors, Inc. (Conference). The Conference membership is comprised of the Radiation Control Program Director for each State. The staff of each state's program make up the associate membership of the organization. For example, Mr. Robert E. Owen, of the Ohio Department of Health, is Ohio's representative, with four members of his staff as associate members. Only one state, Wyoming, does not have a formal full time radiological health employee. Several small states have only one or two people in their program.

One of the issues of interest to all states is the proliferation of ionizing radiation agencies at the federal level of government and the resulting overlap and gaps in enforcement. For example, U.S. Environmental Protection Agency (EPA) has the authority to make recommendations to the President, which, if accepted, become Federal Guidance which all Federal agencies must take into account in carrying out their responsibilities. EPA also develops ionizing radiation standards under the authority of several pieces of legislation; these standards set limits on human ionizing radiation exposure level or on quantities or concentrations of radioactive materials that may be released to the environment. The U.S. Nuclear Regulatory Commission (NRC) implements these standards for all users of byproduct, source, and special nuclear materials. The Safe Medical Device Act of 1990 authorizes the establishment of special controls for Class II devices which may include the qualifications of users. Further, P.L.90-602 was used as the authority to initiate a notice of intent to propose rules and develop guidelines for ionizing radiation therapy equipment. It is my understanding, neither of the latter Acts have had final implementing actions taken by the agency.

Prior to World War II, all medical uses of ionizing radiation were regulated by the States as a part of the overall regulation of medicine. This followed the normal practice of the States being the natural regulator of "Professions." With the passage of the "Pure Food and Drug Act," the federal authority began to extend to the manufacture of medical goods.

Other organizations which helped standardize the use of ionizing radiation were the National Council on Radiation and Measurements, the National Bureau of Standards, and the professional organizations such as the Radiological Society of North America and the American College of Radiology. All of these were voluntary standards and the individual practitioner could elect not to follow them at any time. A few states elected to use their professional regulatory powers or the occupational safety powers to establish some regulatory standards. These were uncoordinated and were the exception rather than the rule.

The Atomic Energy Act of 1954, as amended (AEA), provided for the regulation of individual users of radioactive materials. This permitted the U.S. Nuclear Regulatory Commission (NRC), formerly the U.S. Atomic Energy Commission, to directly regulate the individual physician using those material covered by the Act, namely source, byproduct, and special nuclear materials. This authority had several benefits;

1. The standardization of training and conditions of use for the users of these radioactive materials.

2. Some organized consideration of the ionizing radiation dose being given to the patient.

3. A standardization of equipment used for the administration of ionizing radiation from radioactive materials covered by the AEA.

Perhaps the most important item to come from the AEA was the national ionizing radiation standard in the form of 10CFR20. Prior to this, several different standards were in existence. One amendment to the AEA provided for a State to sign an agreement with the U.S. Atomic Energy Commission (now the U.S. Nuclear Regulatory Commission) thus becoming an "Agreement State." The Agreement State status required the state to adopt radiation standards consistent with 10CFR20. With the enactment of AEA, Suggested State Legislation for the Control of Radiation was promulgated by the Council of State Governments. At present there are 29 Agreement States.

Additionally, through the cooperative efforts of various federal and state agencies, Suggested State Regulations for the Control of Radiation were developed as a model for states. These regulations are the foundation for all states regulations, i.e. both Agreement States and Non-Agreement States. This in turn allowed the rapid development of nuclear medicine and ionizing radiation therapy utilizing primarily byproduct material. The primary difference between federal and state regulation is that states regulate Naturally Occurring and Accelerator Produced Materials (NARM) and machine produced ionizing radiation at the user level. Most of the states attempt to regulate NARM similarly to AEA materials. The states in regulating NARM have found and corrected several problems. For example, radium sources were not routinely tested to insure their integrity, they were not accounted for by the users, and often they were stored such that the public was exposed to the ionizing radiation. For these reasons and the fact these materials were not regulated by the AEA, the Public Health Service actively promoted the disuse of radium.

In the early 1960s, the Public Health Service offered grants to the States to develop ionizing radiation programs. These programs used the Suggested State Legislation and Suggested State Regulations for the Control of Radiation to assist states to become Agreement States. In the 1980s, the Conference, in order to maintain the quality of State programs and to provide guidance to elected officials, developed a series of guides for State Radiation Programs. These guides were in the form of criteria for resources, procedures, and funding for an adequate radiation control program. Copies of these guides are provided for the Committee's information. The Conference has begun a program to update these guides for future use.

In the 1970s, the States though the Conference and with the assistance of the Food and Drug Administration began the Nationwide Evaluation of X-Ray Trends (NEXT). This was a project to standardize the methodology and measurements of diagnostic x-ray units in the field. The results of these tests are provided separately to the Committee. The rather large ranges of exposure values was and continues to be of concern. To assist the states in the reduction of both patient exposures and public exposures, the Conference has prepared example acceptable exposure ranges for different diagnostic techniques so the user will have a basis to adjust their technique. The NEXT project continues today and is providing data for the future.

Paritially as a result of NEXT, the states began to expand their regulation of the "Professions" to include the technicians actually administrating the ionizing radiation to patients. Today, 26 states have some form of licensing or registration of x-ray technicians as well as technicians in nuclear medicine and radiation therapy. All but one state have a requirement that technicians be trained. California and Vermont have additional requirements for the primary medical care professionals beyond the basic medical practice license to use ionizing radiation.

The regulation of the medical professionals by the States has been a beneficial one for the public. That is not to say that problems have not occurred. Among the problems are those cited in the recent news articles relating to ionizing radiation injuries. For example, clearly several misadministrations of ionizing radiation therapy have occurred; but, were they at a greater incidence than for similar misadministrations of other therapeutic materials and were the consequences greater than with other therapeutic materials? Another question that might be asked is, "Should repeat x-rays be considered misadministrations under some conditions?" After all, this is exposure of rhe patient without a benefit to the patient. If the unit is one that has a higher exposure per examination, this exposure may be significant. I believe that the investigations by this Committee are appropriate and are in the public interest. They should result in a better understanding of the overall occurrence of misadministrations within the medical care community.

The NRC is the only active Federal medical user regulator of medical ionizing radiation use and that is only for byproduct, source, and special nuclear material. The States are the exclusive regulator of the remaining ionizing radiation uses in health care. When adopted by a state, the Conference's Suggested State Regulations for Control of Radiation are a powerful force in the regulation of users. In adopting these regulations quite often Legislative or other officials exercise a veto over the final wording of the regulation. Further, in every case, they control the resources made available for use in the regulation of sources of ionizing radiation. For example,

the State and Territorial Health Officers goals for the year 2000 only mention radon in homes. Nothing is mentioned about ionizing radiation safety for any other use. This is important since most Radiation Control Programs are a subunit of the State Health Agency.

Some areas of concern are;

1. The lack of a consistent radiation standard for all medical (and industrial) users and devices in this country. The two Federal Laws directly addressing medical devices have not been implemented for radiation devices. Further, they **do not** adequately provide for state regulatory control. Most states feel that this is an area that should be implemented at the state level. These laws do not address public exposures related to the devices usage.

2. Rapid communication is needed to report problems with ionizing radiation equipment due to the short half-life of the isotope. Both NRC and FDA have communication systems in place. Unfortunately, they do not always function as well as might be desired. For example, if there is a problem with a Technicium 99m generator lot, the manufacturer may report it to FDA. FDA may report it to the states on a monthly report. This is for a product which has a 10 day useful life. Receiving a report that is over 30 days old is of little use. Further, some of the states are not on the routine distribution of the monthly reports.

3. Another area of concern is the inhibitions of communications within the regulating community. For example, if the Agreement States wish to establish a joint working group with NRC to do the initial development work on regulations, policies, guides, etc. we become advisors and are subject to the Federal Advisory Committee Act. We suggest that this goes beyond the intent of Congress since full public comment will be received by the agency prior to final rulemaking.

4. One other area, not related to the regulation of medical ionizing radiation use, but is of concern, is the lack of a defined system to obtain prompt accurate information about international events. For example the recent Tomsk-7 event the states, did not receive information regarding the event. While it can be argued that nothing would reach the U.S. Continent; therefore, the sates were not interested. States have bands going to Russia and they have returning citizens all of which are asking for guidance and surveying. So even though the event is not widespread we still need some information.

My recommendation is that this Committee should consider the following:

1. Designate one agency to regulate all uses of ionizing radiation. This may or may not be the same agency as the basic standard setting agency. This probably would include transportation and defense issues. Provisions should be made to have something like the Agreement State program of the AEA. The initial phase should allow states to certify that they have adopted and can enforce the basic requirements of the "Suggested State Regulations for the Control of Radiation." The program could require the pre-approval of certain facilities and for conditions of operations.

ADVANTAGES.

A. One agency would have most of the expertise and regulatory control thereby simplifying the coordination of national radiation control activities thereby providing the public better access for assistance. Further, it would be easy to initiate a nationwide information exchange program.

B. A single regulatory program modeled like the Agreement State program should result in improving interstate commerce and possibly research and development.

C. With legislative authority, the federal government could regulate "orphan" ionizing radiation sources such as NARM that are not regulated by the states in all cases amoung the Non-Agreement States.

DISADVANTAGES.

A. This would remove some of the flexibility of local regulation.

B. Unless one agency sets the generic ionizing radiation standards and another agency implements and enforces the standards there is some risk that one philosophy (possibly not in the public interest) will develop.

C. By bringing NARM and X-Ray into the federal scheme the costs to Federal Government of control may be too high. Fees for service may be the only practice revenue for this program and care must be taken to kee[the fees reasonible. Fees may also be reduced if the plan is to allow states to collect fees since the states generally can operate somewhat more efficiently. Start up funding may be an item of consideration.

NOTE. This proposal should include medical, academic, and industrial uses to be adequate. Also mixed hazards, i.e. ionizing radiation and chemical, would have to be addressed.

2. Extent federal control to include discrete sources and users of NARM and particle accelerators which are not covered by the AEA. While many States have exercised jurisdiction in these areas, we believe that nationwide consistency of regulation with the resulting improved commercial development would occur if this were accomplished

Conference of Radiation Control Program Directors, Inc.

Conf Publication #82-2

Criteria for Adequate Radiation Control Programs (Radioactive Materials)

A Report of Task Force E-3 (Formerly 2B)

Published by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

Conf Publication #82-

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS (RADIOACTIVE MATERIALS)

A Report of Task Force E-3 (Formerly 28)

This work was performed under
FDA Cooperative Agreement 5 U01 FD 01201-02S1

Printed November, 1982

Prepared by

Conference of Radiation Control Program Directors, Inc
65 Fountain Place, Frankfort, KY 40601

in cooperation with

The Bureau of Radiological Health and
The Executive Director for Regional Operations, FDA

The U S Nuclear Regulatory Commission

The U S Environmental Protection Agency

FORWARD

The development of criteria for evaluating the adequacy of various aspects of state and local radiation control programs has been given considerable attention by the Conference, the Bureau of Radiological Health (BRH), the Nuclear Regulatory Commission (NRC), and by the individual state programs.

For those states which have become "Agreement States" under the provisions of the Atomic Energy Act, the Nuclear Regulatory Commission has developed detailed criteria to evaluate the state's radiation control program for compatibility with federal regulatory requirements.

In April of 1981, the Conference prepared a document relating to criteria for an adequate radiation control program in the area of x-ray. This document similarly relates to criteria for an adequate radiation control program in the area of radioactive materials, being particularly designed for those "Non-Agreement States" which regulate radioactive materials not covered by the Atomic Energy Act. This document closely parallels the criteria document of the NRC, and can be used as a comparison document to the NRC criteria document for the evaluation of Agreement States.

Wallace W. Hinckley

Wallace Hinckley
Task Force Chairman

Heyward Shealy

Heyward Shealy
Conference Chairman

PREFACE

This guide has been developed by the Task Force on Criteria for Adequate Radiation Control Programs (Radioactive Materials) at the direction of the Conference of Radiation Control Program Directors Inc Adequate resources are essential for the successful implementation of a program to protect the public health of our citizens from unnecessary radiation exposure A guide, therefore, is needed that provides an outline of the basic needs and resources which should be operational to properly carry out a radiation control program

This document presents the guidance of the task force as a result of its research and deliberations It presents a method for determining the quality and quantity of the resources necessary for the successful operation of a balanced thorough and yet efficient radioactive materials program at the state level This report, in conjunction with the document, "Criteria for Adequate Radiation Control Programs (X-Ray)," should serve as the basis by which state radiation control agencies, administrators, and legislative bodies, as well as the public, can make realistic evaluations regarding the adequacy of a comprehensive program for the control of ionizing radiation

This guide embraces the "Licensing State Concept" for radiation control programs The criteria assume that rules and regulations have been adopted which are as effective as the "Suggested State Regulations for the Control of Radiation (SSRCR) which have been prepared by the Conference of Radiation Control Program Directors, Inc , the U S Nuclear Regulatory Commission, the U S Environmental Protection Agency, and the Bureau of Radiological Health of the Food and Drug Administration

CONTENTS

MEMBERSHIP

The following persons served on Task Force E-3

STATE PERSONS

Wallace Hinckley, Chairman, Maine
Michael McCann, Illinois (resigned)
Lynn FitzRandolph, Arizone (resigned)
Warren Jacobi, Colorado (assigned)
Nancy Kirner, Washington (assigned)

FEDERAL RESOURCE PERSONS

Bobby Dillard, EDRO/FDA
Donald Thompson, DTMA/BRH
Joel Lubenau, OSP/NRC
DeVaughn Nelson, ORP/EPA

HISTORY

The need for guidance on adequate criteria was recognized by the Conference at its First Annual Meeting held in Montgomery, Alabama in 1969. The first basic recommendations for an effective radiation control program were presented in a workshop report from this meeting, "Criteria and/or Indices, Program Evaluation and Measures of Progress."

At the Second Annual Meeting in 1970, a Program Criteria Committee recommended that to evaluate an x-ray control program, five major areas should be addressed:

1. Legislative Basis
2. Administration,
3. Operations and Surveys,
4. Compliance, and
5. Education, Training and Public Relations

At the Third Annual Meeting held in 1974, a workshop was charged to consider methods to measure effectiveness of a radioactive materials control program. This workshop recommended that the Conference establish a task force to develop methods of how to measure radioactive material program effectiveness. As a result of the recommendation, a task force was formed, but not funded, and therefore never met.

In 1976, the Executive Committee clarified the charge to the Task Force on Criteria for Adequate Radiation Control Programs, which only included the area of x-ray, radioactive materials being excluded.

In 1979, a separate working group (Task Force 2-B) was formed for developing radioactive materials criteria, but did not meet. In 1980, this working group was charged by the Executive Board "to develop criteria for an adequate radiation control program - radioactive materials."

At the Thirteenth Annual Meeting in Little Rock, Arkansas, held in 1981, Task Force 2B submitted a draft of "Criteria for Adequate Radiation Control Program - Radioactive Materials" to the Executive Board. The document was approved, pending final refinements of one appendix.

The final document with the refined appendix was completed in 1982.

BACKGROUND / ASSUMPTIONS

Although the NARM Task Force and the SSRCR, Subpart C, Task Force have direct policy-making charges related to control of radioactive materials, the problem of developing adequate criteria for a radioactive materials program centers on the need to consider the broad scope of the program and the interaction with the federal rules administered by NRC, EPA, DOT, BHR, OSHA, DOE, etc. The E-3 Task Force has considered the many requirements and constraints placed upon licensing states and non-licensing states. The following assumptions were made by the E3 Task Force:

1. The "Suggested State Regulations for the Control of Radiation" (SSRCR) has been adopted by over 30 states and forms the basis for licensing state criteria. Adoption of Part C for the licensing of radioactive materials is assumed to be adequate criteria.

2. The "Guides for Naturally Occurring and Accelerator Produced Radioactive Materials (NARM)" is adequate licensing criteria for NARM radioactive sources.

3. The "Guides for Evaluation of State Radiation Control Programs Under Agreement with US NRC" is adequate criteria for all states and is essential for the Agreement States.

CHARGE

To develop criteria to be used to evaluate the adequacy of a radioactive materials program, considering the variation that exists among states in enforcement and administrative practive, however, the following assumptions are to be made by the task force

1 The Criteria shall endorse the licensing state concept for all radioactive materials

2 The Criteria shall assume that all states have adopted regulations equally effective as the SSRCR and the provisions of Subpart C

3 The Criteria shall endorse, to the fullest degree possible without losing the flexibility needed for application to all state programs, the state evaluation rationale for Agreement States

4 The Criteria shall be in a format suitable for inclusion with other task force recommended criteria

5 The Criteria shall consider federal authority, rules and guides, such as NRC, EPA, DOT, BHR, OSHA etc

RECOMMENDATIONS

1 The Criteria should be distributed to each radiation control program for use in assessing program adequacy

2 The Criteria should be used by program personnel to develop an understanding of the key elements of a comprehensive radioactive materials program

3 The Criteria should be consistent with other "criteria" established for adequate radiation control programs for other radiation sources, i e , x-ray, non-ionizing, etc

4 Task Force E-3, having met its charge, should assume a monitoring role and revise criteria every three (3) to five (5) years The chairman should maintain a file related to potential revisions

RADIOACTIVE MATERIALS PROGRAM CRITERIA

I LEGISLATION AND REGULATIONS

A. The state radiation control program shall have enabling legislation essentially in conformity with the Council of State Governments' "Suggested State Legislation," 1983 Edition, Volume 42 Likewise, the program shall have regulations essentially in conformity with the "Suggested State Regulations for the Control of Radiation" (SSRCR). Note County or city programs for radioactive materials control may strike reference to "state" in many instances Provision to set license fees by regulation is deemed desirable Statutory authority should include a requirement for surety arrangements Issuance of civil penalties should be included in legislation to support compliance; and authority to appoint an advisory committee is consistent with development of program policy Legislation, consistent with the licensing state concept for radio-active materials set forth in SSRCR and "Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM)," shall include authority to enable the state to license, inspect and enforce all radioactive materials sources not preempted by federal authority. The legislation should include authority for entering into interstate and federal/state agreements.

Federal-state arrangements include, but are not limited to

1 Granting state primacy for the enforcement of regulations for the control of radioactive materials This

includes the entering into agreements with the US Nuclear Regulatory Commission (NRC) for the control of by-product, source and/or special nuclear materials Special authority may be needed for agreements related to the Uranium Mill Tailings Radiation Control Act (UMTRCA), and the regulation of low-level radioactive waste

2 Approval of and preparation of state emergency response plans

3 Training of state staff in licensing enforcement, laboratory radiochemistry, emergency response, quality assurance, etc

4 Assuring sufficient funding, necessary support services, and equipment to the state radiation control program

5 Interchanging of staff to assist state programs Legal staff should be assigned to assist the state radioactive materials program in the enforcement of rules The legal staff should have a working knowledge of all the laws, rules and procedures related to licensing, inspection and compliance

B Uniform regulations shall be adopted The egulations shall embrace reciprocal state cooperation for licensing inspection and enforcement of the shipment, manufacture, and product usage of radioactive materials The state program shall adopt regulations for radioactive materials compatible with the provisions of Part C, "Licensing of Radioactive Material," of the SSRCR

C Regulations should be completely reviewed at least every two (2) years and the revision adopted within one (1) year thereafter A public hearing to allow review and comment by affected groups, and a review and comment period of at least sixty (60) days prior to changes in the regulation, should be provided

II PROGRAM ORGANIZATION

A When responsibility for control of radioactive materials is divided among more than one state agency, administrative letters of agreement should be effected to minimize duplication of services Agencies should work toward a common objective — radiation protection

B A radioactive materials program should be a separate and identifiable government unit with a single person responsible for directing the work of the program When regional offices are utilized for program administration, there should be clear lines of communication

C The program should utilize an Advisory Committee, consultants, or other outside resources to provide as part of its function, guidance and assistance for the radioactive materials program Note
See NRC Guide for Evaluation of State Radiation Control Programs

III PROGRAM PLANNING AND MANAGEMENT

The day-to-day operation of the radioactive materials program should be guided by the overall written management plan of the program The Radiation Control Program Director shall be responsible for development and implementation of the plan The plan should include the following basic components

A Problem — The problem identification section of the plan should demonstrate that the promulgation of rules is justified based upon data showing the extent to which workers and the general population are exposed to radiation

B Objective — The long and short term objectives should be established with specific targets for priority and accomplishment

C Methodology - The strategy, including necessary fundings, should be detailed and include the services provided by support agencies, such as laboratory, emergency response team, and licensing Activities should be described that will fulfill stated objectives

D Evaluation — The plan should include periodic evaluation of program effectiveness. An important component of evaluation would be a method to determine if changes have occurred in the hazards to population groups.

E Quality Assurance

1 Licensees' files should be selected on a predetermined frequency, for complete in-depth review of license, inspection, and enforcement procedures for adherence to quality assurance criteria.

2 Program personnel records should be selected, on a predetermined frequency, for review of time scheduling of inspections, expense records, accuracy of records, etc.

3 The compliance program should be periodically reviewed to assess its effectiveness. For example, consideration should include escalated enforcement policies and effective use of staff. Legal staff should participate in the review.

STAFF, TRAINING AND BUDGET

A Personnel - Professional Staff

1 Radioactive materials program licensing, inspection and enforcement staff should be experienced. Requirements for training and experience will be different for each state depending upon the types of licenses administered by the state. The following guidance may be used to develop a description of positions.

a Supervisor - Senior Level

Entry level qualifications should include

(1) a four year degree in science or engineering and supplemental college level training in health physics and public administration,

(2) specific training in licensing, inspection and enforcement of radioactive materials licensees, and

(3) at least four years of experience serving in a professional health physics position or eight (8) years of equivalent training and experience in other civilian or military employment in radioactive materials plus a record of progressive management responsibility within the position.

b Senior Level — Professional/Technical

Entry level qualifications should include

(1) a four year degree in science or engineering and course training in basic health physics,

(2) specific training in licensing, inspection and enforcement of radioactive materials licensees; and

(3) at least one year of progressive experience in the role of a Junior Level Professional/Technical or eight (8) years as a health physics technician in other governmental, civilian or military employment related to radioactive materials.

c. Junior Level — Professional/Technical

Entry level qualifications should include

(1) college level training in mathematics, physics, and chemistry,

(2) two (2) years of progressive training in radiation protection, and

(3) specific training in inspection and enforcement of radioactive materials licensees or equivalent training and experience in other government civilian, or military training.

2 The supervisor should be part of the management team

3 Each employee should have an accurate, and up-to-date description of the position, detailing specific responsibilities and tasks

4 It should be possible for any professional or technical employee to progress via a career ladder through the various levels up to and including Director of the Radiation Control Agency

5 An organizational structure that supports promotion from within and salary levels adequate to retain persons of appropriate qualifications should be the policy of the agency to minimize staff turnover and maintain continuity

6 Personnel requirements for licensing, inspection and enforcement of radioactive materials licenses should be 1 0 - 1 5 full-time equivalents per 100 licenses Additional staff would be required for

a A major radioactive materials manufacturing facility

b A major milling/processing facility

c A low-level commercial waste disposal area

d Key emergency response activities

Small programs should assign responsibility between two (2) persons to insure continuous program coverage and continuity in the event of sickness, promotion, etc (see Appendix I for example)

B Training

1 Training should be included in the program plan This training should encompass initial and ongoing training necessary to maintain technical competence and maintain the interest and involvement of new and experienced staff At least five percent of program time should be allocated to training and/or cross training

2 Training should be planned as available from universities, federal agencies, private companies, etc , to broaden the capability of the staff and to keep personnel informed of current developments in the control of hazards related to radioactive materials

3 The radioactive materials program should have a planned policy of cycling all professional and technical staff through a variety of training and retraining to periodically update and reinforce previous knowledge

4 States should use training aids available from federal agencies and develop a comprehensive reference library on radioactive materials and licensing

5 Interstate training agreements and exchange of information is desirable to utilize state training staff

C Funding

1. The radioactive materials programs should be funded from sources that insure continuity of the program

Note When states are authorized by legislation to adopt a fee structure to support the radioactive materials program, the fee schedule in 10 CFR 170 may be used as a guide The authority to adopt a fee schedule by regulation rather han by statute is advisable

2 There should be a funding mechanism for agency use of contractual services

V LICENSING INSPECTION AND ENFORCEMENT

A Licensing

1 The radioactive materials program shall license users of radioactive materials in accordance with Part C of the SSRCR The program shall obtain information about the proposed use of radioactive materials facilities and equipment, training of personnel, radiation safety officer, operating and emergency procedures appropriate for determining that the licensee can operate safely and in compliance with rules and license conditions Pre-license visits for major licensing actions should be considered

2 The radioactive materials program should adopt its own licensing guides, checklists and policy memoranda to assure technical quality and uniformity in the licensing program NRC Guides, American National Standards and Radioactive Materials Reference Manual (RMRM) are appropriate for reference

3 The following administrative practices shall be considered

a Appropriate copies of rules, laws, guides and forms shall be printed and made available to each licensee or prospective licensee

b The license should detail the type of radionuclide and form of the radioactive material, the licensed quantity in curies, the authorized use, and all conditions attached to the license

c The license should be reviewed in light of current licensing practices at least every five (5) years License expiration notices should be sent 60 days prior to the due date

d Files should be maintained to provide for fast and accurate retrieval of licensee information, licensee conditions, RMRM evaluation sheets, source data sheets, licensee's consumer warning, licensee's calibration data, waste disposal contractor, staff evaluations, pending enforcement actions, general correspondence, personnel monitoring services, reports and miscellaneous information

e Issuance of licenses shall be based upon written guidelines Renewal of licenses should also be based upon the history of compliance

4 Quality Assurance (QA) and ALARA Programs for controlling exposure of patient and worker

a The radioactive materials program should have a plan to encourage licensees to implement QA and ALARA Written guidance should be developed for evaluating QA and ALARA

b Calibrated test equipment should be used by inspectors in the evaluation of licensee's use of radioactive materials

c Records of worker exposures maintained by licensee should be reviewed and evaluated as a check for a successful QA and ALARA program

B Inspection

1 Inspections shall be conducted by qualified staff It should be normal policy for senior level staff to inspect licensees with higher priority frequency ratings and junior level staff to inspect routine licensees There should be communication and cooperation between the licensing and inspection sections For states with separate inspection and licensing staffs, joint inspections for cross training are desirable

2. Field and laboratory equipment in support f the radioactive materials program shall be adequate to monitor all types of radioactive materials licensed by the agency

a Calibration schedules, procedures, and data should be maintained for all field and laboratory equipment The agency's calibration of instrumentation, calibration records, and calibration

intervals should as a minimum, meet NRC guides

b The laboratory should participate in the US Environmental Protection Agency (EPA) or other cross-check programs

3 Field Check Quality Assurance — Calibration should be verified, e g , calibration sources, flood source etc should be used by inspectors in the evaluation of the licensees program

4 The following administrative procedures should be followed

a An inspection schedule should be developed semiannually The inspection frequency should be based upon the hazard and the inspection history The agency should have written procedures to extend frequency based upon compliance hisory See appropriate NRC guides

b Statistical data from inspections should be developed to permit program management to assess the status of the inspection program on a periodic basis

c Inspection guides and checklists should be used to maintain uniform compliance procedures

d A written policy should establish protocol for announced inspections (announced inspections should not occur except under extenuating circumstances), unannounced inspections, follow-up inspections, exit interviews, notification of violations, and obtaining agreements with licensees on scheduling of corrections

e Procedures should be available for maintaining a sequential record of licensees' compliance history to enable early identification of patterns of repetitive violations

f Inspection reports should be uniform and adequately describe

(1) scope of inspections,
(2) complete substantiation of all items of noncompliance,
(3) scope of licensees' safety programs,
(4) number and type of the inspector s independent measurements, and
(5) follow-up of previous violations

g Procedures should be established for quality assurance, including field review of inspectors

C Enforcement

1 The legal authority shall provide for prompt correction of items of noncompliance Written procedures should be developed by the regulating agency for response to licensee noncompliance Appropriate enforcement actions, should be progressive Options should include the following (not necessarily in order listed)

a Remedy by administrative compliance letter per agreement with licensee at exit interviews with licensee management

b Management conferences

c Orders for correction of serious and imminently hazardous conditions, as defined in Section 13 (a) of the OSHA Act Section 5 (a) (1) of the OSHA Act is a general duty clause which requires a hazard-free place of employment

d Civil penalties

e Modification, suspension or revocation of licenses

f Impoundment of radioactive materials

g Criminal penalties

2 The following administrative practices should be followed

a Issue "notice of noncompliance" letters within 30 days following the inspection, utilizing consistent regulatory language

b Specify all items of noncompliance, referencing the appropriate regulation or license condition and establish a period of time for response, usually 30 days Recommendations that may improve licensees program should be in- cluded, but clearly separated from compliance items

c Respond promptly to all communication related to enforcement letters from licensees

d Establish a written review procedure that gives licensees the opportunity to appeal enforcement actions

VI RADIOLOGICAL INCIDENT RESPONSE

A The State Radiological Incident Response Plan shall be written and should be updated annually This plan should include
(1) a telephone number for a 24 hour response contact,
(2) names, addresses, and telephone numbers of key personnel,
(3) lists of equipment that is available,
(4) equipment calibration procedures, and
(5) Department of Energy (DOE) Regional Inter-agency Radiological Assistance Plan (IRAP) coordinator and 24 hour telephone number

B A vehicle with multi-frequency statewide radio communication should be available for emergency response

C The plan should be filed with other appropriate local, state and federal public health and safety offices

D Prompt on-site investigations should be made of radiological incidents that require reporting to appropriate authorities within 30 days per SSRCR, Part D Lesser radiological incidents should always be followed up

E Results of investigations of radiological incidents should be documented, appropriate enforcement actions taken, and cases followed up

F Federal, state and local agencies should be notified, when appropriate, of pertinent information about radiological incidents

G Information should be provided on failure of devices or sources to appropriate agencies responsible for device or source approval

H Training should be given to local safety officials for responding to radioactive material incidents

I. Public information - see Section X.

VII RECORDS, OFFICE EQUIPMENT, AND CLERICAL SUPPORT

Record-keeping is critical to program planning and evaluation and provides a means for demonstrating the public health impact of the program. Therefore, the data that is collected and retained should be selected to relate, as directly as possible, to the public health impact of the radioactive materials program

A. The program should have a data management system that provides the following:

1. Accurate data that is rapidly retrievable.

2. Up-to-date list of licenses that includes mailing addresses, telephone numbers, locations of use, possession limits, and the principal contact individual.

3. Agency personnel monitoring records.

4. Fiscal and other administrative records.

5. Records of incidents and investigations.

6. An up-to-date list of qualified consultants and health physicists from whom the agency, radiation safety officers and other persons may seek advice.

B. Office Equipment
The program should make maximum use of electronic data and word processing systems.

C. Secretarial and clerical

Adequate secretarial and clerical support should be provided.

VIII. USER EDUCATION

A. The agency should encourage and promote continuing educational programs for radioactive material users. The agency should be prepared to conduct training in radiation safety and regulatory requirements.

B. Inspection personnel should provide information to the licensees related to the safe use of radioactive materials to educate, assist and answer questions related to health physics.

IX. TRANSPORTATION OF RADIOACTIVE MATERIAL

A. Transportation of radioactive materials shall be in accordance with Part C of the SSRCR.

B. Where the state transportation or public safety agency has authority to regulate the transportation of radioactive materials, there should be a written agreement to coordinate activities with the radiation control program.

C. The radiation control agency should provide information regarding transportation to licensees.

X. PUBLIC INFORMATION

A. The radioactive materials program should make files available to the public consistent with State Freedom of Information Acts. A policy for protecting proprietary and/or private information should be established in accordance with state law.

B. The agency should have a designated Public Information Officer (PIO). Information for media distribution, such as press releases and in-depth reports, should be prepared in conjunction with the Public Information Office of the state agency. The program should seek opportunities to inform the public in news releases, TV, radio, incident reports, etc.

C. There should be a liaison with trade and professional groups leading to seminars, training courses, and public documents on radiation control of radioactive materials.

D. Public information procedures should be established for notifying contiguous state directors and federal agencies of radiological incidents and making all pertinent information available.

XI RADIOACTIVE WASTE DISPOSAL

A The radiation control agency should develop a contingency plan to manage radioactive waste in the event that current disposal sites are not available Reliance on a regional waste site is not considered an option unless the regional site is operational

B A periodic survey of waste generated within the state should be conducted to accomplish (A) above

C The agency should maintain information on viable disposal mechanisms for use by licensees

XII SPECIAL STUDIES

Special studies should be performed of potential radioactive material exposures which may be the subject of public concern These studies should assist the radioactive materials program in determining the scope of potential issues and problems developing regulations to control a potential hazard, and determining future program needs

APPENDIX I

DETERMINATION OF ADEQUATE MANPOWER

For Agreement States, the US NRC has staffing requirements of 1-1 5 FTE (full time equivalents) per 100 active RAM licenses The example below is based upon licensing state experience The assumptions listed below were used to develop the example Both the example and assumptions may be used by a state program director to predict staffing requirements for the establishment of a state materials licensing program

The following assumptions have been made for the example

1 One FTE is 225 work days

2 The ratio of licenses, by type, is similar from state to state, regardless of the number of licenses

3 A compliance ratio of 25% is assumed, i e , 75% of licenses would need compliance letters, follow-ups and legal actions

4 The total number of license actions, e g , amendments, renewals, and new applications processed each year, equals the total number of the state program's licenses

5 The state program has developed an inspection frequency schedule, based upon license type, e g , specific licensee, "Medical Institution," "Broad Scope," "Academic," "Industrial," "Non-Portable Gauge," etc (See Table A for example)

6 Work day requirements

a Estimated work days necessary for inspection priority type (based upon state licensing experience)

i Specific licenses - 2 5 days
ii Broad Scope - 7 1 days
iii Follow-up (could include re-visit letter, or legal action - 1 0 day

b Estimated work days necessary for license review and issuance activities - 0 6 days

c Estimated work days necessary for all other personnel duties e g — staff training, public education, emergency response, calibration, etc is 25% of the sum of the estimated work days for inspections plus the estimated work days for licensing activities (sum of 6a and 6b above)

d Estimated work days necessary for administrative activities associated with any licensing program, e g budget preparation, program planning personnel evaluation, etc is 25% of the sum of the estimated work days for inspection plus the estimated work days for licensing activities (sum of 6a and 6b above)

EXAMPLE

(The following example is based upon a new state program with an estimated potential for 100 licenses)

After reviewing his inspection priority schedule, (see example in Table A) the program director has determined that the following license types will require inspection each year

a No of specific licenses — 32
b Broad Scope licenses — 1
c Follow-up — 24

Based upon the above determined number of annual inspections and follow-up actions, Table B shows an example of the method of determining the total work days per year required, and the calculation for determining the annual FTE for the 100 licenses in this example

TABLE A

Inspection Priority Schedule* -

(SAMPLE)

CATEGORY	EXAMPLE	PRIORITY
1 Specific Institutional	Hospital	
	a Nuclear Medicine	2 years *
	b Therapy User	1 year *
	c Educational (dependent upon use)	1 to 3 years *
2 Specific Private Practice	Office	
	a Nuclear Medicine	2 years *
	b Therapy User	1 year *
3 Specific Gauge	a Moisture Density	2 Years *
	b Level, etc	3 years *
	c Non-specific	2 to 3 years *
4 Specific Research		1 to 3 years
5 Broad Medical		1 year
6 Broad Research		1 year
7 Broad Industrial		1 year
8 Manufacturer/Distributor (Medical or Non-Medical)		1 year
9 Consultant/Physicist		1 to 2 years
10 In vitro General License		4 years
11. In vivo General License		4 years

* Inspection frequency may vary depending upon individual state compliance history

+ The US NRC maintains guidance for inspection frequency which also may be used

TABLE B

Determination of Total Work Days For a 100 License Program

(SAMPLE)

WORK ACTIONS	REQUIRED ACTIONS/YEAR		WORK DAYS PER ACTION		TOTAL WORK DAYS/YEAR
1 Inspection Actions					
a Specific licenses	32	x	2 5	=	80
b Broad licenses	1	x	7 1	=	7
c Follow-up	24	x	1 0	=	24
2 Licensing Actions	100	x	0 6	=	60
			Subtotal		171
3 Other Duty Actions	25% of Subtotal			=	43
4 Administrative Actions	25% of Subtotal			=	43
			Grand Total Work Days		257

Once the total work days year have been determined, as shown above, then the required FTE to accomplish the workload for this specific example is

Example

$$\{257 \text{ total work days/year}\} \left\{ \frac{\text{FTE}}{225 \text{ Work Days}} \right\} = 1\ 14 \text{ Total FTE per year}$$

This determined ratio of 1 14 FTE per year for 100 active licenses is an appropriate ratio when the total number of licenses is 100 or greater If the total number of licenses are less than 100 and/or if the licenses include a large manufacturer, a low-level radioactive waste site, or a milling operation, then the FTE ratio will usually have to be adjusted higher

PUBLICATIONS

*First Annual National Conference on Federal-State Implementation of Public Law 90-602, September, 1969, ORO 69-4

*Second Annual National Conference on Radiation Control, The Quest for Quality October 1970, BRH/ORO 70-5

*Third Annual National Conference on Radiation Control, New Horizons, December 1971, DHEW Publication (FDA) 72-8021

*Fourth Annual National Conference on Radiation Control, Save a Rad, July 1972, DHEW Publication (FDA) 73-8003 BRH/OBD 73-3

*Fifth Annual National Conference on Radiation Control, Planning for Protection, October 1973, DHEW Publication (FDA) 74-8008

*Sixth Annual National Conference on Radiation Control New Challenges, October 1974, DHEW Publication (FDA) 75-8010

*Seventh Annual National Conference on Radiation Control, Assuring Radiation Protection, February 1976, DHEW Publication (FDA) 76-8026

*Eighth Annual National Conference on Radiation Control, Radiation Benefits and Risks Facts, Issues, and Options April 1977, HEW Publication (FDA) 77-8021

*Ninth Annual National Conference on Radiation Control, Meeting Today's Challenges, April 1978, HEW Publication (FDA) 78-8054

*Tenth Annual National Conference on Radiation Control, A Decade of Progress, June 1979, HEW Publication (FDA) 79-8054

*Thirteenth Annual National Conference on Radiation Control Problems, Trends, and Issues The Need for Redefinition, HHS Publication (FDA) 82-8054, March 1982

*Bonding and Perpetual Care of Nuclear Licensed Activities, January 1975

*Credentialing Users of Ionizing Radiation in the Healing Arts — A Report of Task Force on Credentialing of Radiation Allied Health Operators, May 1982

*Criteria for Adequate Radiation Control Programs (X-Ray) A Report of Task Force 2A, HHS Publication FDA 81-8160, April 1981

*Directory of Commercial Calibration Services for Ionizing Radiation Survey Instruments NBR GCR 80-296, April 1961

*Guides for Naturally Occurring and Accelerator-Produced Radioactive Materials (NARM), HHS Publication FDA 81-8025, June 1981

*Ionizing Radiation Measurement Criteria for Regulatory Purposes, NBS GCR 79-174 November 1979

*Natural Radioactivity Contamination Problems, EPA 520/4-77-015, February 1978

*Natural Radioactivity Contamination Problems Report No 2, A Report of the Committee, August 1981

*Quality Assurance in Diagnostic Radiology A Guide for State Program Implementation, HHS Publication FDA 81-8147, January 1981

Conference of Radiation Control Program Directors, Inc.

Criteria for Adequate Radiation Control Programs (X Ray)

A Report of Task Force 2A

Published by

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration

HHS Publication FDA 81-8160

Criteria for Adequate Radiation Control Programs (X Ray)

A Report of Task Force 2A

This work was carried out under PHS Contract Number 223-79-6010.

Printed April 1981

Prepared by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.
and
U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Bureau of Radiological Health
Rockville, Maryland 20857

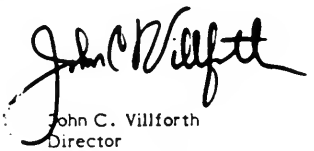
The opinions and statements contained in this report are those of the Task Force and may not reflect the views of the Department of Health and Human Services (HHS).

FOREWORD

The development of criteria for evaluating the adequacy of various aspects of radiation control programs has been given considerable attention by the Bureau of Radiological Health (BRH), the Nuclear Regulatory Commission (NRC) and several State programs. In one instance, the NRC has developed detailed criteria to evaluate Agreement States compatibility with Federal regulation of byproduct materials. Therefore, in recognition of the need in other areas of radiation control, the Conference of Radiation Control Program Directors charged Workshop No. 1 at the 7th Annual Conference in 1975 to consider the development of such criteria. The recommendation of the workshop called for the formation of a Task Force to develop the actual criteria. On two separate occasions the Executive Committee of the Conference established a Task Force to accomplish this task. During this period, the charge has been refined to call for the development of specific criteria for evaluation of a State radiation control program. The charge was divided between two independent subgroups and this report reflects the work of Task Force 2A, which was assigned to develop criteria for x-ray and nonionizing radiation control. It is assumed that upon completion of criteria for other sources of radiation by future Task Forces that it may be possible to integrate the criteria in a manner to enable the evaluation of the overall adequacy of a comprehensive State radiation control program.

This document provides detailed criteria that State radiation control directors may use to evaluate the adequacy of their x-ray control program. By identification of weaknesses or deviation from nationally accepted criteria, individual directors will have more justification for their budgetary or legislative requests.

Marshall W. Parrott, D.Sc.
Chairman
Conference of Radiation Control
Program Directors, Inc.



John C. Villforth
Director
Bureau of Radiological Health

PREFACE

This guide has been developed by the Task Force on Criteria for Adequate Radiation Control Programs (X Ray) at the direction of the Conference of Radiation Control Program Directors. The role of the radiation control program has changed over the years and recently there has been concern raised in the press and in Congress regarding the adequacy of the control of radiation in the United States. In general, these reports have been critical of the programs but there has been very little discussion of the reasons for the problems. Since adequate resources are fundamental to the successful implementation of any program, there needs to be an outline of what should be expected of radiation control programs and the resources needed to properly handle the problems.

This document presents the guidance of the Task Force as a result of its research and deliberations. It presents, for the first time, a method for determining the quality and quantity of the human resources necessary for the successful operation of a balanced, thorough and yet efficient x-ray control program at the State level. This report should serve as the basis by which State radiation control agencies, legislative bodies, as well as the public can make realistic evaluations regarding the adequacy of x-ray control programs.

Edd Johnson

Edd Johnson, Chairman
Task Force 2A

William S. Properzio

William S. Properzio, Ph.D.
Director
Division of Training and
Medical Applications

CONTENTS

MEMBERSHIP

Task Force 2A on the Criteria for Adequate Radiation Control Programs (X Ray) consisted of the following members during the development of this document:

Edd C. Johnson, Chairman
Wyoming Division of Health and Medical Services

Warren Jacobi
Colorado Department of Health

Ernest Ranieri
Idaho Department of Health and Welfare

John W. Shaver - Consultant
Radiological Health Sciences Education Project
Walnut Creek, California

Bobby L. Dillard
Food and Drug Administration, Region VIII

Richard E. Gross
Food and Drug Administration
Bureau of Radiological Health
Division of Training and Medical Applications

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS (X RAY)
A REPORT OF TASK FORCE 2A

HISTORY

Workshop No. I at the 7th Annual Conference in Hyannis, Massachusetts, was charged to consider the development of criteria for an adequate State Radiation Control Program. In its report to the Conference, Workshop No. I recommended the formation of a Task Force to further study this matter. In September 1975, the Executive Committee implemented this recommendation by forming a Task Force, however, support funds were not available. In September 1976, the Executive Committee reactivated the Task Force, clarified the charge, and allotted funding for meetings. Members of the original Task Force—John Shaver, Chairman, Si Kinsman, Jim Hickey, Warren Jacobi, Bobby Dillard, and Charles Showalter (representing Richard Gross)—met in Denver, Colorado, during April 1977. Criteria developed at this meeting were presented to the Conference members for comment at the 9th Annual Conference in Seattle, Washington.

In 1978 the Task Force was reconstituted to include the members mentioned above. The criteria were again submitted to the Conference membership for comment in August 1978. In November 1978, the Task Force met in Rockville, Maryland, to review the comments, and revise the criteria document as indicated by the comments. A final version of the criteria was submitted to the Conference and approved for publication.

BACKGROUND

The problem of developing suitable criteria for radiation control program adequacy has surfaced on numerous occasions, and has been given considerable attention by the Bureau of Radiological Health, Nuclear Regulatory Commission, and several of the State programs. For example, in 1969, the BRH prepared a detailed questionnaire as a part of a study to evaluate the status of State radiation control programs. The questionnaire was carefully developed with input from States, regional offices, and other Federal agencies, such as the NRC. It was pilot tested in most regions, and revised and improved based upon these tests.

Other work in this area includes sending Federal and State survey teams, upon request, to selected States to conduct detailed program evaluations. The Nuclear Regulatory Commission has detailed criteria to evaluate Agreement States to ensure program compatibility. In 1976, the Southern Interstate Nuclear Board conducted a study of radiation control programs in the South. The Conference has also formed workshops to consider the matter. The Task Force has taken full advantage of the previous work.

CHARGE

The charge that Task Force 2A worked under was to develop criteria that can be used to evaluate the adequacy of a State x-ray and nonionizing control program. In carrying out this assignment, the Task Force was reminded to consider mechanisms that would ensure

4. To minimize staff turnover and maintain program continuity there should be an organization structure which provides for:

   a. Promotion opportunities from junior level to senior level and supervisory positions, and

   b. Periodic salary increases which are commensurate with experience and responsibility.

B. Training

1. A formal training program should be established for all new professional employees. New employees should be provided with copies of and instructions on the regulations and written program procedures which include registration, inspection, and compliance requirements. New inspectors should be accompanied by experienced personnel during initial field surveys.

2. Personnel should participate in a planned continuing program of in-service training consisting of seminars, demonstrations, lectures by consultants, short- and long-term training and attendance at professional meetings (Health Physics Society, Regional Training meetings, annual meetings of the Conference, and so forth) to keep abreast of current developments in the control of radiation hazards.

V. Registration, Inspection, and Enforcement

A. Registration. The program should have authority to require the registration of all x-ray sources. The "Suggested State Regulations for the Control of Radiation - Part B" may be used as a guide in developing the extent of the registration function.

B. Inspection Authority. The program should have authority to conduct its own inspections. Survey reports from qualified private consultants or from radiation safety officers employed by the owner of an x-ray installation may be useful in augmenting the inspection program.

The program should have authority to set qualifications for private consultants or radiation safety officers when the survey reports of such individuals are used by the State to evaluate continuing compliance with its regulations in lieu of installation inspections by program staff.

C. Inspection Procedures. The program should have written procedures to insure that uniform inspections are conducted. These procedures should provide for the evaluation of the overall radiological performance of the facility. The "Suggested Optimum Survey Procedures Manual" can be used as a reference to develop written procedures for machine parameter measurements.

D. Inspection Schedule. The program should have a written priority schedule which sets routine inspection frequencies by type of x-ray installation. The schedule should be reviewed annually and adjusted to reflect any changes in program objectives. The inspection priority should take into account the following considerations:

1. Inspect every facility within a year of initiation of operation.

2. Utilize screening techniques, i.e., DENT, BENT, NEXT, and so forth, whenever possible.

3. Utilize facility/machine workload information and other previous inspection data, in addition to screening data, to develop specific inspection priorities.

4. Inspect every facility (except dental) at least once every five (5) years (see Appendix II). Facilities with higher priorities should be inspected more frequently.

An example of a program-determined priority schedule is given in Appendix III.

E. Enforcement. The program should have written enforcement procedures. These procedures should detail the steps to be taken within a specified time period to accomplish compliance with the regulations. The Office of the State Attorney (Attorney General) should be consulted in the development of these procedures. Interpretations based on policy occasions should be accumulated and maintained to ensure consistent enforcement policy.

VI. Survey Equipment

The Program should have sufficient field x-ray survey equipment and instrumentation capable of detecting and measuring x-radiation exposure to determine compliance with applicable guides and regulations, and to provide estimates of radiation doses to patients, operating personnel, and the general public.

Ideally, a survey kit should be provided for each FTE in the field. (Refer to the Optimum Survey Procedure Manual for a partial listing of the equipment, materials, and supplies that can be useful to the field inspector. However, special equipment will be needed for special studies, that is, low-energy detectors for evaluating mammography equipment, and high-energy detectors for evaluating certain therapy equipment.)

The x-ray control program should be capable of providing for the servicing and calibration of all x-ray survey equipment and instrumentation. There should be a written procedure and schedule for calibration and servicing of each radiation detection instrument. The schedule should call for a calibration at least annually, with calibration checks performed on a quarterly basis. Each instrument should bear a tag stating the latest date of servicing and calibration, and a calibration curve or correction factors for each detection range. Responsibility for calibration and servicing should be assigned to one staff person. Calibrations may be done by the radiation control program using its own calibration source(s), equipment, and procedures, or by a commercial instrument calibration and repair service under contract.

The complexity of the agency calibration program is dependent upon the purpose for which the data was obtained and should be detailed in the written procedures.

VII. Records

Recordkeeping is critical to program planning and evaluation and provides an objective means for demonstrating the public health impact of the program. Therefore, the data that is collected and retained should be selected to relate as directly as possible to this public health impact.

A. The program should have an efficient data management system that provides the following:

1. Data accurately and rapidly retrievable.

2. A continuing integrated registration program.

3. Physical survey forms containing minimum uniform data, and compliance and enforcement actions.

4. Agency personnel monitoring records.

5. Fiscal and other administrative records.

6. Records of x-ray machine transfers and vendor notifications.

7. Records of incidents and investigations.

B. The program should utilize the above records for:

1. Program planning.

2. Evaluation of program objectives.

3. Establishing priorities for x-ray inspections.

4. Carrying out field survey and inspection programs.

C. The program should make maximum use of available electronic data processing systems.

VIII. User Certification

The program should establish a credentialing program for all users of x-ray equipment. (See Appendix IV.)

IX. User Education

A. The program should encourage, sponsor, or conduct continuing formal education programs for users or operators of x-ray sources.

B. The inspector should take advantage of his time in x-ray facilities to educate, assist, and answer questions regarding radiation safety and good radiological health practices.

X. Quality Assurance

The program should have a plan to encourage and assist healing arts registrants in establishing quality assurance programs to ensure that all images are of a consistent, high diagnostic quality, and that all treatments are properly administered.

XI. Public Information and Education

A. The program should maintain liaison with professional groups, sponsor seminars and training courses, and develop/distribute public documents on radiation.

B. The program should provide x-ray registrants with current reference material, guidelines, and standards as they are available.

C. The program should serve as a resource for technical information on radiological health to the public at large (through newspaper releases, TV, radio, incident reports, and so forth) and participate in public education efforts at the State and local levels.

XII. Special Studies

The program should have adequate personnel, instrumentation, and initiative to undertake special studies including x-ray protection; for example, identify new problems that need investigation, develop more efficient procedures and methodology, and cooperate with Conference and/or Federal programs.

Appendix I

Staffing requirements can be determined using the following rationale. Clerical and administrative/managerial personnel are not included.

A. The following assumptions have been made in this analysis:

1. For each 1,000 x-ray tubes, there will be approximately 10 percent annual turnover or replacement.

2. For each 1,000 x-ray tubes, approximately 50 percent will be dental tubes.

B. Inspection, Followup, and Registration

Regardless of program size, an annual inspection workload of 500 x-ray tubes per FTE is a reasonable figure.

1. Dental facilities (assume 50 percent followup, to screening programs) 500 tubes X 0.2 (priority) X 0.50 (followup) = 50 tubes/yr.

2. Other facilities 500 tubes X 0.5 (priority) = 250 tubes/yr.

3. New installations 1,000 tubes X 0.10 (turnover) = 100 tubes/yr.
400 tubes/yr. = 0.8 FTE

4. Other followup and registration 0.2 FTE / 1.0 FTE per 1,000 tubes

C. Other Activities

Larger programs (larger number of x-ray tubes) can be more efficient with respect to other aspects of program, that is, education and quality assurance, staff training, special projects, and so forth. Other factors which will influence program efficiency are geographical distributions of population, age and experience of program, and possible regionalization of program operation. A range of staffing requirements has been derived, based on these considerations for other program functions.

	"Program Size"	
	Larger*	Smaller*
Education and Quality Assurance	0.1	0.5
Staff Training	0.1	0.1
Special Projects	0.1	0.2
Miscellaneous	0.1	0.3
Totals	0.4	1.1

*Values are for full-time equivalents (FTE) per 1,000 tubes.

D. Total staffing requirements, as derived above, will range from 1.4 to 2.1 FTE's per 1,000 x-ray tubes.

Appendix II

The rationale for this criterion is based upon the following considerations:

1. When operation is initiated, the dental facility will be surveyed and compliance determined.

2. Dental x-ray equipment tends to stay in compliance. The major problem is patient exposure, and while it is recognized that a screening program cannot identify all problems, such a program can cost-effectively identify those facilities that should be revisited.

3. DENT should be conducted on at least five (5) year intervals.

Appendix III

Each radiation control program should have a written priority schedule for inspection frequencies that will reflect the program's current objectives.

The following is only an example of such a priority schedule:

Hospital or Similar facility	every year
Radiology Clinic	every year
Other Medical facility	every 2 years
Chiropractic facility	every 2 years
Veterinary facility	every 2 years
Dental facility	every 5 years
Industrial facility	every 2-4 years

Appendix IV

All x-ray machine operators in the healing arts should demonstrate a minimal level of competence in the use of x-ray equipment which is consistent with national criteria.

Conference Task Force No. 5 "State Credentialling Program for Allied Health Operators" is currently working to develop recommendations and provide suggestions for implementation.

The staffing requirements for implementing this program have not been included in section IV.A.6.

U. S. GOVERNMENT PRINTING OFFICE 1981—726-348/1330

CRCPD Publication 86-4

Conference of Radiation Control Program Directors, Inc.

Criteria for Adequate Radiation Control Programs

(Environmental Monitoring and Surveillance)

A Report of Task Force E-10

Published by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

Printed May 1986

DISCLAIMER

The information contained in this document has been developed by the Conference for consideration by radiation control programs, and other interested parties.

The implementation and use of the information and recommendations contained in this document are at the discretion of the user. The implications from the use of this document are solely the responsibility of the user.

The opinions and statements contained in this document are those of the Conference, and may or may not reflect the views of the cooperating federal agencies.

CRCPD Publication 86-4

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS (ENVIRONMENTAL MONITORING AND SURVEILLANCE)

A REPORT OF TASK FORCE E-10

This work was performed under:
FDA Cooperation Agreement FD-U-000005-05-2

Printed May 1986

Prepared by

Office of Executive Secretary
Conference of Radiation Control Program Directors, Inc.
71 Fountain Place, Frankfort, KY 40601

in cooperation with

The Center for Devices and Radiological Health and
Office of Regulatory Affairs, FDA

The U.S. Environmental Protection Agency, and
The U.S. Nuclear Regulatory Commission

FOREWORD

The development of criteria for evaluating the adequacy of various aspects of radiation control programs has been given considerable attention by the Center for Devices and Radiological Health (CDRH), the Nuclear Regulatory Commission (NRC), the Environmental Protection Agency (EPA) and by the radiation control agencies for individual states. For those states which have become "Agreement States" for the licensing of certain radioactive materials, under provisions of the Atomic Energy Act, the NRC has developed detailed criteria with which to evaluate the compatibility of the States' regulations with the Federal regulations of these materials. In response to similar needs in other aspects of radiation control, the Conference of Radiation Control Program Directors, Inc., (CRCPD) established task forces and committees to formulate appropriate criteria.

In April of 1981, the Conference published "Criteria for Adequate Radiation Control Programs (X-Ray)," in November of 1982, "Criteria for Adequate Radiation Control Programs (Radioactive Materials)," and in April of 1985 "Criteria for Adequate Radiation Control Programs (Nonionizing)." This document presents the criteria for adequate programs of monitoring ionizing radiation in the environment.

The CRCPD will utilize these documents in its State Comprehensive Review Program.

By identification of weaknesses or deviation from nationally accepted criteria, directors of state and local programs will have a basis to strive for improved programs.

Warren E. Jacobi

Warren E. Jacobi
Chairman, Task Force on
of Criteria for Adequate Radiation
Control Programs (Environmental
Monitoring and Surveillance)

Eddie S. Fuente

Eddie S. Fuente
Chairman, Conference
of Radiation Control
Program Directors,
Inc.

PREFACE

A program for monitoring radioactive materials and ionizing radiation in the environment, both actual and potential, is essential for the protection of the public health and of the environment. Such a program is necessary, for a state, whether or not the state licenses radioactive material, and whether or not a major nuclear facility is lccated within the state. States that do license facilities which contribute to the radiation environment should provide a monitoring program which has at least the quality that is required of the facilities.

Adequate resources are essential for the successful implementation of every program for the protection of the public from unnecessary radiation exposure. Guides are therefore needed which provide outlines of the specific needs and resources of particular control programs.

This guide has been developed by the Task Force on Criteria for Adequate Radiation Control Programs (Environmental Monitoring and Surveillance), E-10, at the direction of the Conference of Radiation Control Program Directors, Inc., (CRCPD). The document provides guidance as to the resources required for a balanced, thorough and efficient surveillance of ionizing radiation and radioactive materials in the environment.

This report is the fourth in the series of "Criteria for Adequate Radiation Control Programs," for X-Ray, for Radioactive Materials, and for Nonionizing Radiation. These reports provide guidance by which state radiation control agencies, administrators, legislators and the public can make realistic evaluations of radiation control programs. The CRCPD will utilize these four documents in their State Comprehensive Rev'ew Program.

The criteria assume that rules and regulations have been adopted which are as effective as the "Suggested State Regulations for the Control of Radiation" prepared by the CRCPD, the U.S. Nuclear Regulatory Commission, the U.S. Environmental Protection Agency and the Center for Devices and Radiological Health.

TABLE OF CONTENTS

TASK FORCE MEMBERS

The following persons served on Task Force E-10

State Persons

Warren Jacobi, Colorado, Chairman
Nolan Bivens, South Carolina
Melanie Hamel, Illinois
Robert Mooney, Washington
Margaret Reilly, Pennsylvania

Federal Resource Persons

Robert Bores, NRC
Ronald Colle', NBS
Bobby Dillard, ORA/FDA
Charles Phillips, EPA

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS (ENVIRONMENTAL MONITORING AND SURVEILLANCE)

HISTORY

The need for guidance criteria in the development, organization and operation of an adequate program to control radiation was recognized at the first annual meeting of the Conference, in 1969. Since that time three guidance documents have been developed by the Conference. These are:

1) "Criteria for an Adequate Radiation Control Program (X-Ray),"
2) "Criteria for an Adequate Radiation Control Program (Radioactive Materials)" and
3) "Criteria for an Adequate Radiation Control Program (Nonionizing)."

In 1982, the Conference also developed a program providing a comprehensive review and evaluation of a state or local radiation control program, upon request from a state. The above three criteria documents were used as the primary basis for making these reviews. It soon became apparent that one major component of a radiation control program, that of environmental monitoring and surveillance, had no established criteria with which to conduct the reviews and evaluations.

As a result of this need, in 1983, the Executive Board of the Conference established a committee for the development of environmental monitoring and surveillance program criteria. This report is the result of the work of this committee.

CHARGE

The committee is to develop a criteria document that can be used in the evaluation of the adequacy of a state routine environmental monitoring and surveillance program. Such criteria will consider and recommend mechanisms whereby it is assured that state programs are compatible with various federal standards and programs of environmental monitoring and surveillance.

RECOMMENDATIONS

1. The Criteria should be distributed to each radiation control program for use in assessing program adequacy.

2. The Criteria should be used by program personnel to develop an understanding of the key elements of a comprehensive program for environmental monitoring and surveillance.

3. The Task Force on Radon should develop criteria for screening, sampling and assessment of radon levels in the ambient environment.

4. The Task Force on Nonionizing Radiation should evaluate the need to perform environmental monitoring of nonionizing radiation.

5. The Conference should pursue, with the U.S. Nuclear Regulatory Commission, the U.S. Environmental Protection Agency and the Department of Energy, the uniform reporting of environmental radiological data.

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS - ENVIRONMENTAL MONITORING AND SURVEILLANCE

LEGISLATION AND REGULATIONS

1. A state which has regulatory authority over sources of ionizing radiation must have appropriate legislation and regulations. An environmental surveillance program should have specific legislation and regulations as a basis for its authority and evaluations. However, the authority for environmental monitoring may derive from more general statutes.

2. The program should have authority to enter into interstate, and Federal-State arrangements for training, travel, joint inspections, equipment loans, and so forth.

3. The legislation and/or regulations should contain provisions for reciprocity with neighboring States for the exchange of monitoring data and reports.

PROGRAM ORGANIZATION

The environmental unit of a radiation control program should have equal organizational status with other units of the program. This will allow independent environmental assessments distinct from the program's licensing and compliance function, and will allow a greater degree of independence.

The environmental monitoring program should be in the radiation control program. Persons responsible for sample collection, analysis, and reporting should all be under the chain of command of the radiation control program director.

Program functions should be assigned to two or more persons to assure continuous program coverage and continuity in the event of sickness, promotion, leave or other unavailability of program principals. However, one person needs to have overall responsibility for ensuring all aspects of the environmental monitoring program are properly addressed.

When responsibility for different aspects of the environmental monitoring program, e.g., sample collection, radiochemistry, etc., are divided among more than one state agency, administrative letters of agreement should be established to document respective roles, responsibilities, and understandings, and to promote coordination and cooperation in conducting an effective program.

Provisions should be made for significant increases in effort when emergencies occur. Details of those provisions should be addressed as part of the state's emergency response plan.

The program should utilize advisory committees, consultants, and other resources, e.g., NRC, EPA, and CRCPD.

For facilities and activities that have a potential for major public health concerns, there should be a mechanism for the exchange of environmental information among the states, other appropriate organizations and interested individuals.

PROGRAM PLANNING AND MANAGEMENT

The day-to-day operation of the environmental monitoring program shall be guided by the overall written management plan of the program. The radiation control program director shall be responsible for development and implementation of the plan.

PROBLEM

The plan should identify radiation sources and areas of environmental radiation concern. It should also address the need for background data to evaluate existing and potential problems.

OBJECTIVE

The adequacy of an environmental monitoring program is determined, in part, by how well the program meets its objectives. The objectives of a program will vary from state to state and depend upon many factors, including:

1. The program's level of support;
2. The number of facilities which have a potential environmental impact (the objectives may differ between pre-operational, operational, and post-operational activities, and may also differ between facilities);
3. The state's regulatory authority;
4. The need to either screen samples or provide detailed analyses;
5. The desire or need to verify a facility's data or to do independent environmental evaluation; and
6. The state's participation in national monitoring programs.

As a minimum, the state program should meet the following objectives:

1. Characterize the state's general radiological, environmental profile, including ambient conditions as well as the effect of any radiation facilities;

2. Obtain background data around nuclear facilities to be used in evaluating operational effects;

3. Verify source terms and possible changes including both natural and man-made sources;

4. Provide in-place monitoring for use, after-the-fact, in the event of a facility accident or other radiological crisis;

5. Assure the quality of data;

6. Evaluate public health and environmental impacts, if any, due to radiation insults; and

7. Provide information on program activities.

METHODOLOGY

The plan should specify the actions necessary to fulfill the above objectives.

EVALUATION

The plan shall include periodic evaluations of program effectiveness. Audits shall be performed annually by qualified individuals who do not have day-to-day responsibillities in the environmental monitoring program. Results of the audits shall be reviewed by management and corrective actions shall be taken where indicated.

Additionally, the radiation control program director should annually review the environmental monitoring program to assure that:

1. The program is continually meeting its objectives, and that the quality assurance (QA) procedures are followed;

2. Appropriate changes in methods, priorities and agreements are made in accordance with administrative procedures;

3. Reports are timely; and

4. Program deficiencies and deviations are brought to management's attention and appropriate action is taken.

STAFF, TRAINING AND BUDGET

PERSONNEL - PROFESSIONAL STAFF

The environmental monitoring program staff should have adequate experience in environmental monitoring. Requirements for training and experience will be dependent on the job classification and assigned responsibilities, e.g., training needs for a health physicist vs a radiochemist. The following guidance may be used to develop a description of positions.

Supervisor

Minimum qualifications should include:

1. A four (4) year degree in science or engineering, and additional college level training in public administration and health physics, chemistry, or environmental science;

2. Specific training in environmental monitoring and exposure pathways; and

3. At least four (4) years of experience in a professional position in health physics, chemistry, or environmental science; or eight (8) years of equivalent training and experience in other employment in health physics, radiochemistry, or environmental monitoring, plus a record of progressive management responsibility within the position.

Senior Level

Minimum qualifications should include:

1. A four (4) year degree in science or engineering and course work in basic health physics, chemistry or environmental science;

2. Specific training in their appropriate field - health physics, radiochemistry, and/or environmental science; and

3. At least one (1) year of progressive experience in the role of a Junior Level Professional/Technical, or eight (8) years employment as a health physics technician related to radiological environmental monitoring.

Junior Level

Entry level qualifications should include:

1. A four (4) year degree in a science or engineering field; or

2. Equivalent training and/or experience consisting of:

   (a) College level training in mathematics, physics, and chemistry;

   (b) Two (2) years of progressive experience in radiation protection, chemistry, or environmental science; and

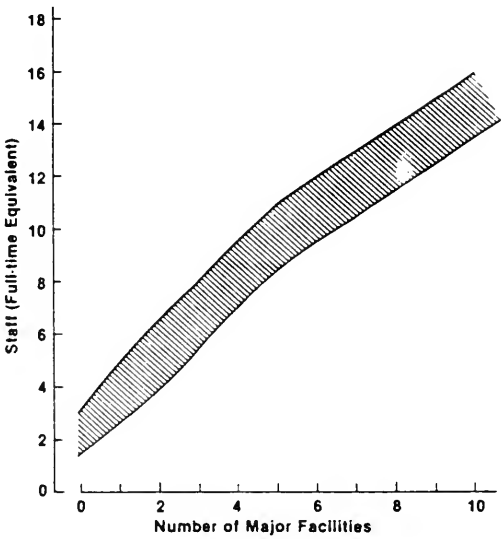
   (c) Specific experience in radiological environmental monitoring.

The supervisor should be part of the management organization.

Each employee should have an accurate, current description of the position, detailing specific responsibilities and tasks.

It should be possible for any professional or technical employee to progress via a career ladder through the various levels up to and including Director of the Radiation Control Program. An organizational structure that supports promotion from within and salary levels adequate to retain persons of appropriate qualifications should be the policy of the agency to minimize staff turnover and maintain continuity.

Personnel requirements are shown in the Figure which provides the range of staff required for an environmental monitoring program.[1]



The graph relates staff requirements to the number of major facilities which impact a state. (A major facility includes, but is not limited to, a reactor site, a uranium mill, a low-level radioactive waste facility, or a Department of Energy nuclear facility.) This graph should not be interpreted as indicating the number of Full-Time Equivalents (FTE) required to monitor a major facility. Rather it is a convenient method of relating staff needs to characteristics of a state. The FTE include management, health physicists, chemists, field personnel, and other professionals. It also includes any individual from any other program or agency which assists in sample collection, analysis, or any other environmental monitoring function. A range has been provided because of circumstances which differ from state to state. Appendix A provides the basis for the graph in this Figure.

[1]It is recognized that some states may not want to have a complete environmental monitoring program, just as some states do not control both NARM and by-product material.

TRAINING

Training should be included in the program plan. This training should encompass initial and ongoing training necessary to maintain technical competence and maintain the interest and involvement of new and experienced staff. At least five (5) percent of program time should be allocated to formal training and/or cross training.

Training should be planned as available from universities, federal agencies, private companies, professional societies, and the CRCPD to 1) broaden the capability of the staff, 2) provide professional development, 3) to enable staff to progress up their career ladders, and 4) to keep personnel informed of current developments in environmental monitoring and the control of hazards related to radioactive materials.

The environmental monitoring program should have a policy of cycling all professional and technical staff through a variety of training and retraining to periodically update and reinforce previous knowledge. Individual development plans for each staff member are encouraged.

States should use training aids available from federal agencies and develop a comprehensive reference library on radioactive materials and environmental monitoring.

Training agreements and exchange of information is desirable between states, and between the state of 1) its licensees, 2) federal facilities and 3) federal licensees.

FUNDING

The environmental program should be funded from sources that assure continuity of the program. There should be a funding mechanism for agency use of contractual services.

QUALITY ASSURANCE

The role of an analytical laboratory is to ensure that all measurements being performed are precise and accurate and to provide qualitative and quantitative data that will assist in decision making. To be of value, analytical data must be accurate and legally defensible.

POLICY STATEMENT

The program shall have a written statement of its QA objectives. This should include:

1. A commitment of management; and

2. A statement of required precision and accuracy.

At least 10% of the overall program effort should be voted to ensuring that analytical results are accurate and ecise, and ensure that measurements reflect actual conditions. e effort needed for particular types of analyses will be case ecific.

One person shall be assigned the overall responsibility for e quality assurance program.

OCEDURES

Procedures shall be written, approved, and followed for:

1. Sample collection and receipt. Sample size should be sufficient to perform a second independent analysis.

2. Sample preparation and analysis, including the degree of precision and accuracy and the lower level of detection required for each type of analysis.

3. Health physics relating to the handling of samples and the surveying of both the samples and the laboratory.

4. Calibration and operation of instrumentation.

5. Quality control.

6. Maintenance of standards.

7. Coding individual samples for the purpose of identification and tracking through the analytical process.

8. Computer program documentation, if applicable.

9. Reporting

10. Data analysis procedures, including anomalous data follow-up.

11. Prevention of cross-contamination. Samples with different activity levels should be segregated into separate laboratory areas.

12. Operating procedures under emergency conditions which address both operations and analysis.

13. Storage of samples before and after analysis.

14. Preventive maintenance schedules for each piece of equipment.

15. Disposal of materials which must be treated as radioactive waste and/or are regulated under RCRA.

STANDARDS

NBS or NBS-traceable standards[2] and/or calibrated instrumentation shall be used. The documentation of standard sources and the certification of instruments must be maintained by the radiation control program.

When available, standards should be in a similar chemical and physical form to that of the samples to be analyzed. The activity of the standard should be balanced between the activity of the samples being counted and realistic counting times necessary to assure adequate precision and accuracy.

CALIBRATION AND OPERATIONAL CONTROLS

The program shall have a sufficient number of check sources and standards to verify the calibration of all instruments at any time.

All instrumentation, radiological and nonradiological, shall be calibrated at least annually or at the manufacturer's recommended intervals, whichever is more frequent. Check sources should be used daily or before each use of the instrumentation.

Backgrounds should be obtained daily or before each use. When analysis requires very long counting times, a background with the same counting time should be obtained at least monthly.

Blanks should be run with each batch unless otherwise justified.

The isotopes used for gross alpha and beta counting should be specified.

---

[2]Satisfactory measurement assurance interactions between source suppliers and NBS involve two (2) basic mechanisms: 1) The supplier submits a calibrated radioactivity source to NBS for confirmation that the supplier's calibration value agrees with NBS results within certain specified limits; or 2) NBS provides calibrated radioactivity sources of undisclosed activity to a supplier who is able to make activity or emission-rate measurements on the source that agree within certain specified limits with the measurements of NBS.

Control charts shall be maintained for background, check and calibration sources. Operational checks shall indicate results are within stated parameters. If they are not, the instrument shall not be used until the problem with the instrument has been corrected.

PERFORMANCE TESTING

Interlaboratory

States shall participate in interlaboratory performance testing programs. Comparisons should be made with the following:

1. Federal facilities - Environmental Protection Agency, Department of Energy, and the Bureau of Mines for radon;

2. Other states' radiation control programs; and

3. Facilities which have the potential to impact the state's radiological environment.

For certain analyses, it is preferable to use cross-comparisons rather than standards, e.g., radon.

Intralaboratory

Blind, spiked and duplicate samples should be used. At least one (1) spiked sample should be analyzed quarterly for each type of analysis routinely performed.

Contracts

If the radiation control program contracts for laboratory and/or analytical services, the program shall ensure that the laboratory's QA program is adequate to meet the program's needs.

COMPUTATIONAL CHECKS

A substantial fraction of any calculations and data reductions shall be verified by a person other than the one performing the original computation.

If calculations are performed by computer, the computational program shall be verified before initial routine use and after each modification of the program.

ANALYTICAL REPORTS

All measurement results should include an estimate of their overall uncertainty. The uncertainty estimate should incorporate "counting errors," and all other known sources of uncertainty.

All analysis results should be reported. If an analysis is questionable, it should be reported and "flagged" to indicate the reason for questioning. If it is voided for the purposes of averages, ranges, etc., reasons for the voiding should be stated.

Records of quality assurance activities should be maintained.

The method(s) used to determine the lower levels of detection should be defined.

AUDITS

Analytical results should be reviewed within a period of time consistent with sample stability and nuclide half-life.

PROGRAM RECORDS AND REPORTS

Record keeping and report publication is critical to program planning and evaluation, and further provides a means for documenting any radiological impacts on public health or the environment. All data should be retained. Annual reports of the data should include an executive summary stating the radiological impacts on public health and the environment.

RECORDS

Records shall be accurate and rapidly retrievable. They shall discuss all anomalies and permit trend analysis. All units shall be clearly stated. The International System of Units (SI) should be used. If both SI and conventional units are used, the conventional units should be included in parentheses.

Records should include an estimate of overall uncertainty for all measurements. The uncertainty estimate should incorporate "counting errors" and all other known sources of uncertainty.

REPORTS

Annual reports which include all routine analyses should be completed within six (6) months after the year's end. These reports should be published and include:

1. Maps identifying sampling locations;
2. Sampling procedures, and analytical procedures;
3. A discussion of data, including trends, anomalies, and program deviations;

4. Documentation of any modeling;

5. A description of the QA program;

6. A discussion of any changes in previous data;

7. Dose projections, including uncertainty estimates, should be included for actual and potential pathways; and

8. The name of the person(s) responsible for the report.

Reports should not be released until they have been reviewed by appropriate personnel.

RETENTION PERIODS

1. All sample data and annual reports should be maintained indefinitely.

2. Samples should be maintained until the results of their analysis have been reviewed. If a sample is involved in a compliance action, it should be maintained until the compliance action is complete. For certain facilities, such as low-level waste facilities and uranium mills, some samples, e.g., soil samples, should be maintained until post-reclamation.

EQUIPMENT

A state shall have equipment which: 1) is capable of performing the required analyses; 2) will facilitate the required precision and accuracy; and 3) allows the state to reach the recommended lower levels of detection.

There should be sufficient redundancy for a program to continue to perform the routine analyses during instrument down time.

Both computerized analytical equipment and a computerized data management system should be used.

SAMPLING CRITERIA

Tables I and II represent the minimum environmental monitoring needs for ambient conditions (Table I) and for certain facilities (Table II).

Other facilities, not listed, which have the potential for environmental releases should be evaluated. If a net dose equivalent of 0.1 mSv/yr (10 mrem/yr) at the site boundary might occur, that facility should be appropriately monitored. If

after one (1) year of monitoring, results indicate that it is unlikely for the hypothetical "highest exposed individual" to receive a dose equivalent of 0.25 mSv/yr (25 mrem/yr). surveillance may be reduced to quarterly screening unless conditions change.

PUBLIC INFORMATION

The environmental monitoring program should make reports available to the public. However, information should not be made available until it has been reviewed by appropriate program personnel.

The radiation control program should have a designated Public Information Officer. Information for media distribution, such as press releases and in-depth reports, should be prepared in conjunction with the Public Information Office of the state agency. The program should seek opportunities to inform the public in news releases, TV, radio, incident reports, etc.

There should be a liaison with public and professional groups which leads to seminars, training courses, and public documents on the radiological environment.

Procedures should be established to provide to contiguous state program directors and federal agencies information on environmental samples that contain radioactivity in excess of specified reporting levels.

SPECIAL STUDIES

As resources permit, special studies should be performed of potential radiological exposure pathways or situations which may be the subject of public concern. These studies should assist the radiation control program in determining the scope of radiation exposures, developing regulations to control a potential hazard, and determining future program needs.

TABLE I

SURVEILLANCE CRITERIA FOR THE AMBIENT ENVIRONMENT[1]

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS[2]	LOWER LIMIT OF DETECTION (LLD)[3]		
Air	5 regional samples	168 hr/month	Fiber particulate Weekly-gross alpha, beta[4] Qtrly-composite gamma[5]	alpha beta gamma[6]	3.7 E-5 Bq/m^3 3.7 E-4 Bq/m^3 1.9 E-4 Bq/m^3	(0.001 pCi/m^3) (0.01 pCi/m^3) (0.005 pCi/m^3)
Ambient Gamma	5 regional samples	Qtrly	gamma dose		1.3 E-3 mC/kg/mo	(5 mR/mo)[7]
Surface Water	5 regional samples	Qtrly, Grab	Gross alpha, beta tritium	alpha beta tritium	1.9 E-1 Bq/l 1.9 E-1 Bq/l 1.5 E+1 Bq/l	(5 pCi/l) (5 pCi/l) (400 pCi/l)
Ground Water	5 regional samples	Qtrly	Gross, alpha, beta tritium	Same as Surface water		
Soils	1 per year per station in conjunction with air sampling for Radon	Annually	Gamma	Ra-226	7.4 E-3 Bq/g	(0.2 pCi/g)
Radon	4-5 most probably as identified by geological data. Sample lowest occupied level[8]	Qtrly for 1 year	Passive monitors Radon or working Levels	Rn	1.9 E-2 Bq/l	(0.5 pCi/l)

SEE FOOTNOTES AT END OF TABLE II

TABLE II

SURVEILLANCE CRITERIA FOR CERTAIN FACILITIES

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS[2]	LOWER LIMIT OF DETECTION (LLD)[3]		
REACTORS: Ambient Gamma	10 per site; four or 10%, whichever is greater, located jointly with utility; one control. Routinely monitor to 16 km., areas of high population and/or interest to 80 km.	Qtrly	gamma dose	1.3 E-3 mC/kg/mo	(5 mR/mo)[7]	
Air Particulate	3 located jointly with utility, including one at highest X/Q and one control[10]	Continuous with weekly filter changes	Weekly-individual filters gross beta; Qtrly-composite gamma	beta gamma	3.7 E-4 Bq/l 1.9 E-4 Bq/l	(0.01 pCi/m^3) (0.005 pCi/m^3)
Air Iodine	3 located jointly with utility	Continuous with weekly filter changes	Weekly-gamma	I-131	2.6 E-3 Bq/m^3	(0.07 pCi/m^3)
Surface Water	2 split with utility one up and one down stream	Monthly	Gross alpha, beta tritium, gamma. (continuous sampling best for streams; grab samples are of questionable value)	alpha beta tritium gamma	1.9 E-1 Bq/l 1.9 E-1 Bq/l 1.5 E+1 Bq/l 4.4 E-1 Bq/l	(5 pCi/l) (5 pCi/l) (400 pCi/l) (12 pCi/l)
Ground Water	If affected, minimum of one control and one affected well	Qtrly	Gross alpha, tritium, gamma if used for consumption	Same as surface water		

SEE FOOTNOTES AT END OF TABLE

TABLE II (CONT.)

SURVEILLANCE CRITERIA FOR CERTAIN FACILITIES

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS[2]	LOWER LIMIT OF DETECTION (LLD)[3]
REACTORS (CONT.):				
I-131 in water	1 closest point of use below discharge	Weekly	Chemical separation followed by gamma isotopic	I-131 3.7 E-2 Bq/l (1 pCi/l)
Drinking water	1 Control; up to 3 of nearest water supplies which could be affected	Monthly composite; one split with utility	Monthly-gross alpha, beta; I-131 if dose projection ≥0.01 mSv/yr (1 mrem/yr). Qtrly-composite tritium	Same as surface water and milk
Sediments	1 up and 1 down stream in area of settling	Annually, in conjunction with utility	Gamma	3.7 E-3 Bq/g wet weight (0.1 pCi/g)
Fish	In vicinity of discharge one bottom and one top feeder	Semi-annually	Gamma	3.7 E-3 Bq/g wet weight (0.1 pCi/g)
Milk	1 near highest X/Q; 1 control	Monthly during grazing	Iodine and gamma	3.7 E-2 Bq/l (1 pCi/l)
Vegetation	1 sample broad leafy vegetable or ground cover, one of each type produced for commercial distribution within 10 km	Monthly	Gamma isotopic of edible portion	3.0 E-3 Bq/g wet weight (0.08 pCi/g)
		At harvest	Gamma isotopic of edible portion[7]	3.0 E-3 Bq/g wet weight (0.08 pCi/g)
Shell Fish	2 samples near facility, one control	6 months	Gamma	3.7 E-3 Bq/g wet weight (0.1 pCi/g)wt

SEE FOOTNOTES AT END OF TABLE

TABLE II (CONT.)

SURVEILLANCE CRITERIA FOR CERTAIN FACILITIES

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS[2]	LOWER LIMIT OF DETECTION (LLD)[3]	
URANIUM MINING:					
Radon	1 at highest X/Q plus one at nearest resident[9]	Qtrly	Passive	7.4 E-3 Bq/l	(0.2 pCi/l)
Ground Water	Site specific[9]	Qtrly	Unat, Ra-226 Gross alpha, beta	U 7.4 E-3 Bq/l Ra 7.4 E-3 Bq/l alpha 1.9 E-1 Bq/l beta 1.9 E-1 Bq/l	(0.2 pCi/l) (0.2 pCi/l) (5.0 pCi/l) (5.0 pCi/l)
Surface Water	1 up and 1 down stream discharge exists[9]	Qtrly	U,Ra; verify NPDES permit	Same as ground water	
URANIUM MILLING:					
Conventional Ambient Gamma	4 at fence line, 1 bkg, 1 at high X/Q, 1 at nearest resident if within 10km, all co-located with facility. Additional at any place(s) of interest.	Qtrly, less for post-operation	Gamma dose	1.3 E-3 mC/kg/mo (5 mR/mo)	
Air Particulates	1 co-located at nearest resident if within 10 km; else at high X/Q[9]	Continuous (low volume) less for post-operation	Qtrly composite-U,Ra,Th,Pb	U 3.7 E-6 Bq/m^3 Ra 3.7 E-6 Bq/m^3 Th 3.7 E-6 Bq/m^3 Pb 7.4 E-5 Bq/m^3	(0.0001 pCi/m^3) (0.0001 pCi/m^3) (0.0001 pCi/m^3) (0.002 pCi/m^3)
Radon	4 stations; 2 co-located[8]	Qtrly	Passive	7.4 E-3 Bq/l	(0.2 pCi/l)

SEE FOOTNOTES AT END OF TABLE

TABLE II (CONT.)

SURVEILLANCE CRITERIA FOR CERTAIN FACILITIES

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS[2]	LOWER LIMIT OF DETECTION (LLD)[3]	
URANIUM MILLING (CONT):					
Ground Water	3-4 samples annually to verify operator data	Annually unless elevated levels are observed	U,Ra,Pb,Po,Th,gamma,TDS, Sulfates, Se, Mo	U	7.4 E-3 Bq/l (0.2 pCi/l)
				Ra	7.4 E-3 Bq/l (0.2 pCi/l)
				Th	7.4 E-3 Bq/l (0.2 pCi/l)
				Po	3.7 E-2 Bq/l (1 pCi/l)
				Pb	3.7 E-2 Bq/l (1 pCi/l)
				Gamma	1.9 E-1 Bq/l (5 pCi/l)
				TDS	500 ppm
				Sulphates	250 ppm
				Se	0.01 ppm
				Mo	0.05 mg/l
Vegetation	Select predominant broad leafy and root type vegetables within 2 km. More samples may be necessary based on MILLDOSE	At harvest	U,Ra,Th,Pb,gamma,Se,Mo	U	7.4 E-6 Bq/g (2.0 E-4 pCi/g)
				Ra (wet wt)	1.5 E-6 Bq/g (5.0 E-5 pCi/g)
				Th	7.4 E-6 Bq/g (2.0 E-4 pCi/g)
				Pb	3.7 E-5 Bq/g (1.0 E-3 pCi/g)
				Se	5 ug/g
				Mo	10 ug/g
				Gamma	3.0 E-3 Bq/g (0.08 pCi/g)
Soil	4 co-located with facility	Annually	Th,U,Ra,Pb,gamma	Th	7.4 E-3 Bq/g (0.2 pCi/g)
				U	7.4 E-3 Bq/g (0.20 pCi/g)
				Ra	7.4 E-3 Bq/g (0.2 pCi/g)
				Pb	7.4 E-3 Bq/g (0.2 pCi/g)
				Gamma	3.0 E-3 Bq/g (0.08 pCi/g)
HEAP-LEACH:	Water only, site specific	Qtrly	Gamma, U,Ra,Th,Pb,Po,TDS, Sulfates, Se,Mo	Same as uranium milling	
IN-SITU:	Ground water only if above the water table If associated with a plant/dryer, sample as a conventional mill.	Qtrly	Gamma, U,Ra,Th,Pb,Po,TDS, Sulfates, Se,Mo	Same as uranium milling	

SEE FOOTNOTES AT END OF TABLE

TABLE II (CONT.)

SURVEILLANCE CRITERIA FOR CERTAIN FACILITIES

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS[2]	LOWER LIMIT OF DETECTION (LLD)[3]		
FUEL FABRICATION:						
Air Particulate	1 bkg, 1 high X/Q	Continuous, changed weekly	Individual samples-gross alpha, beta Qtrly-composite-isotopic uranium	alpha beta gamma U	3.7 E-5 Bqm^3 3.7 E-4 Bqm^3 1.9 E-4 Bqm^3 3.7 E-5 Bqm^3	(0.001 pCi/m^3 (0.01 pCi/m^3 (0.005 pCi/m^3 (0.001 pCi/m^3
Soil	1 bkg, 1 high X/Q	Annually	Isotopic uranium	U	3.7 E-4 Bq/g	(0.01 pCi/g)
Surface Water	1 up and 1 down stream or area of discharge	Monthly if associated with drinking water. Qtrly grab otherwise	Isotopic uranium	U	3.7 E-4 Bq/g	(0.01 pCi/l)
Vegetation	1 control; 1 at high X/Q	At harvest	Isotopic uranium	U	3.7 E-1 Bq/kg	(10 pCi/kg)
Sediments	1 up and 1 down stream or area of discharge	Annually	Isotopic uranium	U	3.7 E-3 Bq/kg	(0.1 pCi/g)
WASTE REPOSITORIES:						
Ambient Gamma	Co-locate a minimum of 4 or 10% of licensee's whichever is greater	Qtrly	Gamma dose		1.3 E-3 mC/kg /mo	(5 mR/mo)
Air Particulate	1 bkg, 1 co-located at high X/Q, closest resident, at population center if within 5km	Continuous with weekly filter changes	Weekly-individual filters-gross alpha, beta Qtrly-composite gamma	alpha beta gamma	3.7 E-5 Bq/m^3 3.7 E-4 Bq/m^3 1.9 E-4 Bq/m^3	(0.001 pCi/m^3) (0.01 pCi/m^3) (0.005 pCi/m^3)
Air H-3	1 bkg, 1 high X/Q	Qtrly	Qtrly	tritium	1.5 E-6 Bq/ml	(4 E-5 pCi/ml

SEE NOTES AT END OF TABLE

TABLE II (CONT.)

SURVEILLANCE CRITERIA FOR CERTAIN FACILITIES

EXPOSURE MEDIA	NUMBER OF SAMPLES AND SAMPLING LOCATION	SAMPLING FREQUENCY	TYPE AND FREQUENCY OF ANALYSIS [2]	LOWER LIMIT OF DETECTION (LLD)[3]
Surface Water	1 up and 1 down stream split with operator	Qtrly	Gross alpha, beta; gamma; tritium (chemical indicators to include pH, temperature, chloride, iron, color, turbidity, chemical oxygen demand, and total organic carbon)	alpha 1.9 E-1 Bq/l (5 pCi/l) beta 1.9 E-1 Bq/l (5 pCi/l) gamma 4.4 E-1 Bq/l (12 pCi/l) tritium 1.5 E+1 Bq/l (400 pCi/l)
Ground Water	4 or 10% of operator's whichever is greater; co-located	Annually	Same as Surface Water	Same as Surface Water
Soil	1 bkg plus 4 others to include major drainage, high X/Q, and 1 co-located and split with operator	Qtrly	Gamma, Sr if Cs is found	Sr-89 3.7 E-1 Bq/g (10 pCi/g) Sr-90 7.4 E-2 Bq/g (2 pCi/g) gamma 3.7 E-3 Bq/g (0.01 pCi/g)
		Annually	Sr (if Cs-137 > 3.7 E-2 Bq/g)	
Vegetation	1 sample broad leafy vegetable or ground cover	Monthly	Gamma isotopic of edible portion	gamma 3.0 E-3 Bq/g (0.08 pCi/g)
	1 of each type produced for commercial distribution within 10 km.	At harvest	Gamma	gamma 3.0 E-3 Bq/g (0.08 pCi/g)

FOOTNOTES FOR TABLES I and II

1. The intent of the criteria for the ambient environment is to characterize the state's radiological environment, and not to monitor the same locations every year.

2. Unless otherwise stated, the frequency of analysis is the same as the sampling frequency.

3. As used in this document, LLD has the same definition as that used in U.S. Nuclear Regulatory Commission Regulatory Guide 4.14, "Radiological Effluent and Environmental Monitoring at Uranium Mills," Revision 1, April 1980. A Copy of this definition is attached as Appendix B.

4. Gross alpha and beta analyses are for screening purposes only. If elevated levels are observed, procedures should direct which additional analyses may be required.

5. "Gamma" means gamma isotopic.

6. The LLD for gamma isotopic analyses are to be determined for Cs-137 unless stated otherwise.

7. TLD systems should meet the criteria of ANSI Standard N545-1975 and U.S. Regulatory Guide 4.13.

8. The criteria for radon monitoring are interim guidance until the Task Force on Radon Monitoring can make a final recommendation.

9. Sample collection and analysis is desirable, but not required.

10. X is the short-term average centerline value of the ground concentration in Bq/m^3, and Q is the rate of release of radioactivity in Bq/sec.

APPENDIX A

STAFFING REQUIREMENTS

The personnel requirements indicated below for an environmental monitoring program provide the range of staff required for an environmental monitoring program.

The graph relates staff requirements to the number of major facilities which impact a state. (A major facility may include a reactor site, a uranium mill, a low-level radioactive waste facility, or a Department of Energy nuclear facility.) This graph should not be interpreted as indicating the number of Full-time Equivalents (FTE) required to monitor a major facility. Rather it is a convenient method of relating staff needs to characteristics of a state. The FTE include management, health physicists, chemists, technicians, field personnel, and other professionals. A range has been provided because of circumstances which differ from state to state.

The chart is based upon the fact that the base level of an environmental monitoring program is 1.5 - 3 FTE. An additional 1 - 2 FTE will be required if the state is impacted by a major facility. For two to five major facilities, the program will need an additional 1.5 FTE per facility. For 6 or more facilities, the program will need an additional 1 FTE per facility.

# OF FACILITIES	FTE REQUIREMENTS PER FACILITY	TOTAL FTE REQUIREMENTS
0	1.5-3	1.5 - 3.0
1	1.5-3 + 1-2	2.5 - 5.0
2	1.5-3 + 1-2 + 1.5	4.0 - 6.5
3	1.5-3 + 1-2 + 2 x 1.5	5.5 - 8.0
4	1.5-3 + 1-2 + 3 x 1.5	7.0 - 9.5
5	1.5-3 + 1-2 + 4 x 1.5	8.5 - 11.0
6	1.5-3 + 1-2 + 4 x 1.5 + 1	9.5 - 12.0
7	1.5-3 + 1-2 + 4 x 1.5 + 2 x 1	10.5 - 13.0
8	1.5-3 + 1-2 + 4 x 1.5 + 3 x 1	11.5 - 14.0
9	1.5-3 + 1-2 + 4 x 1.5 + 4 x 1	12.5 - 15.0
10	1.5-3 + 1-2 + 4 x 1.5 + 5 x 1	13.5 - 16.0

APPENDIX B

LOWER LIMIT OF DETECTION

For the purposes of this guide, the Lower Limit of Detection (LLD) is defined as the smallest concentration of radioactive material sampled that has a 95% probability of being detected with only a 5% probability that a blank sample will yield a response interpreted to mean that radioactive material is present. (Radioactive material is "detected" if it yields an instrument response that leads the analyst to conclude that activity above the system background is present.)

For a particular measurement system (which may include radiochemical separation):

$$LLD = \frac{4.66\, S_b}{3.7 \times 10^4\, E V Y \exp(-\lambda \Delta t)}$$

where

LLD	is the lower limit of detection (microcuries per milliliter);
S_b	is the standard deviation of the instrument background counting rate (counts per second);
3.7×10^4	is the number of disintegrations per second per microcurie;
E	is the counting efficiency (counts per disintegration);
V	is the sample volume (milliliters).
Y	is the (fractional radiochemical yield (when applicable);
λ	is the radioactive decay constant for the particular radionuclide; and
Δt	is the elapsed time between sample collection and counting.

The value of S_b used in the calculation of the LLD for a particular measurement system should be based on the actual observed variance of the instrument background counting rate rather than an unverified theoretically predicted variance.

Since the LLD is a function of sample volume, counting efficiency, radiochemical yield, etc., it may vary for different sampling and analysis procedures. Whenever there is a significant change in the parameters of the measurement system, the LLD should be recalculated.*

*For a more complete discussion of the LLD, see "HASL Procedures Manual," John H. Harley, editor, USERDA, HASL-300 (revised annually) and Currie, L.A., "Limits for Qualitative Detection and Quantitative Determination–Application to Radiochemistry," *Anal. Chem.* 40, 1968, pp. 586-93, and Donn, J. J. and R. L. Wolke, "The Statistical Interpretation of Counting Data from Measurements of Low-Level Radioactivity," *Health Physics*, Vol. 32, 1977, pp. 1-14.

Conf. Publication #85-2

Conference of Radiation Control Program Directors, Inc.

Criteria for Adequate Radiation Control Programs (Nonionizing)

A Report of Task Force H-2

Printed April 1985

Published by

CONFERENCE OF RADIATION CONTROL PROGRAM DIRECTORS, INC.

DISCLAIMER

The information contained in this document has been developed by the Conference for consideration by radiation control programs, and other interested parties.

The implementation and use of the information and recommendations contained in this document are at the discretion of the user. The implications from the use of this document are solely the responsibility of the user.

Conf. Publication #85-2

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS (NONIONIZING)

A REPORT OF TASK FORCE H-2

This work was performed under:
FDA Cooperative Agreement FD-U-000005-04-2

Printed April 1985

Prepared by

Conference of Radiation Control Program Directors, Inc.
71 Fountain Place, Frankfort, KY 40601

in cooperation with

The Center for Devices and Radiological Health and
Office of Regulatory Affairs, FDA

The U.S. Environmental Protection Agency

The opinions and statements contained in this document are those of the Conference, and may or may not reflect the views of the cooperating federal agencies.

FOREWORD

The development of criteria for evaluating the adequacy of various aspects of radiation control programs has been given considerable attention by the Center for Devices and Radiological Health (CDRH), the Nuclear Regulatory Commission (NRC), the Environmental Protection Agency (EPA) and several State programs. In one instance, the NRC has developed detailed criteria to evaluate Agreement State compatibility with Federal regulation of byproduct materials. Therefore, in recognition of the need in other areas of radiation control, the Conference of Radiation Control Program Directors (CRCPD) charged Workshop No. 1 at the 7th Annual Conference in 1975 to consider the development of such criteria. The recommendation of the workshop called for the formation of a Task Force to develop the actual criteria. On two separate occasions the Executive Committee of the Conference established a Task Force to accomplish this task. During this period, the charge has been refined to call for the development of specific criteria for evaluation of a State radiation control program.

In April of 1981, the Conference prepared a document entitled "Criteria For Adequate Radiation Control Programs (X-Ray)." In November of 1982 the Conference prepared a document entitled "Criteria for Adequate Radiation Control Programs (Radioactive Materials)."

This document provides detailed criteria that State radiation control directors may use to evaluate the adequacy of their nonionizing control program. By identificaiton of weaknesses or deviation from nationally accepted criteria, individual directors will have more justification for their budgetary or legislative requests.

The CRCPD will utilize these three documents in their newly developed State Comprehensive Review Program.

Robert M. Hallisey
Task Force Chairman

Maury Nenweg
Conference Chairman

PREFACE

This quide has been developed by the Task Force on Criteria for Adequate Radiation Control Programs (nonionizing)) at the direction of the Conference of Radiation Control Program Directors Inc. Adequate resources are essential for the successful implementation of a program to protect the public health of our citizens from unnecessary radiation exposure. A guide, therefore, is needed that provides an outline of the basic needs and resources which should be operational to properly carry out a radiation control program.

This document presents the guidance of the task force as a result of its research and deliberations. It presents a method for determining the quality and quantity of the resources necessary for the successful operation of a balanced, thorough and yet efficient nonionizing program at the state level. This report, in conjunction with the documents "Criteria for Adequate Radiation Control Programs (X-Ray), and "Criteria for Adequate Radiation Control Programs (Radioactive Materials) shall serve as guidance by which state radiation control agencies, administrators, and legislative bodies, as well as the public, can make realistic evaluations regarding the adequacy of a comprehensive program for the control of ionizing and nonionizing radiation. The CRCPD will utilize these three documents in their newly developed State Comprehensive Review Program.

The criteria assume that rules and regulations have been adopted which are as effective as the "Suggested State Regulations for the Control of Radiation" (SSRCR) which have been prepared by the Conference of Radiation Control Program Directors, Inc., The U.S. Nuclear Regulatory Commission, the U.S. Environmental Protection Agency, and the Center for Devices and Radiological Health.

CONTENTS

MEMBERSHIP

The following persons served on Task Force H-2

STATE RESOURCE PERSONS

Robert M. Hallisey, Chairman, Massachusetts
Susie Kent, Texas
Danny McGlohorn, South Carolina
Michael Mays, Arizona

FEDERAL RESOURCE PERSONS

Bobby Dillard, ORA-FDA
Richard Gross, DTMA-CDRH
William Murray, NIOSH-CDC

CRITERIA FOR ADEQUATE RADIATION CONTROL PROGRAMS (NONIONIZING)

HISTORY

Workshop No. 1 at the 7th Annual Conference in Hyannis, Massachusetts, was charged to consider the development of criteria for an adequate State Radiation Control Program. In its report to the Conference, Workshop No. 1 recommended the formation of a Task Force to further study this matter. In September 1975, the Executive Committee implemented this recommendation by forming a Task Force; however, support funds were not available. In September 1976, the Executive Committee reactivated the Task Force, clarified the charge, and allotted funding for meetings. Members of the original Task Force-John Shaver, Chairman, Si Kinsman, Jim Hickey, Warren Jacobi, Bobby Dillard, and Charles Showalter (representing Richard Gross)--met in Denver, Colorado, during April 1977. Criteria developed at this meeting were presented to the Conference members for comment at the 9th Annual Conference in Seattle, Washington.

In 1978 the Task Force was reconstituted to include the members above. The criteria were again submitted to the Conference membership for comment in August 1978. In November 1978, the Task Force met in Rockville, Maryland, to review the comments and revise the criteria document as indicated by the comments. A final version of the criteria was submitted to the Conference and approved for publication.

The former Task Force 2A "Criteria for Adequate Radiation Control Programs (X-Ray)" decided not to attempt to develop criteria for nonionizing radiation control as part of their charge due to time limitations. The Executive Committee, in turn, formed a new Task Force to develop criteria for nonionizing radiation.

BACKGROUND

The problem of developing suitable criteria for radiation control program adequacy has surfaced on numerous occasions, and has been given considerable attention by the Center for Devices and Radiological Health (CDRH), Nuclear Regulatory Commission (NRC), and several of the State programs. For example, in 1969, the Bureau of Radiological Health (BRH) prepared a detailed questionnaire as a pa: of a study to evaluate the status of State radiation control programs. The questionnaire was carefully developed with input from states, regional offices, and other Federal agencies, such as the NRC. It was pilot tested in most regions, and revised and improved based upon these tests.

Other work in this area includes sending Federal and State survey teams, upon request, to selected states to conduct detailed program evaluations. The Nuclear Regulatory Commission has detailed criteria to evaluate Agreement States to ensure program compatibility. In 1976, the Southern Interstate Nuclear Board conducted a study of radiation control programs in the South. The Conference has also formed workshops to consider the matter. The Task Force has taken full advantage of the previous work. In addition, the Conference has recently provided a comphr.nsive review program of any state requesting such, and criteria for a adequate nonionizing program are needed for such review.

CHARGE

The charge that Task Force H2 worked under was to develop criteria that can be used in the evaluation of the adequacy of a State radiation control program in the nonionizing radiation area. Such criteria will also consider and recommend mechanisms whereby it is assured that state programs are compatible with nonregulatory federal programs in addition to those which address the enforcement of standards and regulations in the achievement of radiation protection.

CONCLUSIONS AND RECOMMENDATIONS

Following a careful review of available materials, the Task Force concluded the following:

1. The charge could be best implemented by developing a comprehensive list of criteria to be used by radiation control program directors. The criteria should reflect the needs of a comprehensive program and should be detailed enough to assess staffing and funding needs, but flexible enough to account for the wide spectrum of individual program needs and resources.

2. Program directors should compare their program with these criteria to determine deficiencies or weak areas. Upon identification of a weakness, a director can emphasize the deviation from nationally accepted criteria to add support or justification for budget or legislative requests.

3. Unlike other program areas, the members of this Task Force had only their limited backgrounds and program experiences to guide them in the development of these criteria. There were not any available publications or criteria to serve as a source document and very few states have structured nonionizing programs; those that do exist have not been in operation very long. In addition biological risk information is more limited and inconclusive than it is for its ionizing counterpart.

4. When the environmental radiation program criteria is developed, it should be recognized that the environmental aspects of nonionizing radiation are covered in the nonionizing criteria of this document.

5. These criteria should be combined into one document with the criteria established for adequate control programs for other radiation sources, i.e., radioactive materials, environmental radiation, and X-radiation.

NONIONIZING RADIATION CONTROL PROGRAM CRITERIA

I. Legislation and Regulations

A. The radiation control program should have enabling legislation and regulations essentially compatible with the Council of State Governments' suggested legislation and the "Suggested State Regulations for the Control of Radiation."

B. The program should have authority to enter into interstate and Federal-State arrangements for the control of radiation hazards. "Federal-State arrangements" refer to formal or informal agreements between the program and Federal agencies for training, travel, joint inspections, equipment loans, and so forth.

C. The legislation and/or regulations should contain provisions for reciprocity with other States for coverage of nonionizing radiation hazards.

D. At least every five (5) years, regulations should be critically reviewed and updated as necessary. This does not preclude individual programs from exercising their own prerogative for more frequent revision of their regulations. The appropriate affected groups should be provided an opportunity to review and comment on proposed changes.

II. Program Organization

A. The nonionizing radiation control program should be located in the same agency as all other radiation control activities. However, when responsibility for control of nonionizing radiation is divided among more than one State agency, administrative letters of agreement should be effected to delineate responsibility and to minimize duplication of services.

B. The program should have an established radiation advisory committee which provides guidance on implementation of the nonionizing radiation control program.

III. Program Planning and Evaluation

Each program should have a written action plan which should include the following basic components:

A. Problem. The plan should define the problem, and should identify radiation sources.

B. Objective. The long and short-term objectives should be established with specific targets for priority and accomplishment.

C. Methodology. The plan should describe those methods necessary to fulfill stated objectives.

D. Evaluation. The plan should include periodic evaluation of program effectiveness. An important component of evaluation would be a method to determine if changes have occurred in the hazards to population groups.

IV. Staffing

A. Personnel

1. Professional/inspection personnel for the nonionizing radiation control program should require a minimum of 0.5 Full Time Equivalent (FTE's). Additional staffing requirements should be based upon the number of sources and be derived from guidance in the Appendix.

2. Nonionizing radiation control program administrative and inspection personnel should meet one of the following minimum qualifications of training and/or experience in the field of nonionizing hazards and control:

a. A bachelor's degree in engineering or physical sciences from an accredited college or university;

b. Two (2) years of study in an accredited institution plus two (2) years of job experience in radiation activities;

c. Graduation from a two year approved program in engineering or physical science areas plus two (2) years job experience in radiation activities;

d. Four (4) years of equivalent training and experience.

3. Each permanent staff position should have an accurate, up-to-date description which details specific responsibilities.

4. To minimize staff turnover and maintain program continuity there should be an organizational structure which provides for:

a. Promotional opportunities from junior level to senior level and supervisory positions, and

b. Periodic salary increases which are commensurate with experience and responsibility.

B. Training

1. A formal training program should be established for all new professional employees. New employees should be provided with copies, of and instructions on, the regulations and written program procedures which include registration, inspection, and compliance requirements. New inspectors should be accompanied by experienced personnel during initial field surveys.

2. Personnel should participate in a planned continuing program of in-service training consisting of seminars, demonstrations, lectures by consultants, short- and long-term training and attendance at professional meetings (Professional Societies, Regional Training meetings, American Industrial Hygiene Association, annual meetings of the Conference, and so forth) to keep abreast of current developments in the control of radiation hazards.

V. Registration, Inspection, and Enforcement

A. Registration. The program should have authority to require the registration of all nonionizing radiation sources. The Suggested State Regulations for the Control of Radiation may be used as a guide in developing the extent of the registration function.

B. Inspection Authority. The program should have authority to conduct its own inspections. Survey reports from qualified private consultants or from radiation safety officers and safety and health professionals employed by the owner of a nonionizing radiation installation may be useful in augmenting the inspection program.

The program should have authority to set qualifications for private consultants or radiation safety officers or safety and health professionals when the survey reports from such individuals are used by the state to evaluate continuing compliance with its regulations in lieu of installation inspections by program staff.

In some program areas (such as tanning booths, microwave ovens, sun lamps, etc), adequate control may be effected by use of local health personnel. Technical assistance and direction should be provided by the State Radiation Control Program.

C. Inspection Procedures. The program should have written procedures to insure that uniform inspections are conducted. These procedures should provide for the evaluation of the overall radiological performance of the facility.

D. Inspection Schedule. The program should have a written priority schedule for items in the Appendix, section B, which sets routine inspection frequencies by type of nonionizing radiation installation. The schedule should be reviewed annually and adjusted to reflect any changes in program objectives.

1. The inspection schedule should include initial inspection of every facility within a year and periodically thereafter.

2. In certain situations, such as production line or manufacturing processes using RF heating, laser welding, etc., nonionizing radiation exposure can change frequently. In these applications, inspection frequencies may need to be increased.

E. Enforcement. The program should have written enforcement procedures. These procedures should detail the steps to be taken within a specified time period to accomplish compliance with the regulations. The Office of the State Attorney (Attorney General) should be consulted in the development of these procedures. Interpretations based on policy should be accumulated and maintained to ensure consistent enforcement policy.

VI. Survey Equipment

The Program should have sufficient field survey instrumentation capable of measuring nonionizing radiation to determine compliance with applicable guides and regulations. The instrumentation should also be capable of estimating radiation exposure to patients, operating personnel, and the general public. The report of Task Force GN-3 should be referred to for information on survey equipment.

The Radiation Control Program shall assure that all nonionizing radiation survey equipment and instrumentation is properly serviced and calibrated. There should be a written procedure and schedule for calibration and servicing of each radiation detection instrument. The schedule should call for a calibration at least annually. Each instrument should bear a tag stating the latest date of servicing and calibration, and a calibration curve or correction factors for each detection range. Responsibility for calibration and servicing should be assigned to one staff person.

The complexity of the agency calibration program is dependent upon the purpose for which the data was obtained and should be detailed in the written procedures.

VII. Records

Recordkeeping is critical to program planning and evaluation and provides an objective means for demonstrating the public health impact of the program. Therefore, the data that are collected and retained should be selected to relate as directly as possible to this public health impact.

A. The program should have an efficient data management system that provides the following:

1. Data accurately and rapidly retrievable.

2. A continuing integrated registration program.

3. Physical survey forms containing minimum uniform data, and compliance and enforcement actions.

4. Fiscal and other administrative records.

5. Records on nonionizing radiation source transfers and vendor notifications.

6. Records of incidents and investigations.

B. The program should utilize the above records for:

1. Program planning.

2. Evaluation of program objectives.

3. Establishing priorities for nonionizing radiation inspections.

4. Carrying out field survey and inspection programs

C. The program should make maximum use of available electronic data processing systems.

D. The program should maintain agency personnel medical evaluation records, e.g., ophthamological for eye injuries and dermatological for skin injuries.

VIII. User Education

A. The program should encourage, sponsor, or conduct continuing formal education programs for users or operators of nonionizing radiation sources.

B. The Radiation Control staff should take advantage of their time to educate, assist, and answer questions regarding radiation safety and good radiological health practices.

IX. Quality Assurance

The Program should have a plan to encourage and assist nonionizing radiation users in the healing arts in establishing quality assurance programs to ensure that all treatments are properly administered and all diagnostic uses are of consistent high quality.

X. Public Information and Education

A. The program should maintain liaison with professional groups, sponsor seminars and training courses, and develop/distribute public documents on radiation.

B. The program should provide nonionizing radiation registrants with current reference material, guidelines, and standards as they are available.

C. The program should serve as a resource for technical information on radiological health to the public at large (through newspaper releases, TV, radio, incident reports, and so forth) and participate in public education efforts at the State and local levels.

XI. Special Studies

The program should have adequate personnel, instrumentation, and initiative to undertake special studies leading to exposure reduction in the nonionizing radiation area; for example, identify new problems that need investigation, develop more efficient procedures and methodology, and cooperate with Conference and/or Federal programs.

XII. Federal/State Relations

The Radiation Control Program should actively pursue a working relationship with Federal agencies responsible for licensing, authorizing or controlling nonionizing radiation sources within the state. This is especially critical in this area of radiation control due to the ubiquitous nature of many nonionizing radiation sources.

APPENDIX

Staffing requirements can be determined using the following rationale. Clerical and administrative/managerial personnel are not included.

A. The following assumptions have been made in this analysis:

1. At a minimum, RF heaters, industrial microwave ovens, fixed laser light shows and industrial and medical laser installations will require routine compliance inspections in order to maintain standards and protect the public health and safety. Therefore the normal activities of registration, inspection, and follow-up are essential. The remaining other sources (including transient laser light shows) will be addressed under C. (other activities).

2. Most RF heaters will require a follow-up visit in the same year and most industrial oven inspections will not.

3. Fixed laser light shows are those maintained in the same location for an extended period of time. These will require approximately 50% follow-up within the same year.

4. Stricter compliance with recommendations is presumed for industrial and medical installations, since radiation safety officers at these facilities are responsible for compliance.

B. Inspection, Followup, and Registration

Regardless of program size, the personnel requirements are based upon an annual compliance workload per source and do not include program initiation activities.

1. RF heaters and industrial ovens
   3 days/unit

2. Fixed lasers
   5 days/unit

3. Industrial/Medical lasers
   3 days/unit

4. Registration activities
   1 day/month/100 sources

C. Other Activities

In addition to the above, the following other nonionizing radiation sources were considered to demand program time. These can vary in impact due to public health issues and perceptions. Examples of such sources are: transient laser light shows, mercury vapor lamps, tanning booths, ultrasound devices, microwave ovens, NMR imaging devices, RF communications systems, radar, high voltage transmissions lines, medical microwave uses and noncoherent optical sources.

APPENDIX CONTINUED

Estimated Program Time:

Public education & information	.1
Non-routine inspections	.15
Special investigations	.1
Staff training	.1
Miscellaneous	.05
	.50 FTE

D. Total staffing, as derived above, will require a minimum of 0.5 FTE. Additional staffing requirements should be based upon the number of sources and derived from the guidance in section B.

E. Example: State XYZ Annual Requirements;

20 Lasers	x 5 days/unit	=	100 days
30 RF heaters	x 3 days/unit	=	90 days
18 Industrial lasers	x 3 days/unit	=	54 days
21 Medical laser	x 3 days/unit	=	63 days
Registration (100 sources)			12 days
			319 days
	or		
			1.4 FTE
Other Activities (Sect. C.)			0.5 FTE
Total Program Need			1.9 FTE

Note: The Task Force strongly recommends against cross-training personnel between the X-ray and nonionizing program, since they feel X-ray activities will always have priority.

THE PLAIN DEALER

☆☆☆☆☆☆ $1.00

OHIO'S LARGEST NEWSPAPER CLEVELAND, SUNDAY, DECEMBER 13, 1992

FIRST OF A SERIES **LETHAL DOSES** RADIATION THAT KILLS

Dangerous medicine, deadly mistakes

Barbara Goistein shows how skin peeled from the face of her 9-year-old son, Dwight.

At age 9, Dwight's skin peeled, his tongue bloated and fluid leaked from his ear.

"I made sure to hug and kiss him," says his mother. "He really looked grotesque and he knew it, but I wanted him to know we loved him."

Like little Dwight, scores of Americans have met horrible deaths due to medical blunders and overdoses of radiation. This Plain Dealer series tells their stories and unveils shocking facts about hospital cover-ups and government laxity.

By TED WENDLIND and DAVE DAVIS

THE PLAIN DEALER

1 of 3

By TED WENDLING and DAVE DAVIS
PLAIN DEALER REPORTERS

DEC. 1 3 1992

His doctor said it was as though 8-year-old Dwight Golstein had been in an atomic bomb blast. Only the "bomb" was a cancer-treatment machine that had beamed lethal doses of cobalt radiation into a tumor in his sinus cavity.

The radiation was a slow killer. After a few months, Dwight's skin turned jet black and began to peel, spinal fluid drained from his right ear and his swollen tongue forced its way out of his mouth.

"It was the worst case of radiation injury I've ever seen in my career," said Dr. William M. Ward, a San Francisco oncologist who examined Dwight before he died. "I can only describe it as horrible. . . . You can . . . describe him as someone who had a nuclear reactor accident or an atomic bomb exposure."

Dwight's mother, Barbara, watched her son die. "I made sure to hug him and kiss him," she said. "Dwight's face was disfigured and his tongue was so fat he looked like a little monster. He really looked grotesque and he knew it, but I wanted him to know that we loved him."

Dwight died of radiation induced respiratory failure on Aug. 31, 1988. By then, he bore little resemblance to his twin brother, Dwayne. Three weeks of accidental double doses of cobalt-60 radiation at Alta Bates Medical Center in Berkeley, Calif., had burned him beyond recognition.

The U.S. Nuclear Regulatory Commission and its state counterpart, the California Radiologic Health Branch, never knew Dwight Golstein existed, although his death should memorialize him as the only person in California known to have died from a medical overdose of radiation.

Until recently, the NRC also was unaware of the over-radiation of Jean Matelik, a medical secretary who committed suicide in 1989 after a doctor at Ohio Valley Hospital in Steubenville burned a hole in her chest while treating her for breast cancer. Nor did the agency know that Florida resident Connie Norris was forced to give up her twin sons for adoption after radiation treatments in 1984 left her quadriplegic.

Although the NRC was created Oct. 11, 1974, "to protect the public health and safety" by regulating the civilian uses of nuclear materials, it has no record of scores of deaths and serious injuries caused by radiation oncology in the United States.

That is partly because the NRC's 3,338 employees spend well over 80% of their time, energy and $812 million budget regulating nuclear power plants, the failures of which have potentially catastrophic health repercussions.

But even at the nation's most serious reactor accident — the March 1979 meltdown at Three Mile Island in Middletown, Pa. — no deaths or serious injuries have been proven. Critics say that raises questions about the NRC's allocation of resources because less than 5% go toward the regulation of medical institutions.

SEE ERRORS/18-A

Wendling Davis Shaw

An extensive effort

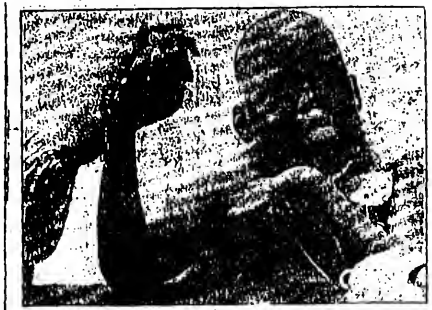
DEC. 1 3 1992

Plain Dealer reporters Dave Davis and Ted Wendling traveled from San Francisco to Burgettstown, Pa., and from Washington, D.C., to West Palm Beach, Fla., to gather records and conduct interviews for this series. They interviewed more than 150 people, including doctors, lawyers, government officials and radiation victims. Bryanne Shaw photographed the victims and their families.

The reporters gathered more than 10,000 pages of court records, inspection reports and investigative files kept by the U.S. Nuclear Regulatory Commission and numerous state agencies.

They filed more than 100 requests under the federal Freedom of Information Act and state public records laws, including numerous appeals when documents were denied. One of the appeals prompted the NRC to reverse its policy of withholding the names of people who have died.

The reporters also used a computer to analyze and search more than 1.6 million NRC records. Olivia Wallace provided research and library assistance. This series was directed by City Editor John Griffith.



This is how Dwight Golstein looked a few weeks before he died of a radiation overdose. Holding his hand is his mother, Barbara.

BRYANNE SHAW

Dwight Golstein's twin brother, Dwayne, 13, listens as his mother describes Dwight's last days.

THE PLAIN DEALER

Unless a patient's distres medical errors are likely to be overlooked

DEC 13 1992

FROM/1-A 2 of 3

Interviews and Freedom of Information Act requests found NRC officials unable to identify a single fatality. A computer search of the agency's own database located just two.

Radiation experts claim the annual number of deaths actually is in the thousands, but that they rarely are directly attributable to radiation because radiation-induced cancers are indistinguishable from other cancers.

Some of the radiation errors are made in medical institutions known to have excellent radiation safety programs. But most occur in hospitals where radiation safety is neglected, underfunded and, in some cases, openly scorned.

The PD probe found a vast array of diagnostic and therapeutic blunders routinely deemed to be inconsequential unless patients show immediate signs of distress. That rarely happens because radiation injuries usually take years, even decades, to develop.

The PD also found that some hospital officials fail to report radiation overdoses to the NRC and then lie or try to cover up nuclear medicine program deficiencies. Other cases reveal doctors implicated in criminal misconduct who were never disciplined. And civil fines are so low they embarrass agency officials.

Some of the nation's best hospitals have compiled the worst radiation safety records. They include the Cleveland Clinic and Riverside Methodist Hospitals in Columbus.

'The NRC doesn't do anything to protect patients.'

— Walter J. Wolske Jr., Columbus lawyer

The NRC has fined the clinic $16,875 since 1987, a figure that ranks it No. 4 among all 2,200 NRC-regulated medical institutions. Riverside was the site of the worst radiation catastrophe in modern-day medicine, which occurred in the mid-1970s when more than 400 patients received cobalt overdoses during cancer treatments.

At least 28 Riverside patients died of injuries related to their overdoses, medical reports show.

"The NRC doesn't do anything to protect patients," said Walter J. Wolske Jr., a Columbus lawyer who represented more than 70 Riverside victims. "Look at Riverside. The hospital burned all those people up and the NRC didn't do anything to them. They found two (actually three) violations, insignificant stuff. One was for a missing sign on a door."

Elsewhere, stories of incompetence and criminal conduct abound.

In Bloomington, Ind., the radiation safety officer and president of Bloomington Hospital lied when questioned about multiple overdoses of radiopharmaceutical drugs, an NRC investigation found. Although the radiation safety officer was convicted of a felony for failing to report an overdose, both he and the president are still on the hospital's staff today.

In Honolulu, a nuclear medicine technologist at Tripler Army Medical Center gave a dose of radioactive iodine-131 to Rensely Phillip, who recently had given birth, but forgot to ask whether she was breastfeeding. Phillip's infant daughter, Pearlyn, subsequently ingested radioactive milk, destroying the baby's growth-regulating thyroid gland.

And in Houston, a West Houston Medical Center technologist destroyed Shi-Jen Wen's thyroid with 80 millicuries of iodine-131, unaware that the dose was 1,000 times stronger than the prescribed dose of 30 microcuries.

"We take the view that probably 80 or 90 percent of the people who are treated ... receive a level of care we would be very pleased with," said NRC Chairman Ivan Selin. "Our responsibility is to try to extend that to 95 or 99 percent."

Achieving that perfect regulatory balance may be impossible because the NRC's regulation of medicine pleases virtually no one — neither the victims of careless hospital practices, nor the nuclear medicine community, which accuses the NRC of invading the sanctity of the doctor-patient relationship.

"The NRC is made up of a bunch of leftover people from the nuclear power industry who don't have anything to do," said Dr. Carol S. Marcus, director of the nuclear medicine outpatient clinic at UCLA-Harbor Medical Center and one of the NRC's most strident critics. "All they do is baby-sit 100 (actually 112) dying nuclear power plants.

"You don't have a federal regulatory agency regulating orthopedic surgeons to make sure that every bone they set is done right. God help medicine if every field were to have a bunch of useless regulators like the NRC."

Many serious radiation injuries never come to the NRC's attention. In part, that's because hospitals don't have to report therapeutic overdoses as long as the total dose the patient receives doesn't exceed the prescribed dose by more than 20%. That is true even in cases where the prescribed dose exceeds all recognized medical standards of care.

'The NRC is made up of a bunch of leftover people from the nuclear power industry who don't have anything to do.'

— Dr. Carol S. Marcus, UCLA-Harbor Medical Center

Although the NRC requires hospitals to report radiation "misadministrations" — NRC jingo for overdoses, underdoses and unintended doses — it has no national data on hospital radiation errors because it doesn't require the 29 self-regulated states to report them.

Data on the 21 agency-regulated states — which include Ohio — show that about 475 patients a year are victims of such radiation errors. Scientists at the National Council on Radiation Protection and Measurements, an independent research agency, estimate the number nationally at slightly over 1,400 a year.

At best, that's a rough estimate, said Harriet Karagiannis, an NRC data analyst.

"We haven't come up with any conclusions because it's impossible," she said.

Conclusions also are impossible because the NRC repeatedly has declined to regulate devices such as X-ray machines and supervoltage linear accelerators, which are commonly used in cancer therapy and produce the same kind of radiation as the cobalt unit that killed Dwight Golstein. Overdoses involving X-ray units and accelerators are not required to be reported, except in a few states, unless the error involves a machine malfunction and the patient dies or is seriously injured.

The reported percentage of radiation errors is small when compared with the roughly 7 million diagnostic procedures and 180,000 therapy procedures performed annually in the United States. But critics question the accuracy of NRC statistics because the agency does such a poor job of keeping data on the most serious errors — those that result in death.

"It's not just that they're not reporting the misadministrations; they're not reporting the deaths."

Radiation mistakes

Hospitals that reported the most radiation errors on patients between 1983 and 1991.

1	Davis Memorial Hospital, *Elkins, W. Va.*	47
2	William Beaumont Army Medical Center, *El Paso, Texas*	29
3	Milwaukee County Medical Complex, *Milwaukee*	23
4	William Beaumont Hospital, *Royal Oak, Mich.*	20
	Mayo Clinic Foundation, *Rochester, Minn.*	20
6	Washington University Medical Center, *St. Louis*	19
	Thomas Jefferson University Hospital, *Philadelphia*	19
8	Washington Hospital Center, *Washington, D.C.*	18
	Graduate Hospital, *Philadelphia*	18
	Fox Chase Cancer Center, *Philadelphia*	18
	Yale-New Haven Hospital, *New Haven, Conn.*	18
	Marshfield Clinic, *Marshfield, Wis.*	18
	Others in the state	
13	Ohio State University Hospital, *Columbus*	17
20	Cleveland Clinic, *Cleveland*	15
27	St. Francis-St. George Hospital, *Cincinnati*	13
	Toledo Hospital, *Toledo*	13
	University of Cincinnati Medical Center, *Cincinnati*	13

NOTE: Figures are for 2,200 hospitals that practice nuclear medicine and radiation therapy in 21 states regulated by the NRC.
SOURCE: U.S. Nuclear Regulatory Commission

DEC 1 8 1992

3 of 3

said David M. Bridge, Texas member on the House Subcommittee on Environment, Energy and Natural Resources. "At best, the system isn't working. At worst, they're covering up."

Dr. Sidney M. Wolfe, director of Public Citizen Health Research Group in Washington, is among those who challenge the NRC's contention that deaths from medical overexposures of radiation are rare.

"Translate that into English and what the NRC is saying is that nobody has ever gotten fatal acute radiation sickness," Wolfe said. "Well, most of the people who die from radiation exposure don't die immediately, other than the people who were in the closest circle of Hiroshima and Nagasaki. They don't have any valid data on five or 10 years down the line, when you start seeing the latency period elapsing for the radiation-induced cancers."

Representatives of the American College of Radiology and Society of Nuclear Medicine argue that health concerns are overblown and part of an anti-nuclear hysteria. They are particularly emphatic when discussing diagnostic doses of radiation.

Edward W. Webster, a physicist and professor of radiology at Harvard Medical School, equates diagnostic errors with "giving an aspirin to the wrong person."

UCLA-Harbor's Marcus said, "We burn out between two and four thyroids a year. So the patient has to take thyroid hormone for rest of his life. Nobody dies from it. Nuclear medicine is probably the safest medical specialty that there is."

Despite those protests, the NRC and its predecessor, the Atomic Energy Commission, have long been criticized for having a cozy relationship with the nuclear community. The criticism led Congress to abolish the AEC in 1974 and replace it with the NRC and the Energy Research and Development Administration, now part of the Department of Energy.

But allegations that the watcher is too close to the watched have continued.

A recent example came from the NRC's Office of the Inspector General, its internal watchdog unit.

The 1990 investigation found that the NRC's Office of Nuclear Material Safety and Safeguards had spent eight months secretly drafting a rule-making petition for two nuclear medicine societies.

The NRC staffers believed the NRC had been overregulating nuclear pharmacists, but were concerned that commissioners wouldn't change the rule if the request came from within the agency. So the staffers volunteered to write the proposal to give it "a better chance of succeeding because it would be viewed as having a broad consensus," according to the investigative report.

After traveling around the country to meet with Marcus and others, the NRC employees drafted the 15-page petition, did the "legal review" and submitted it to commissioners on behalf of the nuclear medicine societies without acknowledging that it was their own work.

Although the NRC investigation found the assistance improper, no disciplinary action was taken because the NRC had no regulations limiting staff assistance. The NRC passed such a rule in March 1991.

Selin, the NRC chairman, dismissed suggestions that the NRC was cozy with the nuclear medicine community.

'We want to be more in the position of an auditor rather than in the position of a record keeper.'

—Ivan Selin, NRC chairman

"These are all reasonable things to do," Selin said. "But they're not right. But it's not because they're cozy with the industry. It's because it's sort of grown up as a reasonably responsible way to do business ... and I think the commission has made it quite clear to the staff that that's not what we'd like to see in the future."

In keeping with the anti-regulatory trend that defined the Reagan-Bush years, Selin believes the NRC should be less didactic toward hospitals.

"The general trend is to get away from what many of us think has been an overly prescriptive approach to the medical side of things — that you must do this, you may not do that ..." he said. "We want to be more in the position of an auditor rather than in the position of a record keeper."

Whatever the NRC's proper role might be, it's irrelevant to Barbara Golstein. To her, the NRC has failed to protect the public health.

Dwight's doctor and the West Coast Cancer Foundation in San Francisco, which did the computer calculations for Dwight's radiation therapy, have paid $500,000 to settle lawsuits. Last Monday, the last defendant, Alta Bates Medical Center, settled for an undisclosed sum.

Dwight was autistic, and Golstein is particularly bitter because the hospital's lawyer questioned her characterization of the quality of Dwight's life and their relationship.

"They wanted to know how it was I could have as normal a relationship with Dwight as with my other children," said Golstein, who is separated and has four other children. "I think what they're trying to say is Dwight was just this thing in the closet, that he was just there and we functioned separately."

Dwight's final days are etched forever into her memory.

She remembers the TV being on and Dwight looking in that direction, but she isn't sure whether the radiation had already blinded him. Because of Dwight's autism, they had developed a special bond over the years that enabled her to feel his joy, his pain and his fear.

"I told Dwight before he died that it was OK to leave us," she said. "He was fighting hard. I told him that he was going to go to heaven and live with Jesus and that it was better for him.

"Three days later, he died."

THE PLAIN DEALER

Who were the 28 who died?

More than 400 patients received overdoses of radiation in the mid-1970s during cancer treatments at Riverside Methodist Hospitals in Columbus.

U.S. Nuclear Regulatory Commission officials say only two people died of radiation injuries. A Plain Dealer investigation found 26 other people whose medical records show that radiation overexposure contributed to their deaths. Here are their names:

Baby Girl Valentine, was delivered stillborn Dec. 1, 1975, at 7½ months as a result of radiation overdose administered to her mother.

Edna Gail Valentine, 25, of Columbus. Elementary school teacher and mother of Baby Girl Valentine. Died Dec. 30, 1975.

Ruth T. Howell, 58, of Columbus. Saleswoman. Died March 9, 1976.

Agnes Carro, 48, of Columbus. Bookkeeper and mother of two. Died April 19, 1976.

Margaret E. Baby, 56, of Worthington, O. Retired registered nurse. Died May 11, 1976.

Betty L. Denbeck, 55, of Columbus. Homemaker and mother of four. Died May 16, 1976.

Charles F. Wermmer, 52, of Galanna, O. Ohio Bell Telephone Co. foreman. Died May 25, 1976.

Edward J. Adelmann, 51, of Columbus. Controller for Jeffrey Processing Systems division of Dresser Industries. Died May 28, 1976.

Patricia J. Bavicka, 41, of Blacklick, O. Homemaker and mother of four. Died June 1, 1976.

Leah Wanda Henderson, 66, of Columbus. Died June 2, 1976.

Donald E. Manning, 45, of Columbus. Insurance underwriter and father of three. Died June 24, 1976.

Everett L. Diebenmett, 70, of Delaware, O. Retired Realtor. Died June 30, 1976.

Claude E. Springer Sr., 65, of Hilliard, O. Father of six. Died July 3, 1976.

Edna Wells, 65, of Upper Arlington. Homemaker, bookkeeper and mother of one. Died July 12, 1976.

Velma S. Basley, 66, of Columbus. Died July 27, 1976.

Janice Elizabeth Buss, 57, of Harmony Township, O. Homemaker. Died Aug. 4, 1976.

Mary P. Crabtinger, 36, of Worthington. Homemaker and mother of four. Died Sept. 18, 1976.

Frances E. Pargel, 56, of Columbus. Registered nurse at Westmore Convalescent Center and mother of one. Died Oct. 4, 1976.

Sheila Selm, 58, of Columbus. Homemaker. Died Nov. 2, 1976.

Clifford R. Van Gundy, 60, of Grove City, O. Owner of Columbus Printing Ink Co. Died Dec. 21, 1976.

Mary Louise Flanagan, 65, of Columbus. Retired secretary at Ohio State University. Died Dec. 29, 1976.

Lila J. Clapsaddle, 52, of Columbus. Retired doctor's assistant. Died Jan. 3, 1977.

Clarence J. Woodall, 38, of Columbus. Disabled truck driver. Died Jan. 16, 1977.

Kenneth J. McElroy, 64, of Columbus. Retired chief landscape architect for city of Columbus. Died Jan. 22, 1977.

Gertrude Phelps, 59, of Columbus. Homemaker. Died March 2, 1977.

Myrtle K. Beech, 50, of Marengo, O. Died March 26, 1977.

Anne Wellmeister, 54, of Columbus. Homemaker. Died March 30, 1977.

James O. Baily, 42, of Columbus. Ohio Bell account manager and father of three. Died Aug. 11, 1978.

Chronology of events at Riverside

DEC 1 5 1982

September 1974 — John C. Art, a Riverside radiation physicist, begins using the wrong type of graph paper to calculate the strength of the radioactive cobalt used in the hospital's cancer-treatment machine. The error goes undetected until January 1976, resulting in radiation overdoses to more than 400 patients treated with the machine.

March 1975-January 1976 — Physicians and a deputy coroner at Riverside raise concerns in staff meetings about what they say are excessive side effects from radiation treatments. They are assured by administrators that the burns and other problems result from differences in how individual patients tolerate radiation.

Dec. 30, 1975 — Edna Gail Valentine, a 25-year-old elementary school teacher from Columbus, dies of radiation injuries. She is the first of at least 28 Riverside patients to die from the overdose.

Jan. 30, 1976 — Art notifies hospital staff that patients have been overdosed. He blames the error on an equipment malfunction.

Feb. 18, 1976 — The executive committee of Riverside's Board of Trustees meets to discuss the overexposures. The committee decides to hire consultants to review the overdoses before notifying patients and their doctors.

April 19, 1976 — Stories in Columbus' two daily newspapers inform Riverside patients for the first time that they have received overdoses of radiation. The stories say 275 patients were overdosed. "Some people may experience side effects," a hospital spokesman says, "but most people have little, if anything, to worry about."

That evening, at 10:30, Agnes Carro, a 48-year-old mother of two, dies at Riverside from radiation injuries. At least four other Riverside patients have already died.

Media attention on the overdoses prompts the U.S. Nuclear Regulatory Commission to begin an investigation.

April 21, 1976 — Dr. Eugene L. Saenger, an NRC consultant and leading expert on the biological effects of radiation, arrives at Riverside to begin the investigation. Saenger immediately appears at a news conference with Riverside officials and praises them for their quick actions and concern for patients.

May 6, 1976 — Art admits to hospital officials that his error, not an equipment malfunction, caused the overdoses. He also admits falsifying hospital records to cover up his mistake.

Aug. 16, 1976 — NRC releases results of its investigation: 418 patients received radiation overdoses of up to 41%. The agency cites the hospital for three infractions, none of which relate to the overdoses. The hospital is required to correct the violations, but no fine is issued. Dr. Lawrence J. Fahey, the radiation oncologist who oversaw the treatments, dies of a heart attack the same day at age 37.

April 19, 1978 — Riverside pathologist and Deputy Coroner Dr. Robert E. Zipf Jr. resigns, saying the hospital pressured him to drop his investigation into the radiation deaths. In a speech at a national coroner's convention, Zipf had said at least 10 people died from radiation overdoses. The NRC never attempted to verify Zipf's finding.

Hospital says issue long settled

Riverside Methodist Hospitals officials declined to discuss the overexposures of 418 people at their hospital in the mid-1970s. The hospital's chief executive officer, Erie Chapman, issued a statement that said:

"Partly as a result of this tragic accident, we now have one of the safest and finest radiation departments in the country. Our department continues to receive the highest level of accreditation from the Joint Commission of Accreditation of Health Care Organizations and the American College of Radiology. . .

"The lawsuits from this incident have long since been settled. We have always felt that the best remaining way to honor those who suffered is to ensure that this kind of problem would not recur. We have done that."

'Translate that into English and what the NRC is saying is that nobody has ever gotten fatal acute radiation sickness. Well, most of the people who die from radiation exposure don't die immediately, other than the people who were in the closest circle of Hiroshima and Nagasaki.'

— Dr. Sidney M. Wolfe, director, Public Citizen Health Research Group

Dec 13

NRC acknowledges death caused by radioactive iridium-192

When The Plain Dealer filed a Freedom of Information Act request asking for all records of accidental deaths resulting from radiation overexposures at U.S. hospitals, the Nuclear Regulatory Commission responded June 8 that it was "not in possession of documents subject to your FOIA request."

Although PD reporters insisted that the agency must be mistaken, NRC spokesman Dick Lawless said there was no need to reconsider the agency's response because he had been assured the NRC had no records of any deaths. "The only thing I can tell you is that's what the staff responded with," he said.

On Dec. 4, as The PD was preparing to publish this five-day series on deaths caused by medical overdoses of radiation, the NRC called a news conference in Indiana, Pa., to announce that a preliminary investigation had determined that an 82-year-old cancer patient had died when a piece of radioactive iridium-192 was accidentally left inside her body for four days.

The woman, identified as Mildred Colgan of Cherry Tree, Pa., died Nov. 21 of "acute radiation syndrome," according to NRC spokesman Karl Abrahmm.

Both the NRC and the Food and Drug Administration's Center for Devices and Radiological Health are investigating the apparent failure of a machine that was used to surgically implant the iridium into Colgan's rectum.

The agencies also are investigating a separate medical mishap involving an apparently identical machine this June 10 Monday in which a piece of iridium broke off inside a patient during a medical procedure at the Greater Pittsburgh Cancer Center. In that case, Abraham said the iridium was immediately removed and the patient was not expected to suffer any adverse effects.

COMING UP

Tragedies across Ohio and the U.S.

PD DEC 1 5 1994

TOMORROW: A series of blunders at the Cleveland Clinic in May 1991 led to a record third fine by the NRC and prompted a top clinic official to call the institution's radiation safety program an embarrassment. So the clinic fixed its problem: It fired the radiation safety officer, who had been complaining about violations for years.

TUESDAY: The nation's worst radiation therapy disaster occurred at Riverside Methodist Hospitals in Columbus in 1975-76. Although more than 400 people received radiation overdoses and at least 28 died, the NRC's medical consultant shut down his inquiry because he didn't want to expose the hospital to malpractice lawsuits.

WEDNESDAY: Jean Matalik doesn't show up in NRC records as a radiation therapy casualty because she took her own life after her doctor burned a hole in her chest. Neither does Stella Johnson, even though a radiation overdose killed her. They are among hundreds of people who are overdosed in our nation's hospitals each year.

THURSDAY: NRC investigators have caught dozens of hospital officials lying, falsifying records and covering up radiation overdoses. Yet only three people have been convicted of crimes and no one has evegone to jail. Some still work at the same hospitals.

I

THE PLAIN DEALER

THE PLAIN DEALER

14-A

LETHAL DOSES

Maryland hushe 20 patients' dea

By TED WENDLING
PLAIN DEALER REPORTER

(192)

DEC. 1 3 1992

If Maryland had been one of the 21 states — including Ohio — regulated by the NRC, most of the records pertaining to the 20 deaths at Sacred Heart would be available under the federal Freedom of Information Act. Medical consumers then could decide whether Sacred Heart and the state acted responsibly.

In October 1988, officials at a Maryland hospital informed the state that 20 patients had died after accidentally receiving overdoses of cobalt radiation.

Another 15 patients who underwent radiation therapy for brain cancer also had received doses that exceeded their prescriptions by 75%, officials at Sacred Heart Hospital in Cumberland told the Maryland Department of the Environment.

Because Maryland has a so-called "agreement state" relationship with the U.S. Nuclear Regulatory Commission — meaning the state fills the NRC's role in the licensing and inspection of nuclear materials other than power plants — the state's Radiological Health Program began an investigation.

What did it find? Maryland citizens will never know.

In what a spokesman for the Environment Department called "the weirdest thing I've seen since I've been here," the Maryland attorney general's office signed an agreement with Sacred Heart in 1989 pledging that all records of the investigation would be withheld from anyone who was not a "subject" of it.

The state further promised not to publicize the agreement or a $9,500 fine of the hospital for failing to promptly report the overdoses.

The agreement also required that in the event a request under the state's Public Information Act forced disclosure of the mere existence of the agreement, the state would notify Sacred Heart to allow the hospital to take "whatever action it deems appropriate to protect its interest."

The result has been a news blackout of what appears to be the most serious radiation incident in the state's history. Sacred Heart officials would not discuss the overdoses, and Joel Quinter, the assistant Maryland attorney general who signed the agreement, said the state was "satisfied with the outcome of the corrective action."

Quinter would not discuss that "action," but said the state never determined whether, or how many, deaths were caused by the hospital's

"It's questionable whether they contributed to the deaths of 20 people," he said. "That's one of the ambiguities of this case."

Although the National Governors' Association has called the NRC's agreement-state program "one of the most successful state/federal partnerships yet established," the Sacred Heart saga points up what critics say is just one of the program's many problems.

If Maryland had been one of the 21 states — including Ohio — regulated by the NRC, most of the records pertaining to the 20 deaths at Sacred Heart would be available under the federal Freedom of Information Act. Medical consumers then could decide whether Sacred Heart and the state acted responsibly.

Patients also are deprived of important consumer information because of a wide variance in regulations from state to state, and between agreement states and NRC-regulated states. Also, states and the NRC often don't share information.

For instance, patients at the Diagnostic Clinic of Houston might want to know that the clinic's radiation safety officer, Dr. Maynard L. Freeman, was convicted in 1988 on felony counts relating to concealing evidence and failing to report radiation overdoses at the Veterans Administration Medical Center in Hines, Ill.

But they don't, and neither does the Texas Bureau of Radiation Control, which relicensed Freeman.

After being fired by the VA, Freeman moved from Illinois, an NRC-regulated state, to Texas, an agreement state that has what the NRC considers one of the top radiological health programs in the country. The Bureau of Radiation Control checked Freeman's academic qualifications, found them in order and issued him a radioactive materials license.

"Unless somebody informs us officially that somebody is a bad actor, we don't dig into their background," said David Wood, a radiation licensing reviewer in Texas.

Not only does the bureau not dig into applicants' backgrounds, applicants aren't even asked whether they have a criminal record, Wood said. And the NRC has no mechanism to disseminate that information to state programs or hospitals, concedes Carlton C. Kammerer, director of the NRC's Office of State Programs.

"It certainly sounds to me like we'd be delighted to share that kind of information," said Kammerer, a former defensive end for the Washington Redskins. "There may be a gap there that needs to be filled."

Another gap exists in the NRC's enforcement of its so-called misadministration reporting rule.

The rule sets strict standards under which medical institutions must report misadministrations — overdoses, underdoses and other radiation errors. The NRC gives state-run programs three years to pass compatible standards.

But states don't always do it.

California, for instance, waited 10 years, until October 1989, to pass a reporting rule. Consequently, the state's Radiologic Health Branch doesn't know that 9-year-old Dwight Golstein died from a huge radiation overdose at Alta Bates Medical Center in Berkeley in 1988.

Radiologic health officials said they were unaware of the death but had no responsibility to investigate it because California's reporting rule wasn't in effect then. They said their records showed that no one in California had ever died of an acute medical overdose of radiation.

"There's never been a death that I know of, and I've been in the pro-

THE PLAIN DEALER

THE PLAIN DEALER, SUNDAY, DECEMBER 13, 1992

RADIATION THAT KILLS

d up ths

10/2 DEC 13 1992

gram since 1968," said Donald Bunn, a senior health physicist.

"It's a cop-out," Dr. Sidney M. Wolfe, director of Public Citizen Health Research Group, said of the agreement-state program. "The NRC, for budget reasons, is up for turning this over to states. And the record of how the states do is pretty clear. Some do well and some do terribly. And that should not be tolerated."

In recent years, the NRC has been at loggerheads with agreement-state program directors, many of whom believe the agency is a dictatorial Big Brother. Although NRC audits have criticized states for not passing compatible regulations, the NRC has never decertified a program against a state's will.

"Reporting misadministrations is just one of the things states have heartburn over," said Greta Dicus, director of Arkansas' Division of Radiation Control. "But the problem is much broader than that. The agreement states regulate more radioactive material than the NRC does and ... in some cases, we believe we have more expertise than the NRC does."

That may be, but medical consumers in Arkansas have cause to question the state's commitment to enforcing radiation safety rules: Arkansas, which has been an agreement state since 1963, has never fined a hospital for radiation violations.

Similarly, Illinois, which has one of the larger agreement-state programs and licenses about 400 medical institutions, has fined just one medical institution for a radiation violation since becoming an agreement state in June 1987.

Dicus simply boasts that radiation programs at Arkansas hospitals are better than elsewhere.

"When we have had an incident at a hospital, they mind it as much as we do," she said. "A fine is another penalty on top of what has occurred. We're lucky. We know the NRC fines a lot, as do other states, but we haven't had to."

Representatives of the nuclear medicine community, most of whom resent any intrusion by government, are split over whether the NRC or the states do a better regulatory job.

"Agreement states can be a boon or a bust," said Dr. Barry A. Siegel, a St. Louis radiologist and chairman of the NRC's Advisory Committee on the Medical Uses of Isotopes. "If you end up with enlightened regulators, who are willing to talk with the medical folks and really understand their problems and try to have an appropriate regulatory balance, then ... you can achieve a comfortable status.

"The bust part would be if your state's got a limited budget and hires people who aren't very qualified, you end up with a hopeless program. It's not very good and it doesn't do a good job of protecting the public. Or, worse yet, you get people whose only approach is, 'I don't know what's really going on here, but let's regulate the hell out of them.' They become irrational."

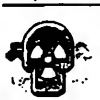
NRC officials eventually would like to see every state become self-regulated, but realize some states simply can't afford to operate strong programs.

"What we say is, 'This is available,'" Kammerer said. "It is an option ... but we're not out beating the bushes to tell everybody to become an agreement state."

Radiation and you

Radiation is part of the environment around us. It bombards us throughout our lives at levels ranging from harmless to dangerous to lethal.

Scientists measure X-ray or gamma radiation in units called roentgens. The unit used to express the quantity of radiation you receive is the rem (roentgen equivalent man). The annual permissible occupational dose of whole-body radiation is 5 rem.

	Whole-body Dosage in rems	Effects & exposures
	<.001	Gamma ray exposure from TV per year.
	.002-.003	Gamma ray exposure at Perry plant site boundary per year.
	.08	Dental X-ray.
	25	Lifetime dose from natural background radiation, including radon exposure.
	50	Possible radiation sickness; headache, dizziness, malaise, nausea, vomiting, diarrhea, decrease in blood pressure, irritability and insomnia.
	250	Acute radiation sickness, few or no deaths and significant life shortening. Radiation sickness includes vomiting, diarrhea, loss of hair, nausea, hemorrhaging, fever, loss of appetite and general malaise. Recovery (if no complications) in about three months.
	1,000	Death within 30 days.

SOURCE: National Council on Radiation Protection and Measurements, National Academy of Sciences PD

X-ray victim cringes at 'idea' of 'safe' dose

By TED WENDLING
PLAIN DEALER REPORTER

When John Hughes was growing up on Cleveland's West Side in the 1930s, the X-ray was in its heyday.

In shoe stores, curious shoppers exposed themselves to X-rays so they could marvel at the bones in their feet. Doctors X-rayed pregnant women to give parents a glimpse of their unborn children. And the mass media flooded society with stories and programs touting the wonders and potential horrors of life in a fast-approaching atomic age.

FROM/1-A

DEC. 1 S 1982

He went to China, Burma and India, where he served in Army Air Forces intelligence during World War II. Then, in the '40s, after returning to Cleveland, a doctor discovered skin cancer eating away at his nose.

Today, more than 100 surgeries later, Hughes, 76, carries scars caused by the cancer that eventually claimed his nose and disfigured his face. He was overdosed with so much radiation as a young man that any amount now — even from natural sources — is potentially dangerous.

"When I hear the term 'safe exposure,' I wince," he said. "I maintain there's no safe exposure to radiation. That's because it's cumulative."

Although no other carcinogen has been studied as intensively as radiation, scientists disagree on that point, particularly as it relates to low levels of radiation. While some believe low doses pose no risk whatsoever, others are convinced — as is true of lead — that there is a linear progression in which the body's toxic burden increases with each dose.

"Doctors have all sorts of reasons for giving X-rays, but there's no economy of thought going into this process: 'Am I doing this patient any good?' " said Dr. Alice Stewart, an epidemiologist at the University of Birmingham in England. Stewart's landmark research in the 1950s found that even one X-ray to a fetus doubled the risk of contracting leukemia.

chairwoman of an organization of state radiation programs. "The problem is, when the public's faced with nuclear issues, they overreact. I think it has to do with those of us in the field not doing a good job of talking about the facts.

"When we started using radiation for good things, we didn't make that clear."

Unlike the nuclear power industry, medicine has benefited from the extraordinary trust people place in their doctors.

In researching this series, The Plain Dealer found numerous instances in which patients suspected that doctors or technicians were administering doses of radiation to the wrong areas of their bodies, but allowed it because they assumed the professionals knew what they were doing.

In other cases, identity mix-ups by hospital personnel led to patients being treated with radioactive drugs when they were scheduled for an entirely different medical procedure. Again, some of those patients never questioned the errors beforehand.

"With patients, you get into a situation where it's almost a rat mentality," said James A. Johnson, a lawyer in Rhinelander, Wis., who has represented many people in malpractice lawsuits involving radiological errors. " 'Where do I go? Do you want me to lie down on this table?'

"There's a lot of trust that you put in those doctors."

It was against this backdrop that Hughes' doctor said he could clear up the 17-year-old's acne with X-rays.

"I remember distinctly the first time my mother and I went to see him," Hughes said. "I'll curse it' was the first thing he said. In those days, when a doctor said something, that was the Word — with a capital W."

Once a week for about six months, Hughes dutifully traveled to his doctor's office behind Terminal Tower. While his mother waited outside, the doctor focused the X-ray beam on different parts of the boy's pockmarked face.

Hughes never felt a thing — at least not for the first decade.

SEE DOSE/14-A

...ing as safe dose, victim of cancer

"Doctors would argue that it's worth the risk ... and right now the American doctor is under intense pressure to over-X-ray the patient because of (the fear of) malpractice," said Stewart. "And since it's almost certain that the cancers are not going to surface for many years, the doctors are never going to see the cancers they cause."

Most doctors, however, say the benefits of radiology far outweigh the risks and that the incidence of radiation-induced cancer is small.

"We're always dealing with risk/benefit. The rule I use is if it's a diagnostic test that's indicated, it should be done with the lowest achievable dose, but it should be done," said Dr. Philip R. Cascade, a Michigan radiologist and chairman of the American College of Radiology's quality assurance committee. "There's no authority in the world that can say with certainty how many cancers are going to be induced in women over 40 by exposing them to periodic mammography. But in our best knowledge, we think the benefits outweigh the risks."

Few people argue the point that since the amazing discovery of "X-light!" by the German physicist Wilhelm Roentgen in 1895, radiation has revolutionized the healing arts, saving and prolonging countless lives.

Doctors use radiopharmaceutical drugs to detect early cancers and blood clots. Radioactive iodine has almost replaced thyroid surgery. X-ray therapy using megavoltage linear accelerators destroys tumors that once resulted in death or amputation.

"The discovery of X-rays was probably the thing that had the single greatest impact on medicine," said Joel E. Gray, a medical physicist at the Mayo Clinic in Rochester, Minn. "It's the only way you have of looking inside the body without cutting it open."

But since Enrico Fermi's creation of the first sustained nuclear reaction at the University of Chicago 50 years ago this month, modern-day medical advances have been accompanied by more frightening uses of radiation in the nuclear weapons and nuclear power industries. The realization that doses of radiation once thought to be harmless will cause cancer also has given rise to new fears based in part on pulp science fiction and the powerful mythology that surrounds radiation.

The benevolent genie-in-the-bottle depicted in Walt Disney's 1957 film "Our Friend the Atom" has been offset by visions of the potential extinction of human life in a so-called nuclear winter. Images of a gleaming, white atomic utopia have been displaced by not-in-my-backyard fears that nuclear waste dumps and incinerators will leave a devastating legacy of cancer and genetic mutations.

"I think many of the problems we're having with radiation issues, particularly disposal problems, is that we haven't adequately informed the public of the issues," said Greta Dicus, director of the Arkansas Division of Radiation Control and past

THE PLAIN DEALER

OHIO'S LARGEST NEWSPAPER

☆☆☆☆☆

THE PLAIN DEALER

LAST OF A SERIES

LETHAL DOSES
RADIATION THAT KILLS

Lies, crimes — and nobody goes to jail

By TED WENDLING and DAVE DAVIS
PLAIN DEALER REPORTERS

DEC 17 1989

It's a long way from Ronceverte, W.Va., to Ketchikan, Alaska, and that's the way Dr. Terry D. Lesko likes it.

It was just over two years ago that Lesko was forced to resign as the staff radiologist and radiation safety officer at Humana Hospital-Greenbrier Valley in scenic southern West Virginia. The area is best known for the Greenbrier hotel, a luxury resort recently revealed as the site of a secret underground bunker members of Congress had built for themselves in the event of a nuclear war.

At Humana, just a few miles away, Lesko was a casualty of a nuclear-medicine war.

Whistle-blower

After blowing the whistle in 1990 on Humana's third nuclear medicine scandal in seven years, Lesko moved to Alaska, where he works as a radiologist at Ketchikan General Hospital. Still, he worries that there will be reprisals for having notified the U.S. Nuclear Regulatory Commission that unlicensed physicians were performing nuclear medicine procedures at Humana.

"Humana is very, very powerful," Lesko said. "They are the single most powerful medical corporation in the country. I have to be careful about what I say."

Although former Humana Executive Director Gregory L. Gibson and Associate Director Shirley Ward Jr. also resigned after an investigation by the NRC's criminal division found that they had "neglected to provide complete information" to the NRC, the Humana scandal was typical of NRC hospital probes in that it produced far more sound than regulatory fury.

The probe disclosed that Humana officials provided inaccurate and false information and withheld part of a physics consultant's report that recommended Humana's nuclear medicine department be closed unless serious deficiencies were corrected.

Additionally, Gibson and Ward admitted that four boxes of administration files were destroyed during the probe, NRC records show.

Showing a profit

For those violations and others, Humana Inc. — whose 78-hospital chain showed profits of $282 million during the 1988 fiscal year — paid a $21,500 fine. It was the third largest fine ever levied by the NRC against a medical institution.

Humana spokesman William Shures would not discuss those or past violations, saying simply that the hospital was "committed to complying with the NRC's regulations."

While NRC investigations of medical institutions have repeatedly substantiated allegations that hospital personnel throughout the country lied, falsified records or failed to report radiation overdoses, no one has ever gone to jail as a result of an NRC probe, a Plain Dealer investigation has found.

Since 1982, the NRC has referred 18 hospital investigations to the Justice Department for criminal prosecution. As a result, only three people have been prosecuted and all were convicted.

SEE DECEIVE/16-A

A fourth defendant, Dr. Charles E. Weinstein, former chief of radiology at Humana-Greenbrier Valley, had his record expunged in 1989 by going through a federal program for first-time offenders. Weinstein was charged after three physicians told the NRC they falsified records at his request to get Weinstein's name added to Humana's nuclear materials license, NRC records show. The three physicians were not charged.

NRC investigators say the lack of prosecutions is frustrating but understandable.

"Who's going to put a doctor in jail?" said Roger A. Fortuna, deputy director of the NRC's Office of Investigations.

In the place of criminal prosecutions, the NRC's investigations and enforcement offices have resorted to using press releases and civil fines to punish medical lawbreakers.

"The first question hospital licensees ask is, 'Are you going to have a press release?'" said James Lieberman, director of the Office of Enforcement. "The second thing they ask is, 'Are you going to issue a civil penalty?' They don't like any fine because any fine puts the hospital in the public domain ... and they want to be perceived — as they are in most cases — as an industry that's trying to serve the public."

Of the two, Lieberman and other NRC officials consider the press release to have more punitive value, in part because fines are so low.

Particularly embarrassing to NRC officials is a fine they issued in an industrial case in 1990 — $875 against General Motors Corp. for losing a gauge containing radioactive cesium. "I'll bet that really broke the bank," quipped NRC public affairs officer Diane Screnci.

Among the 134 fines issued to medical institutions between 1980 and September 1992, 116, or 87%, were $5,000 or less. Penalties against operators of nuclear power plants, which the NRC also regulates, are considerably higher, including seven fines of $100,000 or more last year alone.

"Most of our medical licensees are non-profit organizations," said NRC Chairman Ivan Selin. "They're having a tough time making ends meet. You don't want to fine (a hospital) a million dollars ... unless there's some malfeasance there, not just carelessness.

"On the other hand, the amounts do seem awfully small. They do seem like a slap on the wrist."

Dr. Edward G. Allen, radiation safety officer at Allegheny Regional Hospital in Low Moor, Va., didn't even get a slap on the wrist when he admitted falsifying Weinstein's credentials at Humana. No charges were filed against him.

Allen was one of several physicians who railed against unethical lawyers when the NRC first proposed a rule in the late 1970s that now requires hospitals to report certain radiation errors to patients and the NRC.

"I feel that a report should not be given to the patient ... as this would simply lead to initiation of malpractice suits ..." Allen wrote in an angry July 27, 1978, letter to the NRC. "Under this proposal and the Freedom of Information law, we now have any lawyer that can simply request in the public interest a copy of such a report ... and then proceed to contact the patients involved to initiate malpractice procedures."

But Allen wasn't nearly as concerned about medical ethics in 1985, when Weinstein asked a favor of his old friend. Allen filled out a form in which he falsely claimed that Weinstein had completed 220 hours of clinical training under Allen's supervision, NRC records show.

"It's closed now as far as the NRC is concerned," Allen said when contacted by The PD. "Since it's a closed matter, I'm not going to discuss it."

Many lawyers who specialize in medical malpractice criticize the NRC for being too lenient. But almost all nuclear medicine professionals consider the agency too aggressive.

"I think one of the key issues, rightly or wrongly, is that the NRC is viewed by many people in the medical community as being excessively adversarial in terms of the way they deal with people," said Dr. Barry A. Siegel, a St. Louis radiologist and chairman of the NRC's Advisory Committee on the Medical Uses of Isotopes.

THE PLAIN DEALER

White lies

Caught in the act

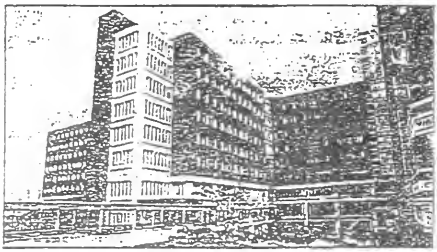
3 of 4

DEC. 1 7 1992

University of Cincinnati Hospitals, Cincinnati

In 1988, the university fired radiation safety officer (RSO) Kenneth M. Fritz after NRC investigators found numerous radiation safety violations, including inadequate training of employees, losing radioactive material and improperly disposing of radioactive material.

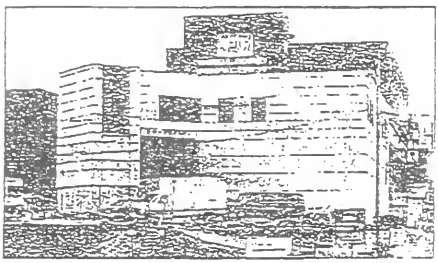
Fritz had issued a written gag order, prohibiting employees from contacting any outside agency about radiation safety problems. One technician was fired for informing the NRC of problems. NRC investigators found that Prince Jason, the deputy RSO, had ordered a technician to hide records that would have revealed that the university had lost some radioactive nickel-63. The investigation also disclosed that the radiation safety office, including Fritz personally, was providing unauthorized for-profit services, including radiation-leak testing and waste brokerage services, to other NRC licensees.



The NRC fined the university $8,750 on Sept. 20, 1991, and another $2,000 on May 1, 1992. The case involving Jason was referred to the Justice Department, which declined to prosecute. Fritz is now RSO at the Cincinnati veterans hospital.

Russell County Medical Center, Lebanon, Va.

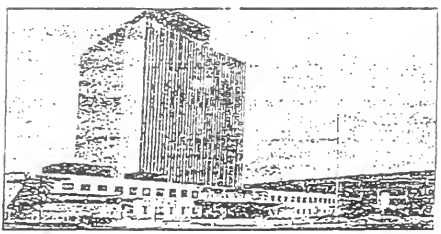
Harrell C. (Hal) Murray, former chief nuclear medicine technologist, admitted to NRC investigators that between June 1985 and April 1986, he intentionally administered huge overdoses of diagnostic radiopharmaceuticals to dozens of patients to speed up the imaging time and lessen his workload. Murray then falsified records to indicate that patients had received the prescribed doses rather than the delivered doses. Murray told investigators the overdoses were necessary for obese patients "to overcome the effects of fat tissue." Doctors said the claim has no medical foundation.



The NRC fined the hospital $2,750 on March 30, 1990. Murray pleaded guilty Aug. 21, 1989, in U.S. District Court in Roanoke, Va., to a felony count of violating the Atomic Energy Act. He was placed on five years' probation and ordered to perform 300 hours of community service.

Edward Hines Jr. VA Hospital, Hines, Ill.

An NRC investigation in 1987 found that Dr. Maynard L. Freeman, assistant chief of outpatient medicine, failed to report two diagnostic overdoses and then lied to NRC investigators, destroyed and falsified evidence, and attempted to influence the testimony of a witness.



The NRC issued no fine. Freeman pleaded guilty July 14, 1988, in U.S. District Court in Chicago to willful failure to report misadministrations and concealing information pertaining to misadministrations, both felonies. He received three years' probation, a $10,000 fine and was ordered to perform 300 hours of community service. The Illinois Department of Professional Regulation, which licenses doctors to practice medicine, issued Freeman a written reprimand in September 1990, but took no action against his license. "Basically, it was a slap on the wrist," said a department spokeswoman. "We kind of officially told him he did wrong." Freeman is now licensed to practice nuclear medicine in Texas and is RSO at the Diagnostic Clinic of Houston.

THE PLAIN DEALER

DEC 17 1992

4079

Lafayette Clinic, Detroit

A 1989 investigation by the NRC determined that Dr. Natraj Sitaram, a researcher, deliberately violated the clinic's license by ordering and using radioactive phosphorus-32 without certification. The investigation found that the clinic subsequently discriminated against radiation safety officer Dr. Lew M. Hryhorczuk by firing him for bringing safety problems, including Sitaram's violation, to the attention of his superiors and the NRC. Investigators also concluded that Dr. Thomas M. Sullivan, the clinic's former acting director, "deliberately misled" the NRC when he told investigators he was unaware that Hryhorczuk had been fired as RSO. NRC records show that it was Sullivan who fired Hryhorczuk, after which Sullivan also appointed Sitaram to the clinic's radiation safety committee.

The NRC fined the clinic $11,500 on Oct. 3, 1991, and barred Sitaram and Sullivan from being involved in NRC-licensed activities for three years. The agency also referred the case to the Justice Department, which declined to prosecute. The clinic went out of business in October.

Virginia Heart Institute, Richmond, Va.

In 1990, an NRC investigation found that owner Dr. Charles L. Baird Jr. had been routinely administering radiopharmaceuticals since 1979 without a license, even though he previously had been advised to obtain certification. Baird also provided false information to the NRC by listing Dr. William S. Dingledine as the heart institute's only licensed user of nuclear materials despite the fact that Dingledine never worked there. Dingledine, who was employed in the medical department of Virginia Power Co., also submitted false documents to the NRC, certifying that he supervised Baird's performance of nuclear medicine procedures. Such supervision would have allowed Baird to legally use radiopharmaceutical drugs even though he had been rejected for a license by the NRC because of insufficient training.

The NRC did not issue a fine, nor did it refer the case to the Justice Department.

Lakeview Hospital, Wauwatosa, Wis.

An NRC investigation found that between 1976 and 1980, dozens of patients were routinely given double doses of radiopharmaceuticals for diagnostic scans of the brain, bones, liver, spleen and lungs. The overdoses were intended to decrease scanning time and obtain brighter images. Two technicians, who were later fired by the hospital, also falsified records to indicate that the proper dosages were given.

The NRC did not issue a fine, nor did it refer the case to the Justice Department.

THE PLAIN DEALER, THURSDAY, DECEMBER 17, 19

TION THAT KILLS

)octors deceive probers, hospitals ıide facts — and no one is jailed

They seem to be interested in king hard to find the bad les, fine them, put them out of iness, punish them and expose m to public ridicule through ss releases — as opposed to be- a little bit more collegial . . .

If I were to pick a single thing has irked people . . . it would the notion that by turning on regulatory screws, that some- the NRC would make the ctice of nuclear medicine fail- . You can't do it. Medicine 't be made failsafe."

lthough hospital officials feel dened by the paperwork the C imposes, the agency's records w it rarely turns on the regula- screws. And even when it s, hospitals often don't follow with administrative sanctions.

Of the three people who were victed as a result of NRC hospi- probes, two are still practicing one at the same hospital at ich he worked when he was con- ted.

That doctor, Glenn B. Mather, entionally failed to report four rdoses of radiopharmaceutical gs because he thought it in- ved "too much paperwork and tape," according to a 1985 NRC estigation report. Mather was ector of nuclear medicine and radiation safety officer at omington Hospital in Indiana.

The investigation disclosed that ther made false statements, nheld records and instructed ployees to lie to NRC investiga- s to impede their probe.

It also found that hospital Presi- nt Roland E. Kohr, who de- ded Mather as a "man of integ- y," provided false information en asked about one of the over- ses.

Although Mather pleaded guilty 1989 in U.S. District Court in In- anapolis to a felony count of fail- g to report an overdose, he re- ains at Bloomington Hospital as staff radiologist. He received a spended sentence and was fined ,050.

Kohr was not prosecuted and is ll president.

"Certainly, nothing's been kept om anybody," said Bloomington wyer James L. Whitlatch, who presents the hospital. "People at e hospital are aware of what the arges were and Dr. Mather paid e debt he had to pay."

When asked why the hospital's hics policy didn't call for Mather nd Kohr to be fired or disciplined, Whitlatch said: "They understand Dr. Mather made a mistake and that he corrected it . . . I certainly don't think Mr. Kohr did anything wrong."

A spokeswoman for the Indiana Medical Licensing Board said no action was taken by the state against Mather because no one had notified the board of his conviction.

Eugene T. Pawlik, director of the NRC's regional Office of Investigations in Glen Ellyn, Ill., said he wasn't surprised to learn that Mather still worked at Bloomington Hospital.

"Not really. This is America," Pawlik said. "I've been at this a long time . . . If I started worrying about what happened to the people we investigate, it would eat me up."

Consequently, hospitals whose employees have been implicated in wrongdoing often don't worry either.

At Grant Memorial Hospital in Petersburg, W.Va., Dr. Earl J. Reckenthaler, the radiation safety officer, admitted to NRC investigators that he allowed another doctor to create records of never-held radiation safety meetings for four years because he considered the mandatory meetings "just another ridiculous government regulation."

Reckenthaler is still a staff radiologist at Grant, which discontinued its nuclear medicine program as a result of the NRC investigation. Hospital administrator Robert Harman said he saw no need to take disciplinary action against Reckenthaler because the NRC never did.

At Mercy Hospital in Wilkes-Barre, Pa., an NRC investigation found that Dr. Salvatore M. Imperiale, the radiation safety officer, told a nuclear medicine technician not to notify the NRC that a patient scheduled for a chest X-ray had mistakenly been given a dose of a radiopharmaceutical drug used for liver scans.

Although the NRC ordered Imperiale's removal as the hospital radiation safety officer and suspended him for one year, he is still a staff radiologist at Mercy. Administrators there would not comment, but Imperiale said they took no additional disciplinary action against him. He said he should have reported the mistake, but didn't because the dose "was really of no consequence" and hadn't harmed the patient.

Likewise, administrators at Milford Memorial Hospital in Milford, Del., never disciplined Radiation Safety Officer Dr. Santos F. Delgado and Julie E. Greenly, a nuclear medicine technologist, after Greenly and another technologist admitted to NRC investigators that they had not done dose-calibration tests from May 1986 to December 1986. The technologists then falsified records to indicate that the tests had been done.

Calibration tests, which take less than a minute to perform, are designed to ensure that doses of radioactive drugs given to patients are accurate.

NRC investigators also learned that Delgado had not held NRC-mandated radiation safety meetings for at least 14 years. Instead, he had instructed a secretary to retype the same minutes over and over for distribution to ghost "participants."

One of those people was Dr. Abraham J. Strauss, who replaced Delgado when the NRC ordered Delgado removed as radiation safety officer. Strauss told investigators he never complained about the falsified minutes because "it was his (Delgado's) business and responsibility."

When asked why Delgado listed him as attending the meetings, Strauss told the NRC, "I don't know. Maybe he needed a quorum."

Today, both Delgado and Greenly remain on Mercy's staff. Hospital spokeswoman Dawn Suitor said because the NRC took action, the matter didn't warrant further discipline by the hospital.

"There was no way that patient care was neglected or impacted from this," Suitor said. "Like all hospitals, we have an ethics policy, but the administration felt that the NRC took their separate actions on the matter."

In other cases, the NRC has permitted doctors it has accused of wrongdoing to become licensed elsewhere.

In October 1986, six months after the NRC ordered Mather removed as radiation safety officer at Bloomington Hospital, the agency relicensed him at Morgan County Memorial Hospital in Martinsville, Ind.

In another case, the University of Cincinnati fired radiation safety officer Kenneth M. Fritz after a series of NRC investigations found numerous violations, including failure to adequately train employees, losing radioactive material, and improperly disposing of radioactive material in sanitary sewers and trash.

Although the NRC commended the university for its prompt action, the agency allowed Fritz to serve in the same capacity at Miami (Ohio) University and at the Veterans Administration Medical Center in Cincinnati.

Fritz is still the radiation safety officer at the Cincinnati veterans hospital.

When Fritz was fired in 1989, a consultant warned university officials of serious deficiencies in the radiation safety program. The consultant also said there was a substantial risk the university could lose its nuclear materials license.

Although NRC investigators determined that Fritz's deputy, Prince Jason, had concealed records, they could not substantiate allegations by Jason that Fritz had ordered Jason to conceal evidence from the NRC. It was on that basis, NRC officials said, that they did not prevent Fritz from being licensed at Miami and UC.

In an interview, Fritz defended his 20 years at UC, saying he ran a good radiation safety program. He said many of the university's problems occurred after he left and had nothing to do with him.

"Keep in mind that they were fined ($10,750) a year or two after I left and after they spent over a million dollars on a consulting firm," Fritz said. "We were never fined while I was there. I never had a problem with the NRC."

Jason countered: "He was the one who issued the directive. I did what I did because he was my superior."

Despite all the criticism of the NRC, Lieberman, the agency's enforcement director, said the NRC is doing all it can to live up to its mission to "protect the public health and safety."

"Obviously, there are only so many resources, and this is a tight area," he said. "We would prefer to have more inspectors, but in this day and age you can't have that.

"What concerns me is we closely regulate nuclear activities. What happens in the rest of the medical community that isn't closely inspected or regulated?"

The first question ıospital licensees ask s, "Are you going to ıave a press elease?" ' The econd thing they ask s, 'Are you going to ssue a civil ɔenalty?" '

— James Lieberman, irector, NRC Office of Enforcement

THE PLAIN DEALER

Letters to the editor

Clinic: Radiation story spread needless fear

DEC 18 1992

"The spill that shook Cleveland Clinic," proclaimed The Plain Dealer (Dec. 14) in front-page double banner headlines worthy of flashing the Chernobyl disaster. The accompanying articles, complete with front-page chronological illustration, featured a phosphorus-32 spill in a non-patient research laboratory more than 1½ years earlier. The spill itself was innocuous; the exposure to those involved was less than what is received in one chest X ray, and at no time did the spill pose a risk to any individual. Radioactive phosphorus may be cleaned up with soap and water. The whole episode was reported in The Plain Dealer and other local newspapers in May 1991.

Although the reputation of the Cleveland Clinic is damaged by such irresponsible reporting, that is of little importance in relation to the incalculable harm caused to patients undergoing or recommended to undergo therapeutic irradiation at the Clinic and elsewhere. Alarm expressed by our patients and others in the several days following publication of the articles caused the Clinic to reassure the public through the radio media and the establishment of a hot line (216-444-2544) that radiation therapy is an extremely safe modality in the treatment of the nation's deadliest killer.

While attempting to inform the public about so-called "radiation that kills," The Plain Dealer appears to have unnecessarily alarmed the public into thinking that radiation therapy is unsafe medicine. What the article did not mention is that 13,933 patients have received 229,090 radiation therapy treatments at the Cleveland Clinic over the past 10 years with a total of six misadministrations reported to the Nuclear Regulatory Commission as required, or 0.0026% of all radiation therapy treatments. The national misadministration rate is 0.04% for all teletherapy procedures and 0.02% of all brachytherapy procedures as reported by the Office of Management and Budget to the NRC earlier this year.

Despite this excellent safety record, three NRC fines for procedural error in five years could not be tolerated at the Cleveland Clinic, where superior quality standards are the norm. Changes were in order, among which was the upgrading of the qualifications of the Clinic's radiation safety officer position. The Plain Dealer's remark that "the Clinic fixed its problem: it fired the radiation safety officer, who had been complaining about violations for years" was a false inference that the Clinic illegally retaliated against a whistle-blower. This is nonsense. A Labor Department inquiry found no improper conduct by the Clinic.

These articles published by The Plain Dealer are the journalistic equivalent of recklessly yelling "Fire!" in a crowded theater. The Plain Dealer needs to recognize the responsibility that comes with freedom of the press and disdain the temptation to print inaccurate information that will sell newspapers regardless of the consequences.

FLOYD D. LOOP, M.D.
Cleveland

Loop is chairman of the board of governors and executive vice president of the Cleveland Clinic.

THE PLAIN DEALER

NRC lifts 6 centers' licenses

Cancer treatment units lose permits

By TED WENDLING and DAVE DAVIS
PLAIN DEALER REPORTERS

JAN 22 1999

WASHINGTON

The U.S. Nuclear Regulatory Commission yesterday suspended the licenses of six Pennsylvania cancer centers, including one in Indiana, Pa., at which an 82-year-old woman received a fatal radiation overdose in November.

The suspensions do not shut down the centers, but they prevent them from performing hundreds of so-called brachytherapy procedures that involve the use of iridium-192, a high-intensity radioactive material that is surgically implanted into deep-seated tumors.

The six centers are owned by Oncology Services Corp. of Harrisburg, Pa. The centers came under scrunity by the NRC following the death Nov. 21 of Sara Mildred Colgan. The NRC is responsible for protecting the public from radiation mishaps.

Colgan died after a doctor at the Indiana Regional Cancer Center accidentally left a sliver of iridium-192 inside one of her treatment catheters for about 91 hours, causing her death. NRC officials estimated that the iridium delivered a radiation dose of more than 1 million rads to the wall of her bowel.

In addition to Colgan, about 90 people, including health care workers, sanitation employees and friends, were exposed while the iridium remained in Colgan's body and after it was inadvertently disposed of as ordinary medical waste.

Indiana County Coroner Thomas Streams, who is investigating Colgan's death for evidence of possible criminal negligence, has said Colgan's radiation dose was more than 100 times the lethal dose. Streams said he was still awaiting results of an autopsy that was done after Colgan's body was disinterred Dec. 18.

Diane P. Screnci, NRC spokeswoman, said the order was issued after NRC investigators found a "breakdown" in the six centers' radiation safety programs. "Oncology Services now has to prove to us that they can use these materials in a safe manner," she said.

Oncology Services has 20 days to request a hearing on the suspension. Executive Vice President Ray Caravan said the company would appeal.

"We're pretty upset about this whole thing," Caravan said. "The NRC did it again. They released this thing (the suspension order) and didn't send it to us. It is absolutely loaded with inaccuracies, untruths and malicious comments."

The unannounced NRC inspections on Dec. 8 of two other Oncology Services centers, the Exton Cancer Center in Exton, Pa., and the Mahoning Valley Cancer Center in Lehighton, Pa., found that personnel were unaware of the requirements and procedures to protect themselves and others from radiation accidents.

So poor was the training that when the brachytherapy machine being used to treat Colgan gave numerous "error" messages followed by an alarm from the room's radiation monitor, the technologists didn't know how to use a survey meter that would have shown the radioactive source was still in Colgan's body.

The NRC was particularly critical of Dr. David E. Cunningham, who serves as the radiation safety officer for all six centers.

NRC investigators said Cunningham had demonstrated that he was "not willing to be responsible" for the centers' radiation safety programs. The suspension order said Cunningham had not visited the Lehighton facility in the past six to nine months and said the medical director of the facility didn't even know that Cunningham was the radiation safety officer.

The NRC also faulted Cunningham for sending a letter to five of the Oncology Services facilities in which he said it was "not possible for corporate administration to supervise your radiation safety program on a routine basis."

Caravan said the 528 brachytherapy procedures done at Oncology Services centers last year represented fewer than 1% of the centers' cancer treatments.

THE PLAIN DEALER

PD radiation articles incorrect, physicians charge

By DAVE DAVIS
and TED WENDLING FEB 11 1993
PLAIN DEALER REPORTERS

A nuclear medicine society yesterday publicly accused The Plain Dealer of inaccurate reporting and of confusing the distinction between nuclear medicine and radiation oncology.

In a news release sent over the U.S. Newswire to the nation's 100 largest daily newspapers, the American College of Nuclear Physicians in Washington, D.C., alleged that a recent PD series on medical radiation incorrectly suggested that nuclear medicine procedures had caused serious patient injuries and deaths, even though no deaths have been attributed to nuclear medicine procedures in more than 20 years.

Asked yesterday to identify the errors mentioned in the release, Margie Kilty, a spokeswoman for the college, could not identify any.

"I want to formulate a statement on that," she said. Pressed further, she said, "Right now, I don't have the information. I'm not going to make a comment right now."

In a series of stories in December, The PD reported that the U.S. Nuclear Regulatory Commission had no record of scores of deaths and serious injuries caused in the practice of radiation oncology in U.S. hospitals. The series also reported that at least 40 people had died since 1978 from acute medical overdoses of radiation.

The NRC has not disputed the findings and has been holding public hearings to identify deficiencies in its medical licensing and inspection programs, which include the limited regulation of radiation oncology and nuclear medicine.

Radiation oncology is the therapeutic use of large doses of radiation to treat various cancers. Nuclear medicine involves the use of comparatively low doses of radiation for diagnostic purposes. Therapeutically, nuclear medicine also is used to treat thyroid diseases, blood disorders and other illnesses.

In addition to criticizing The PD, the college's news release challenged a story in Tuesday's USA Today, which incorrectly reported that an 82-year-old woman who died Nov. 21 from a massive radiation overdose was a victim of a botched nuclear medicine procedure.

The woman, Sarah Mildred Colgan, died in Indiana, Pa., after a radiation oncology procedure in which a sliver of radioactive iridium-192 broke off inside her body during implant surgery.

USA Today printed a correction in yesterday's editions.

"Trying to get a story, occasionally the facts get lost," the college's statement began. "The recent series in the Cleveland Plain Dealer and a more recent story in USA Today both show how small errors can damage reputations. One of the hottest and least accurately reported topics seems to be medical radiation."

The American College of Nuclear Physicians has a membership of 1,200 physicians. In 1990, the college became embroiled in an investigation by the NRC's Office of the Inspector General, which found that the college, the Society of Nuclear Medicine and a group of NRC officials had secretly drafted a rule-making petition that NRC staffers subsequently submitted to commissioners as if it was solely the work of the two nuclear medicine societies.

Members of the NRC's Office of Nuclear Material Safety and Safeguards had been sympathetic to the societies' position that the NRC was overregulating nuclear pharmacists, and so the NRC staffers agreed to write the 15-page petition on their behalf. The NRC staffers spent months traveling around the country to meet with nuclear medicine professionals, after which they did the "legal review" and submitted the petition to commissioners without acknowledging it as their own work.

Although NRC Inspector General David C. Williams found the staff assistance improper, no disciplinary action was taken because the NRC has no regulations limiting staff assistance.

Kilty said yesterday that the American College of Nuclear Physicians had not attempted to deceive NRC commissioners.

"That's your perception," she said. "I think your perception is incorrect."

The Washington Post DEC 19 1992
Circulation 826,262

Md. Cancer Patients Received Radiation Overdoses

By Deb Riechmann
Associated Press

BALTIMORE, Dec. 18—A state investigation of radiation overdoses given to 33 brain cancer patients at a Cumberland hospital found some patients suffered temporary deafness and skin problems after receiving doses 75 percent greater than prescribed.

Investigation documents had been sealed under an agreement the state signed with Sacred Heart Hospital. The state released the documents today after several news organizations requested them this week under the Freedom of Information Act.

Some of the terminally ill patients who received overdoses died, but there was no conclusive evidence to link the deaths to the excessive radiation treatments, which occurred during a 13-month period in 1987 and 1988.

The overdoses occurred because a computer program used to control the intensity of radiation released was not changed when a depleted source of radiation was replaced. The oversight caused radiation doses for brain cancer to be 75 percent greater than prescribed.

The problems at Sacred Heart Hospital could have been detected earlier, investigators concluded.

The person in charge of the hospital's radiation department, Cynthia Brown, denied responsibility and blamed the problem on a physicist whom she trusted to conduct all computer calculations of radiation equipment.

"I responded by telling her that she is the radiation safety officer," state radiological inspector Carl E. Trump Jr. said in his Nov. 23, 1988, report. "Regardless of who loaded the computer with data, her immediate responsibility was to confirm that data to be current and accurate, and that most of the blame in this matter will be directed at her."

The hospital was fined $9,500, partly for not immediately reporting the overdoses. Sacred Heart suspended Brown, who resigned Dec. 14, 1988.

At the time of the problem, Sacred Heart asked the state to keep its investigation confidential.

"At the time, we really felt that was the right thing to do," said Roland Fletcher, administrator of the state's radiological health program. "We had done a detailed investigation and were satisfied that a thorough redirection of the hospital's therapy program had occurred."

Twelve of the 33 patients being treated for brain cancer were over 70 and three were over 80.

"Although the characteristics of this group of patients may have served to mask any consequences of the overdosage, this in no way condones the fact that they received excessive radiation of the order of 75 percent that would have had catastrophic effects in almost any other group," according to a consultant hired by the hospital, who was quoted in the report.

OFFICIAL USE ONLY

OFFICE OF THE INSPECTOR GENERAL
REPORT OF INVESTIGATION

INVESTIGATION OF NRC STAFF ACTIONS ASSOCIATED
WITH ONCOLOGY SERVICES CORPORATION (OSC)

CASE NO. 93-29A

[redacted]

4/14/93

ASSISTANT INSPECTOR FOR INVESTIGATIONS — DATE

THIS REPORT IS THE PROPERTY OF THE OFFICE OF THE INSPECTOR GENERAL. IT MAY NOT BE PLACED IN THE PUBLIC DOCUMENT ROOM WITHOUT WRITTEN PERMISSION.

FREEDOM OF INFORMATION/PRIVACY ACT EXEMPTION (b)(5)(6)(7)(C)(D)

OFFICIAL USE ONLY

TABLE OF CONTENTS

SUBJECTS

STATUTES AND REGULATIONS

10 CFR, Part 0
Conduct of Employees

10 CFR, Part 35
Medical Use of Byproduct Material

Management Directive 8.8
Management of Allegations

18 USC 1001
False Statements

EXECUTIVE SUMMARY

This investigation was based on information developed during the NRC Incident Investigation Team (IIT) examination of the therapy misadministration and loss of an Iridium-192 source at the Indiana Regional Cancer Center, Indiana, PA. This report does not address the same issues discussed by the IIT in NUREG-1480. This Office of the Inspector General inquiry addressed the following areas related to NRC operations: 1) the NRC Region I handling of the licensing actions associated with Oncology Services Corporation (OSC); 2) the NRC evaluation of the Gamma Med IIi High Dose Rate (HDR) afterloader device for use in a portable mode; 3) the September 1991 inspection of OSC by NRC Region I staff; 4) alleged preferential treatment provided to OSC by an NRC Region I staff member; 5) the NRC Region I handling of an allegation made against OSC in March 1991; and 6) NRC Headquarters' responsiveness to requests for policy guidance from the regions.

The investigation disclosed that the existing NRC policy guidance for the licensing of remote afterloading devices was not followed by Region I in handling certain of the OSC licensing actions. Additionally, some license amendments were issued despite the fact that NRC staff was aware that the policy was either unclear or non-existent on the matters involved in the amendments. The investigation confirmed an inappropriate remark was made by an NRC [redacted] concerning [redacted] confidence in the licensee based on friendship with the licensee's [redacted] The investigation also disclosed deficiencies in the handling by Region I of an allegation against OSC in 1991. The shortcomings included the lack of documentation for information which was used to resolve the allegation as well as a lack of adequate issue identification. Additionally, the existence of the allegation was inappropriately disclosed to the licensee [redacted] by an NRC staff member.

Questions concerning the OSC license and transportability of the HDR device were raised by three different individuals in 1991. The NRC staff conducted inadequate inquiries into the concerns and allowed the licensee to continue operating without restriction. The OIG investigation determined there was no evidence that OSC's HDR device had ever been evaluated for use in a portable mode. Additionally, the licensee's RSO had not received the required training to install the device following relocation despite assurances made to the NRC that he had received such training. This investigation also discovered deficiencies in the NMSS system for tracking requests from the regions for policy guidance and technical assistance.

BASIS

This investigation by the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), was initiated based upon information developed in connection with the Incident Investigation Team (IIT) at Indiana, Pennsylvania. This investigation addressed the following issues: 1) the NRC Region I handling of the licensing actions associated with Oncology Services Corporation (OSC); 2) NRC evaluation of the Gamma Med IIi HDR afterloader device; 3) the September 1991 inspection of OSC by NRC Region I staff; 4) alleged preferential treatment provided to OSC by an NRC Region I staff member; 5) the NRC Region I handling of an allegation made against OSC in March 1991; and 6) NRC Headquarters' responsiveness to requests for policy guidance from the regions. Issue (4) in this report was referred to the OIG for investigation by the IIT team leader at the direction of the EDO. The other issues were developed by the OIG while serving in an observer role to the IIT.

BACKGROUND

A review of the U.S. Nuclear Regulatory Commission (NRC) Region I licensing file for the Harrisburg Cancer Center/Oncology Services Corporation (OSC) disclosed that an Application for Material License (NRC Form 313) was received on or about June 4, 1990. [redacted] was listed as the applicant's [redacted] and the point of contact regarding the license. The license application requested the use of a single Iridium 192 source in a Gamma Med IIi High Dose Rate (HDR) afterloader at the Harrisburg Cancer Center. The HDR was designed for use in brachytherapy which is a therapy procedure in which radioactive sources are placed near or in contact with a tumor.

The OSC license application was assigned for review by an NRC Region I staff member in the Licensing Section. A written request for additional information, dated August 1, 1990, was sent to the licensee by [redacted] the NRC Region I [redacted] assigned to process the original license application. Following receipt of the additional information on August 2, 1990, license number 37-28450-01 was issued by Region I on August 3, 1990 bearing the signature of [redacted]

On October 1, 1990, a license amendment request was submitted by [redacted] The license amendment requested the addition of five authorized users with the locations of use expanded to include: Stoneboro, PA, Pittsburgh, PA; Exton, PA; Indiana, PA; and Lehighton, PA. The amendment request did not contain diagrams of the treatment areas in these facilities. The cover letter from the licensee included a statement that the HDR therapy would comply with all requirements of the original license. The license amendment request was assigned to [redacted] from NRC Region I for review.

The OSC license file contained a reconstructed record of a telephone conversation between [redacted] and [redacted] from NMSS/IMAB on November 1, 1990. (Note: The year on the previously mentioned record of conversation incorrectly reflects 1991 rather than 1990.) The issue discussed in the telephone conversation between [redacted] and [redacted] involved the transportability of the HDR device [redacted] reconstructed record reflects that [redacted] indicated that the portability/transportation of the HDR device to remote sites was permissible as long as the Department of Transportation (DOT) requirements were followed. On November 2, 1990, amendment 1 to the license was issued by [redacted] which granted the addition of authorized users and locations contained in the amendment request. Of particular note is the fact that condition 14 of this amendment authorized the licensee to transport licensed material in accordance with the provisions of 10 CFR 71.

On June 20, 1991, a second license amendment request was submitted by [redacted] The request included the addition of an authorized user as well as

additional radioactive sources and HDR brachytherapy units manufactured by Nucletron and Omnitron International. The supporting documents for this amendment request included the shielding diagrams and layout of the treatment rooms for the sites previously added by amendment 1. The amendment request was modified by a letter from OSC dated July 9, 1991, which indicated the corporation's intent to obtain additional HDR units for use at some of the sites approved by amendment 1.

The amendment request was assigned for review to [redacted] in NRC Region I. On August 15, 1991, a request for additional information was sent to [redacted] response to the NRC request for additional information was provided on August 16, 1991. On August 21, 1991, the license amendment request was further modified by [redacted] to include an additional site and authorized user. Amendment 2 to the license was originally forwarded to the licensee on December 26, 1991. The cover letter incorrectly refers to it as a "renewal" of the license. Paragraph 3 of the amendment transmittal letter from Region I states that due to pending policy questions regarding the use of HDR devices in mobile services, a condition of the license had been added which required the HDR device to remain at a fixed facility. The authorization to transport licensed material which had been granted in an earlier license action (amendment 1) was being rescinded by amendment 2. Another version of amendment 2 was issued by Region I on January 22, 1992, which restored the licensee's ability to transport the HDR device and iridium source to other sites as long as it was done in accordance with 10 CFR 71.5 and DOT regulations.

A third license amendment was issued on August 19, 1992 which added a stand-alone HDR brachytherapy shielded facility at the Harrisburg, PA location. This amendment had no effect on the issues discussed in this report. Copies of all pertinent documents from the license file are included as Exhibits 1 (a) - 1(m) to this report.

NRC Policy and Guidance Directive FC 86-4, Information Required for Licensing Remote Afterloading Devices was issued on February 20, 1986. It contained the most recent guidance from NRC Headquarters on the licensing of remote afterloading devices which was a central part of the OSC license. Enclosure 2 to the directive outlined the information required to support a license request (Exhibit 2).

DETAILS

ALLEGATION - 1

This section addresses the NRC Region I handling of the licensing actions associated with OSC.

[redacted] Medical, Academic & Commercial Use Safety Branch (IMAB), Office of Nuclear Material Safety and Safeguards (NMSS), NRC, reported that in about May 1991, [redacted] was assigned to review the agency policy regarding the licensing of mobile brachytherapy services. It was [redacted] understanding that the issue had been raised during a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). While looking at this question, [redacted] reviewed the actions taken by Region I in connection with the licensing of OSC. [redacted] compared the information provided in the license application with the Policy and Guidance Directive FC 86-4 which listed the information required to be submitted to support the issuance of a license. [redacted] review disclosed that certain information listed in the policy guidance was not included in the original license application. The information missing from the original license application package included a lack of data concerning the instructor who was to provide training; incomplete shielding information on the treatment room; the means of assuring that only one radiation-producing device would be in operation at a time; calculation of exposure rate in adjacent areas; independent verification of treatment time calculations; and lack of off-duty telephone numbers for people to be notified in the event of an emergency.

[redacted] analysis also noted that the application for amendment 1 to the license merely stated that the five additional sites requested in the amendment would comply with the requirements of the existing license. Sufficient data was not provided to support the licensee's claim that the additional sites met NRC requirements. [redacted] also noted that the Policy and Guidance Directive was in need of revision. [redacted] prepared two briefing memoranda for [redacted] management which reported the results of [redacted] review (Exhibits 3, 4 and 5).

A review of the ACMUI meeting minutes for May 9, 1991, disclosed that a committee member raised the question of a Pennsylvania firm conducting a mobile brachytherapy service and possibly transporting a remote afterloader device in a trailer to various treatment sites. The member voiced a concern about the safety of shipping radioactive sources by Federal Express from one hospital to another. NRC staff members [redacted] and [redacted] who were in attendance at the meeting indicated no knowledge of such an operation; however, [redacted] agreed that the matter should be explored (Exhibit 6 at 96, 193-195).

[redacted] Region I, NRC, confirmed that [redacted] handled the initial OSC application for a materials license which involved an HDR

afterloader. This was the first HDR license application processed by [redacted] believed that [redacted] may have relied more heavily on a draft Teletherapy Reg. Guide rather than Policy and Guidance Directive FC 86-4 in processing the OSC license application. [redacted] did not recall receiving any in-depth training on HDR licensing matters.

[redacted] review of the initial application of OSC resulted in a request for additional information regarding the training of the authorized user and other minor points. When the licensee provided the requested information, the license was issued. [redacted] was a [redacted] at the time. [redacted] recalled during the processing of the original license request, OSC [redacted] inquired about the procedures for adding additional sites to the license and transporting the HDR device to various sites for treatment. [redacted] said that [redacted] informed [redacted] that such a request would require policy guidance from NRC Headquarters since it was not addressed in the current regulations. After [redacted] informed [redacted] that such a request would hold up the issuance of the license, [redacted] asked that the initial application be processed and commented that the addition of sites would be handled in a future amendment request.

During the OIG interview of [redacted] the deficiencies in the original OSC license application noted during the review by [redacted] were discussed. [redacted] agreed that certain information discussed in Policy and Guidance Directive FC 86-4 was not included in the OSC license application. Most notable of the deficient areas were shielding calculations; the means for assuring only one radiation producing device was in operation at a time; independent verification of treatment time calculations; and off-duty emergency telephone numbers. [redacted] cited [redacted] unfamiliarity with licensing such devices as a contributing factor to the oversight in obtaining the correct information.

[redacted] said that following the granting of the initial license, [redacted] had no further involvement in any OSC license actions. However, [redacted] did recall subsequently seeing a copy of license amendment 1 shortly after the original license was issued. [redacted] said that at the time [redacted] was surprised the license amendment had been issued so quickly since it involved a matter which required policy guidance from NRC Headquarters (i.e., the transportation of the source and device to various treatment locations). [redacted] said that [redacted] expected such a process would have taken at least one year to accomplish. [redacted] did not inquire further about the circumstances surrounding the issuing of amendment 1 (Exhibit 7).

[redacted] Region I, NRC, confirmed that [redacted] handled the first amendment request to the OSC license which added several authorized users and requested authority to transport the HDR afterloader device to various treatment sites. [redacted] recalled that it was handled as a routine amendment matter. [redacted] said

OFFICIAL USE ONLY

[redacted] was concerned about the proposed transporting of the device and conversed by telephone with [redacted] from the NRC NMSS staff on this issue. [redacted] recollection of the guidance provided by [redacted] was that any transporting of licensed material had to be in accordance with DOT regulations. Additionally, [redacted] raised the issue of shielding in the treatment rooms at the various sites. [redacted] said that [redacted] subsequently discussed the shielding issue with [redacted] who informed [redacted] that the HDR treatments would be conducted in rooms which housed either a linear accelerator or cobalt therapy machine. It was [redacted] belief that this meant that the shielding in the treatment rooms was sufficient for use of an HDR device. [redacted] said that [redacted] accepted the explanation of [redacted] and did not request diagrams or shielding calculations for the additional treatment rooms. [redacted] said that [redacted] did not discuss the amendment issue with any other Region I manager prior to issuing the license amendment. [redacted] indicated that at the time of the pending amendment [redacted] was not aware of the NRC Policy and Guidance Directive FC 86-4 on remote afterloaders (Exhibit 8).

[redacted] Medical, Academic & Commercial Use Safety Branch (IMAB), Division of Industrial & Medical Nuclear Safety (IMNS), Office of Nuclear Material Safety and Safeguards (NMSS), NRC, recalled a telephone conversation with [redacted] in which [redacted] questioned whether a licensee could transport sources between locations. [redacted] said that the conversation with [redacted] was relatively short and limited to the issue of whether sources could be transported. [redacted] acknowledged informing [redacted] that transportation was permitted as long as it complied with DOT regulations. According to [redacted] the conversation did not include a discussion of whether such a situation involved mobile brachytherapy services or whether a licensee could transport HDR devices to multiple sites. [redacted] did not maintain any record of the telephone conversation with [redacted] added that the question of mobile brachytherapy services was subsequently raised by a member of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). At that time, [redacted] assigned [redacted] to conduct a review of the issue [redacted] was later advised by [redacted] of certain deficiencies in the handling of the OSC license and amendment applications by Region I.

[redacted] also confirmed that [redacted] later directed Region I to restore the licensee's ability to transport the source in the revised amendment 2 to the license. Exhibit 9 is a handwritten note of [redacted] which documents a conversation with [redacted] on January 21, 1992 during which the issue was discussed. [redacted] said that [redacted] recommended the restoration of the transport condition after the licensee's [redacted] complained to [redacted] about the earlier version of amendment 2 which revoked that ability. [redacted] said that [redacted] did not believe it was proper to use a license amendment as a means to remove an ability which had been previously granted by the NRC. Further, [redacted] felt that the pending policy issues concerning transportability of the HDR device did not raise immediate health and safety issues which would have justified an order to modify the existing license. [redacted] reported that [redacted] said [redacted] was qualified to perform the functions associated with transportation of the HDR unit

OFFICIAL USE ONLY

to the various sites. [redacted] added that the existing policy and guidance directive was outdated and in need of revision. One of [redacted] staff members was currently working on that project (Exhibit 10).

[redacted] Medical Licensing Section, Nuclear Materials Safety Branch (NMSB), Division of Radiation Safety and Safeguards, Region I, advised that [redacted] became the [redacted] in Region I on February 28, 1991. By that time, the original license and amendment 1 had already been issued to OSC.

[redacted] recalled that in the March/April 1991 time frame, questions were raised about the number of health care centers listed on the OSC license, the lack of diagrams for the facilities, and the licensee's plan to transport the HDR device to the various treatment sites. [redacted] view was that such an operation was not permissible under the regulations in effect at that time. [redacted] said that [redacted] spoke with [redacted] about the transportation issue and [redacted] indicated that [redacted] from NMSS had approved it.

[redacted] said that [redacted] realized in about March 1991, that policy guidance from NMSS was needed. [redacted] acknowledged having conversations beginning in June 1991, with [redacted] from NMSS regarding a lack of information in the license and amendment applications. [redacted] said that [redacted] viewed the licensee's failure to provide shielding information in the request for amendment 1 as a health and safety issue; however, since the amendment had already been issued by Region I, [redacted] directed that the information be obtained in connection with a subsequent amendment action in 1991 (amendment 2). [redacted] acknowledged that there was a delay between the time the issues were first discovered in March 1991 and the submission of the request for policy guidance to NMSS in January 1992. The delay was due to a heavy workload as well as the fact that [redacted] desired to conduct an inspection of the licensee in order to gain a better understanding of the operation. That inspection was not conducted until September 199[redacted] said that during that inspection, [redacted] characterized the movement of the HDR as "high risk," or words to that effect (Exhibit 11).

Exhibit 12 is a copy of the request for guidance from Region I which was sent to NMSS in January 1992. According to [redacted] no written response had been provided by NMSS as of January 1993.

[redacted] Nuclear Materials Safety Branch (NMSB), DRSS, Region I, advised that the OSC licensing actions were handled in a routine manner at Region I. [redacted] did not recall any discussion in advance of the issuance of the license and amendment 1. [redacted] first knowledge of a problem with the license occurred around the time that [redacted] submitted the January 1992 request for policy guidance to NMSS. [redacted] felt that it should have been brought to [redacted] attention at an earlier time (Exhibit 13).

OFFICIAL USE ONLY

FINDINGS - ALLEGATION 1

1. The NRC Policy and Guidance Directive (FC 86-4); Information Required for Licensing Remote Afterloading Devices was not followed by Region I in the issuance of the original license to OSC in August 1990.

2. The Region I licensing inspector responsible for the handling of amendment 1 to the OSC license was not aware of the NRC Policy and Guidance Directive (FC 86-4). The licensee should have been required to submit diagrams of the treatment rooms and shielding calculations for the sites added by this amendment.

3. Insufficient information was provided by [redacted] during [redacted] telephone conversation with [redacted] in November 1990 in which the issue of transportation of licensed material was discussed. Moreover, [redacted] should have submitted a formal request for guidance so that NMSS could have made a decision based upon adequate information from the licensee. As a result, all pertinent issues associated with the OSC amendment request were not identified or addressed prior to issuance of license amendment 1.

4. Policy issues related to this license were first raised in Region I in March 1991. In May 1991, the NMSS staff was aware that policy questions had been raised. The Region I written request for NMSS policy guidance was not submitted until January 1992. As of March 1993, policy guidance on the matter had not been provided to Region I.

5. The NRC Policy and Guidance Directive (FC 86-4) is outdated and in need of revision.

6. Amendment 2 to the license which was initially issued in December 1991, revoked the licensee's ability to transport HDR devices and licensed material pending resolution of the mobile services issue. At the direction of an NMSS [redacted] a revision to amendment 2 was issued in January 1992, which restored the licensee's authority to transport the device and radioactive sources. The NMSS [redacted] took no action to assure that the mobile services issue was resolved prior to restoring the licensee's ability to resume transporting the device and sources.

7. The Region I [redacted] said that [redacted] believed in March/April 1991 that the licensee's operation was not permissible under the existing NRC regulations and there were health and safety concerns associated with the lack of documentation provided by the licensee in the application for amendment 1. Additionally, the licensee [redacted] reportedly told the [redacted] during a September 1991 inspection that [redacted] viewed the operation as "high-risk." Despite this, the licensee was permitted to continue operating without restriction.

OFFICIAL USE ONLY

ALLEGATION - 2

This section of the OIG report addresses whether the transportability of the Gamma Med IIi HDR afterloader was properly evaluated prior to the granting of license amendment 1.

As indicated in the previous discussion of the licensing of OSC, amendment 1 was issued by NRC Region I on November 3, 1990. That amendment added five authorized users and five additional treatment locations to the original license. The amended license still listed only one Gamma Med IIi HDR remote afterloading brachytherapy unit. Condition 14 of amendment 1 gave the licensee the authority to transport licensed material in accordance with 10 CFR 71, "Packaging and Transportation of Radioactive Material." Section 19 of the Nuclear Medicine Inspection Field Notes prepared by the NRC Region I inspectors in September 1991, reflect that the source was transported approximately 40 times between April and August 1991.

[redacted] Nucletron Corporation, was contacted in connection with this investigation. [redacted] advised that Nucletron Corporation manufactures HDR remote afterloaders for sale to medical institutions. [redacted] said that [redacted] approached [redacted] from the NRC sometime in about May 1991, with questions concerning OSC's plan to transport a Gamma Med IIi HDR afterloader to various treatment sites. [redacted] explained that the manufacturer of the Gamma Med HDR afterloader was a competitor of Nucletron Corporation and [redacted] salesmen were being questioned as to why Nucletron would not allow their HDR units to be transported to different locations for use in treatments.

[redacted] said that during [redacted] meeting at NRC, [redacted] was not aware that the practice of moving HDR devices between treatment sites had been approved by the NRC. [redacted] then provided [redacted] with a copy of the OSC license which had been obtained by Nucletron through the Freedom of Information Act (FOIA). [redacted] indicated to [redacted] that the matter would be addressed by the NRC. [redacted] said that [redacted] subsequently heard from a source whose identity [redacted] could not recall that OSC had voluntarily ceased transporting the Gamma Med IIi device between treatment sites. [redacted] explained that [redacted] concern with the transport of the Gamma Med IIi device centered around [redacted] belief that the issue of frequent transportation of the device was not considered when the device was originally designed. Although [redacted] had no specific knowledge as to whether the transportation issue was considered during design, [redacted] said that [redacted] is quite familiar with HDR units and believed that the issue was not considered when the device was designed about 14 years ago (Exhibit 14).

[redacted] Sealed Source Safety Section, IMNS, NMSS, confirmed that [redacted] had a conversation with [redacted] from Nucletron concerning a licensee's use of a Gamma Med IIi HDR device in an operation which required transportation of the device between locations. At the time of [redacted] conversation with the

representative from Nucletron, [redacted] believed that the NRC had not approved of the use of an HDR in such an operation. When [redacted] provided [redacted] with a copy of the OSC license which indicated a single device and multiple locations of use, [redacted] surmised that the device was being transported between locations. [redacted] said that he brought the matter to the attention of his [redacted] who was [redacted]

At OIG request, [redacted] provided a copy of the New York State registration for the Gamma Med IIi HDR device (Exhibit 15). After reviewing the registration document, [redacted] advised that there was no indication that the Gamma Med IIi device had been evaluated for suitability of use in an operation requiring frequent transportation. The New York registry was silent on the issue of transportation of the device.

[redacted] indicated that it should not be presumed that a sensitive piece of equipment such as an HDR can be transported on a regular basis and set up for use. Tests and evaluation of the device for that type of use should be conducted [redacted] said that the manufacturer of the equipment normally provides the necessary data for the evaluation. [redacted] described factors which must be considered including the effect of vibrations on the equipment and a discussion of whether the sealed source will be transported inside the device or external to the unit.

[redacted] believed that Region I should have submitted a Technical Assistance Request (TAR) to the Sealed Source Safety Section when the licensee applied to transport the HDR to various sites for treatment. [redacted] section would then have reviewed the device to determine if it could be used in such a manner. [redacted] advised that a later transportable model of the Gamma Med HDR afterloader has been under evaluation by [redacted] section; however, [redacted] believed it was significantly different from the model being used by OSC (Exhibit 16).

When interviewed, [redacted] had no specific recollection of [redacted] bringing this issue to [redacted] attention. However, [redacted] said it was quite possible that [redacted] did so. [redacted] did not feel that the requested action to transport the HDR was a major departure from the manufacturer's intended use of the device [redacted] said that the conditions of use did not appear to differ from those which could have been originally anticipated for the device (Exhibit 17).

[redacted] Division of Industrial and Medical Nuclear Safety (IMNS), said [redacted] was not fully aware of all the developing issues surrounding the OSC license. However, [redacted] acknowledged that the staff should have reviewed the issue of transportability of the HDR device prior to issuing amendment 1. It would have been reasonable for the NRC staff to question whether the device was intended to be transported and to review whether it had been approved for use in a portable mode. In addition, the staff should have reviewed whether the state had evaluated the device for transportability. If there was no record of a review, it would have been appropriate for

either the state or the NRC Sealed Sources and Devices staff to evaluate the device. According to [redacted] the effects of transporting the device and its operability after frequent transportation should have been considered. [redacted] added that the preceding comments were provided retrospectively (Exhibit 18).

[redacted] RTS Technology, Inc., reported that: [redacted] company was a subsidiary of the German firm which manufactures the Gamma Med HDR afterloader. [redacted] identified the manufacturer as Isotopen-Technik Dr. Sauerwein GmbH. [redacted] said that a U.S. firm by the name of Mick Radio-Nuclear handled the sales and service of medical devices at the time the Gamma Med IIi was sold to OSC. [redacted] said that RTS has submitted a more recently developed model of the Gamma Med HDR to the NRC for evaluation of use in a transportable mode. [redacted] described this newer model as significantly different from the Gamma Med IIi which was sold to OSC. [redacted] said that to [redacted] knowledge the model sold to OSC was not specifically designed to be used in a transportable mode. [redacted] added that he did not believe the idea of transporting the HDR unit was considered at the time the Gamma Med IIi was designed. [redacted] said that the unit was never advertised as being suitable for use in a mode which required frequent transport. [redacted] was not aware of any testing performed on the Gamma Med IIi to determine how it would hold up under frequent transportation from site to site (Exhibit 19).

[redacted] Mick Radio-Nuclear, Inc., reported that [redacted] firm handled the initial installation of the Gamma Med IIi HDR afterloader at Harrisburg, PA in September 1990. [redacted] advised that [redacted] dealt with [redacted] during the installation of the device. [redacted] said that [redacted] informed [redacted] of the firm's intent to move the Gamma Med IIi device to different locations for treatment of patients. [redacted] said that [redacted] told [redacted] that the Gamma Med IIi was not designed as a portable device and that [redacted] had concerns about OSC's plan. [redacted] said that [redacted] firm conducted only the initial installation of the device at Harrisburg, PA. [redacted] never installed Gamma Med devices at any other facilities operated by OSC. Any movement of the device from the OSC Harrisburg location was done without the knowledge of [redacted] In [redacted] opinion, anytime the HDR device was moved to another location for treatment, the person making the move should have followed the same procedures as used at the time of an installation. [redacted] said that [redacted] was not certified by [redacted] for installation of the Gamma Med IIi HDR afterloader. [redacted] commented that the only exposure [redacted] had in the installation of the Gamma Med IIi afterloader would have been what [redacted] observed on the one occasion when [redacted] installed the device at Harrisburg. [redacted] advised that no training in installing the device was provided to [redacted] however, [redacted] was provided an installation manual. Representatives from [redacted] were present during a few source exchanges at the Harrisburg site following the initial installation. Source exchanges involved the replacement of a depleted radioactive source with a new radioactive source. [redacted] was authorized to perform that task; however, [redacted] reiterated that a source exchange was different from an installation procedure (Exhibit 20).

(R)

OSC license amendment 1 indicates that licensed material may be transported in accordance with the provisions of 10 CFR 71 (Exhibit 1(g)); however, the amendment is silent on the issue of the transportation of the HDR device. Condition 13 on license amendment 2 which was issued in January 1992, requires that any installation, relocation or removal of the HDR device containing sources shall be performed only by persons specifically licensed by the NRC or an Agreement State. The condition further states that [redacted] may perform any of the above services "for which he has received specific training from a licensed manufacturer's representative" (Exhibit 1(m)).

Licensee training records were not reviewed during the NRC inspection on September 4, 1991. That matter is discussed in more detail under allegation 3.

FINDINGS - ALLEGATION 2

1. No evaluation of the Gamma Med IIi HDR afterloader was conducted in order to determine if it was suitable for use in an operation which included frequent transportation of the device.

2. [redacted] was not specifically trained by a licensed manufacturer's representative on the installation or relocation of the Gamma Med IIi HDR. Therefore, [redacted] did not meet the criteria listed in condition 13 (c) of license amendment 2 as being qualified to install the device following relocation.

3. Licensee training records were not reviewed during the September 1991 inspection by NRC Region I. Had the staff reviewed licensee training records during the inspection, [redacted] lack of training in the areas required to move/reinstall the HDR device may have been detected.

ALLEGATION - 3

This section of the report addresses the issue of whether the September 1991 inspection of OSC by NRC Region I was adequate and conducted in accordance with NRC procedures.

A Region I inspection of OSC was conducted by [redacted] and [redacted] on September 4, 1991. The inspection site was limited to the OSC operation at the Harrisburg Cancer Center, 775 South Arlington Ave., Harrisburg, PA. An inspection report was issued on September 26, 1991, (Exhibit 21), which identified two severity level IV violations. One of the violations dealt with deficiencies in the paperwork required in connection with the transportation of the radioactive source to the various treatment sites. The violation indicates that the licensee had transported radioactive material approximately 40 times between April and August 1991. The second violation dealt with the fact that the [redacted] had not been supplied with a whole body badge by the licensee. The licensee responded to the Notice

of Violation and indicated what corrective action had been taken. The NRC acknowledged the corrective action in January 1992.

Section 2800-04.03 of Manual Chapter 2800, Materials Inspection Program states that initial inspections "shall be conducted of licenses in Inspection Priorities 1 through 5 within six months after material is received and operations under the license have begun" (Exhibit 22). The license was issued in August 1990 and the initial inspection was not conducted until September 1991, a period of 13 months.

[redacted] Region I, NRC, confirmed that [redacted] participated in the inspection of the OSC facility in Harrisburg, PA, along with [redacted] in September 1991. [redacted] explained that [redacted] worked for [redacted] in the Region I Licensing Section at the time of the inspection. [redacted] was aware that a license amendment for OSC was pending at the time which may have influenced the timing of the inspection as well as the fact that it was being conducted by representatives of the licensing section. Additionally, [redacted] was aware that licensing questions had been raised previously concerning whether OSC was operating a mobile brachytherapy service as well as the issue of ownership for the various sites where the OSC treatments were being performed.

[redacted] recalled reviewing the license file at Region I in advance of the inspection. [redacted] asked to see the training records during the inspection at OSC; however, for some reason the records were never reviewed. [redacted] believed that [redacted] may have been diverted to some other aspect of the inspection and never returned to look at the training records.

[redacted] witnessed a conversation between [redacted] and [redacted] in which [redacted] mentioned that an allegation had been made against OSC by representatives from [redacted] could not recall if [redacted] mentioned the alleger by name to [redacted] The allegation is discussed in more detail in allegation 5 of this report. [redacted] said that the inspection identified three violations; however, one of the violations was corrected immediately and not listed on the subsequent Notice of Violation (NOV). [redacted] prepared the inspection report which was subsequently sent to the licensee (Exhibit 23).

[redacted] confirmed that [redacted] was present during the September 1991 inspection at OSC in Harrisburg, PA. [redacted] explained that [redacted] had been anxious to conduct the inspection due to the fact that questions had been raised concerning the nature of the OSC operation. The questions which had been initially raised in the February/March 1991 timeframe centered around the issue of mobile brachytherapy services and the transportation of the HDR afterloader to various treatment locations.

[redacted] reportedly had agreed to notify [redacted] when the HDR afterloader was going to be used at one of the other OSC sites so that an inspection

could be conducted while the machine was being operated away from the Harrisburg Cancer Center. A significant time had elapsed without any such notification, so the decision was made by [redacted] to conduct the inspection at the Harrisburg clinic.

[redacted] primary involvement in the inspection was to observe [redacted] inspection abilities. This stemmed from [redacted] duties as [redacted] supervisor and the requirement to periodically review assigned inspector's work. [redacted] said that [redacted] assisted [redacted] in certain reviews of records. [redacted] acknowledged that [redacted] told [redacted] during the inspection that an allegation had been made against OSC. [redacted] was uncertain if [redacted] provided the alleger's name to [redacted] but believed that [redacted] "more than likely" mentioned the alleger's name or affiliation with a certain [redacted] said that [redacted] realized [redacted] error shortly after making the comment to [redacted] and [redacted] were in agreement on the two violations which were cited. [redacted] acknowledged that [redacted] was surprised during the inspection to learn of the large number of times that the HDR device had been transported by OSC.

An attempt to interview [redacted] regarding this matter was unsuccessful. [redacted] declined to be interviewed due to a separate ongoing investigation involving OSC.

FINDINGS - ALLEGATION 3

1. During the inspection, [redacted] told [redacted] of the filing of an allegation against OSC. It could not be determined if the identity of the alleger was divulged; however, [redacted] believed that [redacted] "more than likely" mentioned the alleger's name or affiliation with a certain medical association.

2. The initial inspection at OSC was not conducted within the six month period specified in Manual Chapter 2800.

ALLEGATION - 4

This section addresses the issue of whether an NRC Region I [redacted] provided preferential treatment to OSC in the handling of license actions.

A file containing copies of various licensing documents related to OSC and maintained at NMSS was reviewed by members of the IIT during the investigation into the incident at Indiana, PA. Contained in the NMSS file were the handwritten notes of [redacted] IMAB, NMSS, relating to [redacted] review of the OSC license file and conversations with Region I [redacted] The notes enumerated certain deficiencies detected by [redacted] in the licensing of OSC activities. Additionally, [redacted] notes reflected a telephone conversation in which [redacted] reportedly made reference to the lack of need for Region I to request additional supporting documents from OSC due to [redacted] confidence that [redacted] operated a safe program. According to

[redacted] said that [redacted] was aware of [redacted] comment to [redacted] regarding the friendship with [redacted] However, based on [redacted] past experience with [redacted] did not feel there was any basis for believing that [redacted] would provide preferential treatment to any licensee (Exhibit 24).

A review of the educational and work experience of [redacted] and [redacted] disclosed that they were both at the University of Delaware, Newark, Delaware, in 1974. At that time, [redacted] was employed at the university while [redacted] was enrolled in a Ph.D. program at the university.

When interviewed by OIG, [redacted] denied any preferential treatment towards [redacted] in connection with the licensing actions for OSC. [redacted] said that [redacted] did not know [redacted] while at the University of Delaware and was not even aware that they were there at the same time in 1974. [redacted] explained [redacted] comment to [redacted] regarding personal friendship with [redacted] as stemming from their mutual involvement in professional health physics societies. [redacted] denied any unofficial involvement with [redacted] outside of activities associated with the societies. [redacted] believed that [redacted] comment to [redacted] concerning the quality of the operation at OSC would have been based on [redacted] awareness of [redacted] professional credentials combined with the knowledge of [redacted] as a person which was gained through their association with the health physics society.

[redacted] said that [redacted] had conducted a previous inspection in the early 1980's of a facility where [redacted] served as the [redacted] and found it to be adequate in all respects. [redacted] denied any attempt to relieve [redacted] of the requirement to submit full documentation in support of license actions. [redacted] said that it was [redacted] decision during the processing of license amendment 2 to require OSC to submit the shielding diagrams for the treatment rooms which had been omitted during the initial processing of license amendment 1. Additionally, [redacted] pointed to [redacted] attempt in license amendment 2 to revoke OSC's ability to transport material as evidence of [redacted] lack of preferential treatment (Exhibit 11).

[redacted] reported that [redacted] assigned [redacted] the responsibility for handling amendment 2 to the OSC license in the summer of 1991. [redacted] recalled that [redacted] directed [redacted] to review the entire OSC license file in order to determine if the previous licensing actions met the NRC requirements. [redacted] viewed this as somewhat unusual since license amendment reviews were usually limited to the issues associated with the pending amendment request. [redacted] felt that the review requested by [redacted] was more thorough than would have been done under normal circumstances. [redacted] also informed [redacted] that the shielding diagrams for the added treatment rooms had not been submitted during an earlier amendment and [redacted] told [redacted] to ensure that the diagrams were requested from the licensee at this time (Exhibit 25).

the notes of the conversation, [redacted] confidence in the safe operation of OSC was based on [redacted] friendship with [redacted] notes contain the following statement: "[redacted] is a personal friend of [redacted] and [redacted] has a great deal of confidence in [redacted]."

When interviewed by OIG, [redacted] advised that in about May 1991, [redacted] was assigned to conduct a review of the NRC policy on brachytherapy with specific emphasis on the question of mobile brachytherapy services. As previously reported, it was [redacted] understanding that the issue of mobile brachytherapy services had been raised at a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) which had included reference to the license held by OSC. [redacted] determined that there was no existing NRC guidance on the allowability of mobile brachytherapy services and 10 CFR Part 35 was silent on the matter. [redacted] evaluated the OSC license file using NRC Policy and Guidance Directive FC 86-4 as the guide for the procedures which should have been followed by Region I in issuing the license to OSC. [redacted] analysis showed several areas where Region I did not follow the Policy and Guidance Directive FC 86-4.

Following review of the licensing actions associated with OSC which disclosed several discrepancies with the existing Policy and Guidance Directive, [redacted] contacted [redacted] in Region I to discuss the deficiencies. It was initially determined that the licensing actions in question had occurred prior to [redacted] assignment as [redacted] reported that during the conversation, [redacted] commented that [redacted] was confident that [redacted] was doing a good job because [redacted] knew [redacted] personally. [redacted] reportedly indicated to [redacted] that the discrepancies did not need to be pursued since [redacted] had confidence in [redacted] impression was that [redacted] considered the matter as "water under the bridge" since the license had already been issued. [redacted] prepared two briefing memoranda containing the results of [redacted] analysis of the licensing package as well as a report of [redacted] comments. The memoranda were provided to [redacted] and [redacted] (Exhibits 3 and 4). A briefing for Division [redacted] on the matter was scheduled and postponed approximately three times; it was never held (Exhibit 5).

During an OIG interview, [redacted] acknowledged that [redacted] informed [redacted] of [redacted] comment concerning [redacted] personal friendship with [redacted] agreed the comment was inappropriate; however, [redacted] did not believe [redacted] would have provided preferential treatment to any licensee. [redacted] believed the comment meant that [redacted] confidence in [redacted] technical ability was based, in part, on [redacted] personal friendship. [redacted] said that [redacted] did not discuss the comment with any of [redacted] superiors at Region I. Additionally, the matter was not referred to the OIG for investigation (Exhibit 10).

An attempt to interview [redacted] regarding this matter was unsuccessful. [redacted] declined to be interviewed by the NRC OIG due to concerns about a separate ongoing investigation involving OSC.

FINDINGS - ALLEGATION 4

1. [redacted] made an improper comment regarding licensing decisions based on a personal friendship with the licensee's [redacted]

2. [redacted] improper comment was reported to NMSS managers by a staff member. However, the NMSS managers failed to report the matter to [redacted] management or the OIG.

3. While the OIG investigation did not substantiate any overt preferential treatment having been provided to the licensee by [redacted] the licensee benefited as a result of NRC's issuance of the license and amendments without full compliance with the existing regulations.

ALLEGATION - 5

This section addresses the NRC Region I handling of an allegation regarding safety concerns associated with the transportation of HDR afterloaders.

A review of the Region I Allegation File concerning allegation number [redacted] revealed a letter dated March 1, 1991, from [redacted] to [redacted] DRSS, Region I. The letter questioned the advisability of transporting an HDR afterloader between various institutions for treatments. The letter expressed concern over the transport of high intensity radioactive seeds in a mobile unit in which adequate protection procedures would be difficult to follow. Additionally, the potential for an accident with resulting damage to the treatment machine was cited. No specific licensee was mentioned in the March 1, 1991 letter (Exhibit 26).

An Allegation Receipt Report was prepared by Region I which contained the following summary of the allegation: "Questions whether transport of HDR and use of the device at a number of facilities is a good idea. Is it safe?" (Exhibit 27). An Allegation Panel was convened at Region I on March 21, 1991, to discuss [redacted] allegation. The panel chairman was [redacted]. Other panel members included [redacted] and [redacted]. The notes of the panel meeting reflect that the following action should be taken to resolve the allegation: [redacted] was to contact a representative from NUCLETRON (a manufacturer of HDR afterloaders) to determine if they had any knowledge of the situation; [redacted] was to contact [redacted] in an attempt to identify the facility involved; and [redacted] was to obtain policy guidance

from NMSS if a license had already been issued which permitted such an operation (Exhibit 28).

The allegation file included a memorandum dated [redacted] which documented an earlier telephone conversation between [redacted] and [redacted] in which [redacted] provided limited and incomplete information regarding the identity of the licensee in question. This memorandum reiterated [redacted] concern about the hazards associated with transporting radioactive sources as well as the possible adverse effects on the HDR device such as misalignment of the machine during shipment. According to the [redacted] memorandum, [redacted] requested confidentiality during the April 29, 1991 telephone conversation. [redacted] directed that the issue of confidentiality be addressed in a subsequent letter to [redacted] (Exhibit 29).

The allegation file also contained a copy of a Region I letter to [redacted], which reported the results of the completed inquiry into the allegation. The response confirmed that OSC had been licensed by NRC and allowed to transport the remote afterloading device between specifically licensed facilities while complying with DOT and NRC regulations. The allegations of [redacted] were essentially found to be without merit. The letter of response also informed [redacted] that [redacted] identity would not be disclosed to the licensee or the public (Exhibit 30).

[redacted] DRSS, Region I, NRC, recalled a meeting with [redacted] to discuss certain aspects of [redacted] operation. At some point in the meeting, [redacted] voiced [redacted] concern about mobile radiation therapy which was reportedly being provided by an NRC licensee. [redacted] recalled that [redacted] did not provide a great deal of detail due to perceived personal liability on his part. [redacted] was uncertain if at any point in the allegation process [redacted] ever identified the licensee being referred to in his allegation. [redacted] was not cognizant of the inquiries at Region I which ultimately led to the identification of OSC as the licensee in question.

[redacted] said that [redacted] was generally aware of the facts which formed the basis for resolution of the allegation. The region's inquiries established that the treatments were not being provided inside a van. Further, the licensee had indicated compliance with all Department of Transportation (DOT) requirements in the transfer of the device to the other sites. [redacted] had no knowledge of any Technical Assistance Request (TAR) asking for NMSS policy guidance on issues associated with this matter (Exhibit 31).

[redacted] advised that [redacted] was present during the [redacted] visit with [redacted] and [redacted] which included a meeting with [redacted] did not participate in any discussion of [redacted] allegation while at the hospital. However, [redacted] subsequently filled out the Allegation Receipt Report and attended the Allegation Panel meeting at the Region I office. [redacted] could not recall ever contacting a representative from NUCLETRON Corporation concerning the allegation as was indicated among the planned actions of the allegation panel (Exhibit 32).

[redacted]

[redacted] reported that [redacted] prepared the notes of the Allegation Panel meeting on [redacted] which included the planned staff action to resolve [redacted] allegation. [redacted] acknowledged adding certain information to [redacted] draft letter to [redacted] concerning the resolution of the allegation. [redacted] said that [redacted] contacted a representative from the Commonwealth of Pennsylvania in order to determine if any licenses had been issued which allowed treatments outside of a specifically licensed facility. [redacted] said that [redacted] prepared no notes of the conversation and was not certain whom [redacted] contacted. [redacted] provided two names of representatives [redacted] may have contacted on the matter [redacted].

[redacted] advised that [redacted] forwarded an allegation to the NRC after learning that an NRC licensee was planning to transport an HDR afterloader to various sites and conduct brachytherapy treatments in a van. [redacted] said that [redacted] was deeply concerned about a licensee's ability to exercise adequate safety and quality control of medical treatment over such an operation. [redacted] described the HDR afterloader as a sensitive instrument which could be adversely affected by frequent transfers over the road from site to site. [redacted] also questioned the manner in which the radioactive sources were going to be transferred between locations. In [redacted] opinion, the above operation was a "disaster waiting to happen." This feeling was due, in part, to [redacted] past involvement with the licensee in question on other matters concerning the quality of medical care.

[redacted] could not recall receiving a letter from the NRC explaining the results of their inquiry into the matter. [redacted] had a conversation with [redacted] from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) in which [redacted] informed [redacted] that the NRC's position was that the Department of Transportation (DOT) regulated the transportation of the radioactive source. [redacted] said that [redacted] has had no contact with any representatives from OSC since the allegation was made (Exhibit 34).

An attempt to interview [redacted] regarding this matter was unsuccessful. [redacted] declined to be interviewed by the NRC OIG due to concerns about a separate ongoing investigation involving OSC.

FINDING - ALLEGATION 5

There is no indication that [redacted] concern over the potential adverse effects caused by the frequent transportation of the HDR device was considered or evaluated by Region I in resolving the allegation.

ALLEGATION - 6

This section addresses whether NMSS is responsive to Regional requests for policy guidance and technical assistance.

As previously reported in Allegation #1, Region I submitted a request to NMSS seeking policy guidance on a number of issues associated with the licensing of OSC. The Region I request was forwarded to NMSS in January 1992, and had not been responded to by March 1993.

OIG attempted to determine if the lack of a timely response in the above case was an isolated instance or if it was indicative of a widespread problem in this area. In pursuing the above issue, OIG conducted a limited review of the systems in place to see if Technical Assistance Requests (TARs) and similar requests for policy guidance from the regions are effectively tracked within NMSS.

[redacted] reported that a manual tracking system for all action items including TARs was initiated sometime in 1990. A computer based system was developed in 1991 and has been partially implemented in the branch. [redacted] said that the [redacted] is responsible for logging in each TAR and assigning a sequential number [redacted] in turn, forwards the TAR to the appropriate section leader who ultimately assigns the work to the staff member. The TAR is normally assigned to the staff member who possesses expertise in the subject area in question. The staff relies on corporate memory to determine if the particular issue has been addressed in a previous TAR or other related document.

According to [redacted] there is an informal goal for responding to TARs within 60 days of receipt. This deadline is not followed closely, however, due to the complexity of issues associated with many of the TARs and the requirement for study as well as coordination with other offices. Section Leaders are responsible for the tracking of the pending TARs [redacted] estimated that 100 to 200 TARs are received in IMAB on an annual basis. The current procedure calls for the TAR responses to be coordinated with the Office of the General Counsel (OGC) which adds time to the process. [redacted] explained that copies of the TAR responses are routinely provided to all NRC Regions (Exhibit 35).

[redacted] IMAB, stated that pending TARs are discussed during general section meetings as well as with the individual staff member assigned to work on a particular TAR. [redacted] said that several times each month [redacted] personally reviews a computer listing of pending TARs in [redacted] section. [redacted] typically assigns a due date of 30 days following receipt of a TAR; however, [redacted] acknowledged that deadline is not strictly followed. [redacted] added that when [redacted] initially assumed [redacted] position, TARs were logged but not tracked to completion. As a result, some items had been pending for as long as five years (Exhibit 24).

The Nuclear Material Safety Branch in each of the Regions was contacted and requested to provide a listing of the pending TARs in their respective offices as of March 1993. IMAB was also requested to provide a list of the pending TARs being tracked within the

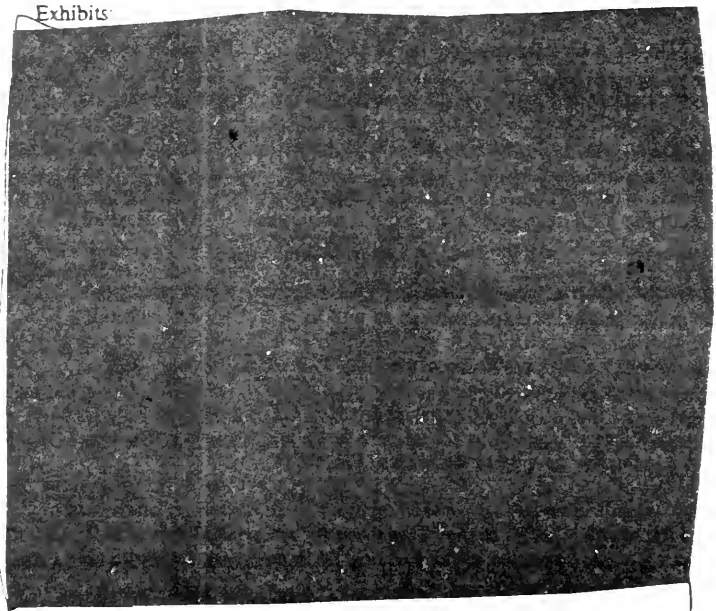
Branch at NRC Headquarters. A comparison of the Region submissions with the Branch listing disclosed significant discrepancies.

The information provided by the Regions reflected a total of 62 pending TARs as of March 1993, including several from 1990 and 1991. The IMAB computer listing reflected only 30 pending TARs as of March 17, 1993. Eighteen TARs did not appear on the list of pending TAR's but were being tracked in another action item list maintained by the Branch. Some TARs appeared as pending on the IMAB list but were not included on the Region submission. Approximately seven TARs reflected a "closed" status on the IMAB listing but were being carried as pending issues by the Regions. Exhibits 36 and 37 are a summary of the review conducted by the OIG regarding this issue.

FINDING - ALLEGATION 6

There is no effective system in place within NMSS for the tracking of requests from NRC Regions for policy guidance or technical assistance. Some of the requests have been pending since 1990. There is significant disagreement between the Regions and IMAB as to which TARs are pending.

Exhibits



OFFICE OF THE INSPECTOR GENERAL
REPORT OF INVESTIGATION

INADEQUATE INSPECTION AND MISHANDLING
OF ALLEGATIONS BY REGION I

CASE NO. 91-076G

TABLE OF CONTENTS

SUBJECT

STATUTES AND REGULATIONS

10 C.F.R. Part O.735-3
Responsibilities and Authorities

NRC Inspection Manual Chapter 2800
Materials Inspection Program

NRC Manual Chapter 0517
Management of Allegations

5

SYNOPSIS

This investigation was initiated by the Office of the Inspector General (OIG) based upon allegations made by [redacted] of Nuclear Energy Services (NES), a consulting services firm, that also specializes in the handling and transport of radioactive material. [redacted] stated that on June 26, 1990, he presented his concerns of radiological safety violations discovered during [redacted] NES to [redacted] Region I and [redacted] Region I. Specifically, [redacted] reported to Region I that NES did not have a Radiation Safety Officer (RSO), failed to post its license and NRC Form 3s (Notice of Rights and Protection as Licensee Employees) at the Danbury, Connecticut facility, and improperly stored radioactive material. On July 24, 1990, a team from Region I conducted an inspection at NES Headquarters, Danbury, Connecticut to address [redacted] concerns. The inspection determined there were no radiological safety violations at NES. Upon receiving this information, [redacted] purported that the Region I inspection was inadequate and incomplete.

The OIG investigation disclosed that [redacted] allegations as presented to Region I were not fully and adequately examined in the July 24, 1990 inspection. Further, the inspectors did not interview witnesses to [redacted] allegations, other than the president of NES and one other NES employee. [redacted] acknowledged that [redacted] provided names of witnesses who could corroborate his claims, however, [redacted] did not contact those individuals. The OIG investigation also determined that the inspection failed to address [redacted] concern regarding improperly stored radioactive material.

The OIG investigation determined that the Region I inspection report (No. 90-001) provided limited findings due to the belief of [redacted] and the inspectors that no licensed activities had taken place at NES. There were issues which were not examined in detail because the inspectors believed NES was not working under the authorization of its license, but rather under the license of clients for whom they were shipping or handling radioactive material. Neither [redacted] nor the inspectors made an attempt to substantiate the NES claim that they were not performing licensed activities under the NES license.

OIG obtained documents that verified NES had, in fact, performed services under the auspices of its license contrary to the belief of [redacted] and the inspectors. Some of these documents were located in the NRC docket file on NES, at Region I. Two of the documents which showed that the NES license had been active consisted of correspondence between [redacted] and NES. In addition, [redacted] mentioned one event in which NES had utilized its license in his Allegation Interview Report, dated June 20, 1990.

A second inspection by Region I, conducted from January to June 1992, examined NES license activities as they related to radiation safety and compliance with NRC regulations and the license conditions. The second inspection revealed that the July 1990 inspection incorrectly stated there had been no use of radioactive material under the NES license. Further, it was disclosed that NES committed seven violations.

7

BACKGROUND

On August 30, 1985, the NRC issued NES a license to possess specified quantities of by-product material and source material. The license authorizes use of these materials for: 1) performing maintenance, repair and/or decontamination of tools, equipment, and containers; 2) analyzing samples; 3) checking instruments; and 4) packaging and transporting of licensed materials. Use of the license is restricted to temporary job sites of the licensee anywhere in the United States where the NRC maintains jurisdiction for regulating the use of licensed material. In addition, the licensee is restricted from the possession or use of licensed material at licensed customer facilities or licensed customer temporary job sites except as specifically authorized under that customer's license. The licensee is required to notify NRC Region I, in writing, three days prior to the establishment of a temporary job site and to submit surveys to the NRC prior to release of the job site for unrestricted use.

8

BASIS

This investigation was initiated by the Office of the Inspector General (OIG) based upon information provided by [redacted] Nuclear Energy Services (NES) to the OIG hotline in November 1990. [redacted] advised OIG that he had reported safety concerns at NES to Region I via letters, telephone conversations and a formal meeting with [redacted] Region I. [redacted] related that an inspection was conducted to address his concerns. [redacted] alleged that the Region I inspection was inadequate and did not completely address his allegations (Exhibit 1).

DETAILS

[redacted] advised that he reported to Region I three primary concerns discovered during [redacted] NES: 1) NES did not have a Radiation Safety Officer (RSO) for approximately eight months; 2) NES failed to post its license and NRC Form 3s, at the NES Danbury facility; 3) NES had radioactive material stored in unsecured locations on at least two occasions resulting in exposure to untrained staff personnel. [redacted] believed these actions by NES were in violation of the license issued by the NRC (Exhibits 2, 3 and 4).

As a result of [redacted] original allegations, an inspection was conducted by Region I on July 24, 1990. Subsequently, [redacted] received a letter and inspection report (No. 90-001), dated October 26, 1990, from Region I, which indicated that no violations were found at NES (Exhibits 5 and 6). [redacted] stated that he severely questioned the conclusions of the inspection and its thoroughness. After reviewing inspection report no. 90-001, [redacted] concluded that the NRC ignored his safety concerns. According to [redacted] his knowledge of NES indicated a disregard of safety procedures and NRC regulations.

[redacted] advised that he learned from a former NES colleague that the July 24, 1990 Region I inspection was a "mosquito bite", lasting only four hours. After receiving this information, [redacted] telephoned [redacted] to inquire about the inspection. According to [redacted] confirmed that the inspection lasted four hours. In addition, [redacted] stated that [redacted] expressed personal frustration about the scope of the inspection. According to [redacted] stated that NES had not conducted any regulated activities under its license, therefore the scope of the NRC inspection was limited. [redacted] noted that the Region I inspection report contained a similar statement as that made by [redacted] The inspection report stated: "The licensee has not performed any services nor has it possessed any licensable radioactive material under this license."

[redacted] stated that he disagreed with the inspection report concerning the lack of activity by NES under its license. [redacted] provided three letters dated February 28, 1989, May 31, 1989, and March 27, 1990, respectively as examples of correspondence between NES and the NRC documenting that the NES license had been active (Exhibits 7, 8 and 9). He added that two of the letters were addressed to [redacted] emphasized that the NES violations covered approximately five years and was during a period that he believed the NES license was active.

[redacted] added that the July 1990 inspection report did not address his primary concerns. [redacted] advised that NES was without an RSO from September 1989 to April 1990. He related that during the period when NES had no RSO, radioactive materials were received by NES and improperly stored in an accounting safe used to store payroll and employment records. According to [redacted] the NES license requires that any radioactive materials received by NES at the Danbury facility be verified by the RSO. Further, [redacted] stated that since the previous [redacted] vacated [redacted] position with NES, time had lapsed before the present [redacted] was appointed. [redacted] added that [redacted] was improperly appointed by [redacted] for NES. He explained that the NES policy and procedures manual, approved by the NRC, required that the RSO be appointed by the Radiation Safety Committee.

[redacted] maintained that the NRC inspection report did not cite NES with a violation for the period NES did not have an RSO or for the improper appointment of [redacted] The inspection report stated that: "During the period of time that [redacted] vacated the position and [redacted] assumed the duties there was no work being conducted under this license." [redacted] reiterated the NES license was active during this timeframe and he stated that the Region I inspectors appeared to accept NES answers without question.

With regard to his allegation that NES failed to post NRC Form 3s and its license, [redacted] advised that Section 2.5 of the report stated: "Inspectors saw the required notices, such as Form NRC-3, were posted." [redacted] explained that he learned NES posted the required forms after he was fired on May 21, 1990. According to [redacted] he notified [redacted] Region I by letter that NES posted the required forms after his termination and prior to the July inspection (Exhibit 10). Additionally, [redacted] offered to provide names of witnesses who could corroborate his statement that the forms were not posted prior to his notifying NES that they were in violation of their license requirements. According to [redacted] Region I did not contact him to obtain the witnesses' names.

[redacted] stated that the allegation that radioactive material was being stored in unsecured locations seemed to be completely ignored by Region I. [redacted] advised that NES' own procedure, approved by the NRC, stated that all calibration

sources which routinely are less than license limits must be stored in a controlled area. [redacted] said that one employee found at least a gallon of radioactive material in the parking lot. In addition, [redacted] said that he found what appeared to be four calibration sources in an uncontrolled accounting safe. Further, [redacted] advised that [redacted] employee discovered the radioactive material in the accounting safe. Section 2.2 of the inspection report stated: "The licensee's evaluation of this incident concluded that the sources were exempt from licensing. No violations were identified."

[redacted] Region I recalled that approximately two years ago [redacted] contacted Region I with allegations against NES. At that time, [redacted] Region I. [redacted] stated that upon being informed of [redacted] concerns, [redacted] accepted [redacted] offer to meet and discuss the allegations. After listening to [redacted] concerns, [redacted] said that [redacted] immediately assessed that there were no health and safety concerns present (Exhibits 11 and 12).

[redacted] stated that as a result of [redacted] allegations and the fact that NES had not been inspected for sometime, an inspection was scheduled at the NES headquarters office in Danbury, Connecticut. [redacted] said that [redacted] was largely responsible for the decisions made concerning the handling of [redacted] allegations. [redacted] directed [redacted] and [redacted] to review [redacted] allegations and to verify whether or not NES was acting in accordance with all license requirements.

[redacted] advised that [redacted] and [redacted] conducted an inspection on July 24, 1990. The inspection was supposed to be unannounced. However, [redacted] believed that [redacted] may have surmised that an inspection was forthcoming as there were telephone contacts with [redacted] after receipt of [redacted] allegations. The purpose of these contacts was to establish whether there was recent activity by NES under its license. [redacted] informed that the inspectors did not tell [redacted] the reason for the inspection. According to [redacted] "What we did was essentially did the inspection to verify to a reasonable extent, to a reasonable ability, whether or not there was any substance to those allegations and close [them] out" (Exhibit 11 Pg. 37).

[redacted] stated that sometime during the inspection [redacted] and [redacted] called [redacted] for advice. [redacted] did not recall the specifics of the conversation, however [redacted] remembered providing direction to the inspectors concerning NES' licensed activity. [redacted] told the inspectors to continue conducting a routine inspection and verify that NES had not performed any activities under the license. According to [redacted] the inspectors were instructed to verify whether or not there had been any licensed activity by NES through an examination of records and by talking to the NES staff. [redacted] maintained that [redacted] was not aware of any documentation which indicated licensed

activities took place at the NES Danbury facility. [redacted] did not recall reviewing the NRC Region I docket file on NES. [redacted] added that [redacted] did not personally check the NES records because that was the responsibility of the inspectors.

[redacted] advised that the inspectors observed the NES facility, reviewed NES files and spoke with NES employees regarding [redacted] concerns. According to [redacted] the inspection did not reveal any evidence of NES' license being active. [redacted] acknowledged that [redacted] provided names of witnesses to support his allegations, however [redacted] did not know if those individuals were contacted by the inspectors. [redacted] stated that the inspectors determined that while NES had a license and it provided for possession, use and handling of radioactive material, NES never really exercised the license. Further, the inspectors purported that any work NES did involving radioactive material was done under the auspices of clients' licenses. Consequently, no radiological health and safety inadequacies were found. These findings were documented in the inspection report. [redacted] maintained that [redacted] concerns were not valid since NES had not performed any work under the auspices of its own license.

[redacted] emphasized that the primary focus of the inspection was on immediate health and safety issues and that [redacted] concerns did not fall into this category. The inspection report reflected that since no licensed activities were performed at the NES Danbury facility, there was no need for NES to establish an RSO or to post NRC Form 3s. [redacted] advised that the radioactive material [redacted] identified as improperly stored was determined to be exempt from licensing. [redacted] said that the inspectors reported that the sources in the accounting safe were not licensable quantities of radioactive material.

In further response to [redacted] allegation that Form 3s were not being posted at NES, [redacted] stated that Form 3s, by regulation, are required to be posted at the job site where licensed activities take place. However, [redacted] explained no licensed activities took place at the NES Danbury site, therefore Form 3s were not required to be posted. Title 10 Code of Federal Regulations 19.11, "Posting of notices to workers," states in paragraph (d), "Documents, notices, or forms posted pursuant to this section shall appear in a sufficient number of places to permit individuals engaged in licensed activities to observe them on the way to or from any particular licensed activity location to which the document applies, shall be conspicuous, and shall be replaced if defaced or altered" (Exhibit 13). [redacted] interpreted this to mean that Form 3s were only required at the place of work where licensed activities were being performed.

[redacted] acknowledged that the inspection report indicated Form 3s were posted as required. However, [redacted] believed that the statement in the report was erroneous because Form 3s were not required. According to [redacted] the inspectors observed Form 3s posted at the Danbury facility. [redacted] opined that some time after [redacted] made allegations and before the July inspection, the Form 3s were probably posted.

However [redacted] explained that: "There were no licensed activities taking place at that location so it was not required by regulations so the fact that Form 3s were posted there is incidental" (Exhibit 11 Pg. 20).

[redacted] said that in [redacted] view, [redacted] allegations were completely and adequately addressed in the July 1990 inspection. [redacted] concluded that the inspection findings were accurate since [redacted] was not aware of any documentation indicating NES had performed work utilizing its license. [redacted] advised that the inspection report was factual and [redacted] concurred with the findings.

OIG showed [redacted] copies of three letters regarding NES activities during the period covered by the inspection. The letters, dated February 28, 1989, May 31, 1989 and March 27, 1990, were purported by [redacted] to show NES had performed various activities under the auspices of their license (Exhibits 7, 8 and 9). After reviewing the letters, [redacted] stated [redacted] had not been aware of their existence.

With respect to the February 28, 1989 letter, [redacted] said that [redacted] did not believe the letter indicated the NES license was active. The May 31, 1989 letter was from [redacted] to [redacted] acknowledged that the letter made it appear that activity authorized by the NES license had occurred. However, [redacted] stated the letter did not reference what type of work occurred or which NES job site was involved. [redacted] stated that the aforesaid was also true of the March 27, 1990 letter by [redacted] said that [redacted] believed the letter referred to work NES performed under a client's license. However, [redacted] related that the letter did not state what type of activity required NES to possess radioactive material or the job site where the material was located.

[redacted] informed that the job site in which activities occurred under the NES license was significant to the inspection process [redacted] explained that if work referenced in the May 1989 and March 1990 letters was performed at the NES Danbury facility then the inspectors should have uncovered the activities. [redacted] believed that the work most likely was performed at an NES off-site facility.

OIG discussed the three letters with [redacted] Region I. [redacted] related that the letters were all standard forms written by either NES or NRC referencing recent NES activities authorized by the NRC license (Exhibit 14).

Regarding the February 28, 1989 letter, [redacted] stated that the details of this letter were somewhat ambiguous. [redacted] acknowledged that the phrase "...please be advised that Nuclear Energy Services will use it's license to ship one (1) Co-60 Irradiator within the Model No. NES-5 Shipping Cask, Certificate of Compliance No. 9193," gives the appearance that work was performed under the license. However [redacted] explained that the licensed activity could have taken place at another facility, Arthur D. LITTLE

(ADL), 20 Acorn Park, Cambridge Massachusetts, which also has a license for such activity. [redacted] stated that the work performed could have been conducted under either the NES license or the ADL license. [redacted] stated that further review of the actual activity was necessary in order to know whose license was used.

In discussing the May 31, 1989 letter, [redacted] said that the activities outlined in the letter were not clear. According to [redacted] the letter does not state if any licensed activity occurred at NES.

[redacted] advised that the March 27, 1990, letter was the result of a telephone inquiry by [redacted] at the time. With respect to the details of the March letter, [redacted] stated the letter indicates the NES license was active. He noted that NES indicated they were in possession of radioactive materials as of the date of the telephone call.

OIG obtained the technical services agreement between ADL, the company referenced in the February 28, 1989 letter, and NES (Exhibit 15). The February 1989 agreement indicated NES would provide consulting, licensing support, technical and cask rental services as requested by ADL. Section 2.7, NES' BY-PRODUCT MATERIALS LICENSE USAGE of the agreement stated: "NES will activate its License No. 06-20775-01 in accordance with license condition No. 17, and will perform the required shipment brokerage services under the subject license." Further, Section 2.7, FIXED PRICE: License Usage Fee: $12,500.00, stated: "Above fee is inclusive of all costs associated with the activation, notification and upkeep procedures of NES' By-Product materials license."

[redacted] for ADL, recalled the period when NES performed the aforementioned work for ADL. [redacted] related that at the time, ADL did not have an approved Quality Assurance (QA) program authorizing them to handle the Co-60 irradiator shipment. According to [redacted] NES had an NRC approved QA program so they were used to ship the Co-60 irradiator. [redacted] maintained that a special condition and expense was placed in the NES proposal to ADL because of ADL's shipping restriction (Exhibit 16).

OIG obtained the "Chronology of communications regarding NES [redacted] from [redacted] Region I (Exhibit 17). The chronology documented the May 31, 1989 letter from [redacted] to [redacted] as confirming that work done under the NES license at the Newburgh Heights, Ohio site (Chemetron) would not involve open containers of material. The May 10, 1989 letter referred to in the May 31st letter was from [redacted] to [redacted] notifying NRC of NES' intent to utilize its license at the Chemetron site in Newburgh Heights, Ohio (Exhibit 18). Exhibit 19 is the telephone inquiry referred to in the May 31, 1989 letter. The telephone call was made by [redacted] NES, to an unknown NRC inspector regarding two uses of the NES license.

[redacted] Region I, recalled making the telephone inquiry to NES referenced in the March 27, 1990 letter. In [redacted] view the NES license was active and believed the letter verifies that NES used its license. [redacted] explained that if the information contained in the letter was incorrect, NES would have written back to NRC Region I correcting the information (Exhibit 20).

[redacted] Region I advised that he initially received [redacted] allegations concerning NES. [redacted] documented [redacted] information in an "Allegation Interview Report" (Exhibit 21). [redacted] recalled [redacted] alleged that NES was in violation of several NRC codes and regulations, some for the past five years. [redacted] immediately informed [redacted] supervisor, [redacted] of the allegations. [redacted] was directed to form an allegation panel to discuss how Region I was going to proceed regarding the allegations. During this period, [redacted] met with [redacted] and [redacted] and documented his concerns in a formal presentation. According to [redacted] the panel decided that an inspection of NES was needed to pursue any health and safety issues (Exhibit 22).

[redacted] stated that in preparation for the inspection [redacted] reviewed the NRC docket file for NES. [redacted] advised that the file revealed that NES had not been inspected in several years, although NES was due for inspection on an annual basis. [redacted] explained that NES had not been inspected because they had not performed any work under the auspices of the license. [redacted] recalled that the file contained a few letters documenting projects NES conducted utilizing the licenses of others. Consequently, [redacted] approached the inspection believing that the NES license was not active.

In July 1990, [redacted] and [redacted] conducted an inspection of the NES Danbury, Connecticut facility. [redacted] stated that upon arriving at the NES facility they spoke with [redacted] was the primary source of information during the inspection. [redacted] told the inspectors that NES had not performed any work under their license, instead NES had worked under the auspices of their clients' licenses.

[redacted] stated that the inspection ended relatively soon after receiving confirmation from [redacted] that NES did not have to adhere to the conditions of its license if no work had been performed under the license. In [redacted] view, [redacted] concerns had been fully examined within the context of the inspection. However, [redacted] did not recall speaking to anyone who had been with NES five years ago to confirm [redacted] allegations. [redacted] acknowledged that [redacted] provided witnesses who could corroborate his claims, but [redacted] did not contact those individuals.

[redacted] and [redacted] briefed [redacted] on their inspection findings. According to [redacted] and [redacted] recommended that NES' clients be contacted to confirm that NES had worked under the clients' licenses. However, there was no effort made by NRC management to contact NES' clients nor was it suggested that [redacted] should do so. [redacted] advised that [redacted] and [redacted] were in agreement with the inspection findings and that [redacted] claims could not be supported. [redacted] stated that based on the conversations with [redacted] a review of the NES records, and the fact that NES had not conducted work under the auspices of its license, [redacted] allegations could not be substantiated.

[redacted] acknowledged that [redacted] concurred with Region I management's recommendation not to make the RSO allegation a violation. [redacted] opined that this decision was due to the section being over-worked and understaffed, the lack of any health and safety significance and the matter being identified by the licensee. [redacted] stated that in retrospect [redacted] should have documented NES' lack of an RSO as a violation because the issue arose as an allegation.

[redacted] Region I was interviewed. [redacted] said that [redacted] became aware of [redacted] allegations from attending the allegation panel meeting. [redacted] recalled the allegation panel decided that an inspection was needed to address [redacted] concerns. [redacted] noted that a full inspection was recommended since there were other elements to be examined in addition to [redacted] concerns. [redacted] recalled reviewing the docket file on NES prior to the inspection. [redacted] did not recall seeing any documents in the file indicating that the NES license was active (Exhibits 23, 24 and 25).

[redacted] stated that upon arriving at NES, [redacted] and [redacted] spoke to [redacted] confronted the inspectors stating: "I know why you are here." [redacted] recalled that the inspection was difficult to conduct because many documents requested were not located at NES, and few NES employees were present. Further, [redacted] indicated that NES had not utilized its license.

[redacted] recalled that the NES records initially reviewed during the inspection indicated the NES license had not been utilized. However, [redacted] subsequently found some NES documents that indicated NES had performed work in NRC's Region III area. [redacted] noted that the NES work performed in the Region III area was conducted under the auspices of NES' client's license. In addition, [redacted] was told by [redacted] that the work conducted by NES was under the auspices of their client's license and therefore NES did not have to adhere to its own license requirements. [redacted] maintained that [redacted] contacted [redacted] supervisor, [redacted] for confirmation of [redacted] statement. According to [redacted] stated that [redacted] was correct.

[redacted] said that when [redacted] and [redacted] were advised NES did not have to adhere to its license requirements, they basically terminated the inspection. [redacted] acknowledged that there were a number of issues which were not examined in detail because they believed NES was not working under the authorization of its license. [redacted] concluded that the NES license had not been active based primarily on discussions with [redacted] said [redacted] was not aware [redacted] provided names of witnesses to support his allegations. [redacted] said that [redacted] was aware of the alleged incident involving radioactive material in the parking lot, however, [redacted] did not recall reviewing this matter during the inspection.

With regard to [redacted] allegation of improper storage, [redacted] stated that the sources found in the accounting safe were exempted quantities. According to [redacted] provided the information about the calibration sources, which led [redacted] to conclude that the sources were exempt from the NRC license requirements. [redacted] related that survey meters were used to check the area where the radioactive material was stored and nothing was found in the surrounding area. [redacted] added that [redacted] did not believe there were any radiological problems at the time. [redacted] said that [redacted] and [redacted] subsequently briefed [redacted] on the NES inspection. According to [redacted] and [redacted] informed [redacted] that NES had performed work under their clients' licenses, most of which were located in NRC's Region III area. [redacted] advised [redacted] of the limited inspection due to the NES license not being active and recommended having a Region III inspector confirm NES' work under their clients' licenses. [redacted] added that to the best of [redacted] knowledge the recommendation was not acted upon.

[redacted] Region I maintained that [redacted] had frequent telephone conversations with [redacted] concerning NES. [redacted] advised that during the period [redacted] allegations were made [redacted] was [redacted] stated that [redacted] immediately examined [redacted] allegations to discern whether there were any safety implications, and [redacted] believed there were none [redacted] decided with other Region I officials that an on-site inspection was appropriate, however the inspection was of low priority due to the low safety concern (Exhibit 26).

[redacted] explained that the inspection was limited because NES had not possessed sufficient quantities of radioactive material during the timeframe of [redacted] allegations. [redacted] believed that NES had not performed any activities under its license, except for a small shipment of materials to the University of Cincinnati. According to [redacted] there was no reason to doubt the inspectors' observations and findings, thus [redacted] was satisfied with the conclusions of the inspection. [redacted] said that the main concern of the inspection was to determine whether there was any safety significance. [redacted] said that in [redacted] opinion the allegations had no safety significance and Region I had been responsive to [redacted] concerns.

[redacted] Region I, stated that the July 1990 inspection of NES was conducted to address [redacted] allegations. [redacted] believed the inspection was sufficient and noted it did not detect any health and safety violations (Exhibit 27).

[redacted] advised that great emphasis was placed on the observations of the inspectors during the July 1990 inspection. [redacted] related that the inspectors wrote their findings based on their observations and DRSS management concurred. [redacted] believed the two inspectors to be very competent. [redacted] stated that if the July 1990 inspection were done again, given the same circumstances and [redacted] allegations, [redacted] would be satisfied with the manner in which the inspection was conducted. However, [redacted] said: "I would have liked a more thorough inspection."

[redacted] opined that a more thorough inspection was needed to resolve a couple of issues. One of the issues [redacted] referred to was [redacted] allegation that NES had not posted Form 3s for the past five years. [redacted] stated [redacted] would have liked the inspectors to pursue the issue further. However, [redacted] said [redacted] believed the concern of whether or not the Form 3s were posted at NES in the past was an integrity issue and if the Form 3s were not posted in the past it would not necessarily be a violation.

[redacted] advised that a second inspection at NES began in January 1992. [redacted] stated that the January inspection was prompted by congressional interest in [redacted] original allegations against NES. According to [redacted] and Region I management believed a second inspection was needed to answer questions posed by Congress and [redacted] added that [redacted] "wanted this [January 1992] inspection to be as thorough as possible to address any future problems [redacted] may bring up".

[redacted] Region I, stated that in the spring of 1991 [redacted] became aware of [redacted] safety allegations against NES. [redacted] became involved in the matter regarding [redacted] allegations due to congressional interest. [redacted] advised that congressional interest caused Region I to examine NES and [redacted] issues in a more in-depth manner (Exhibit 28).

[redacted] provided OIG with a briefing regarding the January 1992 inspection conclusions. [redacted] related that a major finding of the January inspection was that licensed activities were discovered to have taken place at NES. [redacted] said that the statement contained in the July 1990 inspection report, "The licensee has not performed any services nor has it possessed any licensable radioactive material under this license" was a "major mis-statement." [redacted] added that the July 1990 inspection was limited in scope because the inspectors reported no licensed activities had taken place at NES. [redacted] concluded that the inaccurate statement set the tone for the rest of the conclusions of the inspection.

[redacted] acknowledged that some of the issues alleged by [redacted] that were not identified as violations in the first inspection were found to be violations in the second inspection. According to [redacted] the January 1992 inspection at NES revealed seven violations. One of the violations disclosed was the lack of an RSO at NES for a period of time.

[redacted] stated that [redacted] allegation that Form 3s were not posted at NES in the past was neither confirmed nor denied by the January 1992 inspection. [redacted] informed that the NES staff interviewed by Region I related differing stories about the posting of Form 3s. Therefore, the January 1992 inspection did not find conclusive evidence to substantiate whether or not Form 3s were posted at NES in the past.

[redacted] advised that [redacted] concern has always been that [redacted] allegations were not fully examined. [redacted] maintained that [redacted] was concerned with the adequacy of the July 1990 inspection. [redacted] stated that the inspectors took a "snapshot" of NES on the day of the inspection, therefore they could not have addressed [redacted] concerns regarding past incidents.

Although [redacted] said [redacted] believed the July 1990 inspection was not thorough, [redacted] believed the Region I staff followed the proper procedures in handling [redacted] allegations. [redacted] stated that the staff complied with Manual Chapter 0517, "Management of Allegations."

[redacted] conducted the January 1992 inspection at NES. [redacted] related that [redacted] was not involved with the July 1990 inspection and had no knowledge of it until assigned to conduct the second inspection. Upon being assigned the January 1992 inspection, [redacted] reviewed the NRC docket file on NES. [redacted] noted there were a few documents that indicated NES had conducted work under the auspices of its license (Exhibit 29).

[redacted] stated that the major difference between the July 1990 inspection and the January 1992 inspection was how NES license requirements were interpreted. [redacted] opined that the July inspection oversimplified the license requirements in the "Scope of Activities Section." [redacted] maintained that the NRC approved license provisions were complicated and very restrictive. [redacted] added that it was "just plain error that they thought the license hadn't been used."

The second inspection of the activities of NES License No. 06-20775-01 was conducted from January 9 until June 11, 1992. The inspection consisted of observations by [redacted] interviews with NES personnel, and a review of selected NES records. The inspection report (No. 92-001) concluded: "Based on the results of the January inspection, it appears that your activities have not been conducted in full compliance with NRC requirements." The report identified seven violations at NES. One of the

violations cited was a failure of NES to have an NRC approved RSO from September 2, 1989 until June 9, 1990. In addition, NES was cited because the Radiation Safety Committee did not review all NES activities. Specifically, the committee did not review the ADL project in Cambridge, Massachusetts and the Chemetron project in Newburgh Heights, Ohio, prior to initiation of licensed activities (Exhibit 30).

FINDINGS

The OIG investigation disclosed that [redacted] allegations as presented to Region I were not fully and adequately examined in the July 24, 1990 inspection. The inspection did not consider [redacted] allegations as they related to the past. The inspection did not consider witnesses to [redacted] allegations, other than [redacted] and one other NES employee. [redacted] acknowledged that [redacted] provided a list of witnesses who could corroborate his claims, however, [redacted] did not contact those individuals.

The inspection neglected to address [redacted] concern of improperly stored material. The inspection did not verify whether or not the radioactive sources stored in the NES accounting safe were exempt quantities. The inspection concluded the sources were exempted from licensing based solely on the licensee's evaluation of the incident.

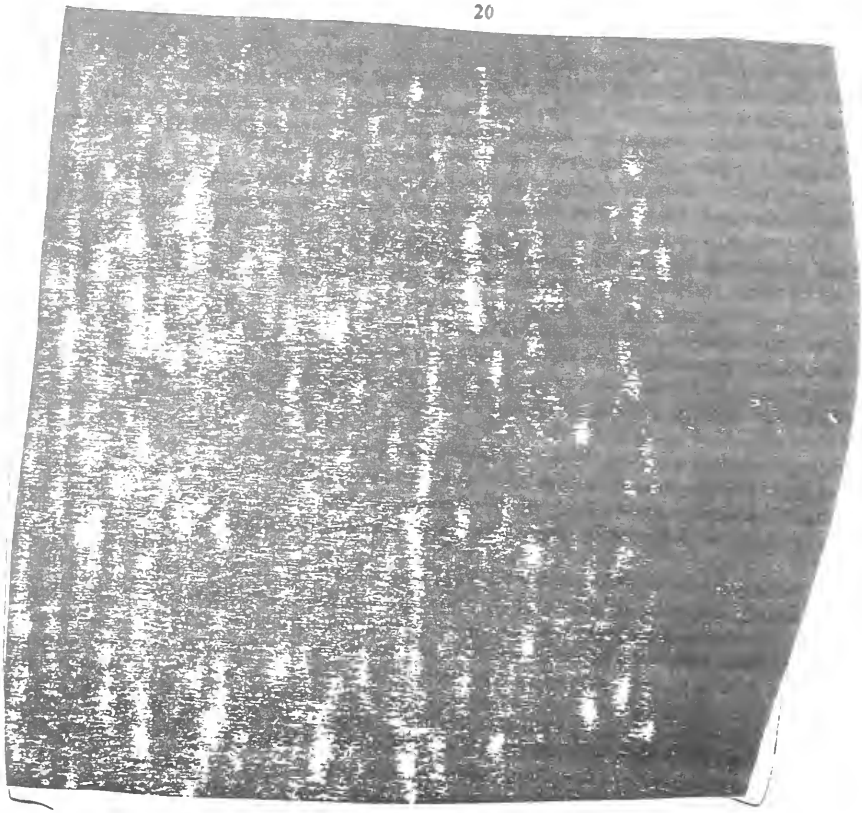
OIG obtained documents indicating that NES had performed services under the auspices of its license. These are documents which were located in the NRC Region I docket file that the inspectors stated they had reviewed. Two of these documents were correspondence between [redacted] and NES.

The January 1992 inspection disclosed that the July 1990 inspection incorrectly stated that there had been no use of radioactive material under the NES license. [redacted] and [redacted] thought that since NES did not possess radioactive material under its license, NES did not have to fulfill all license requirements. [redacted] maintained that [redacted] concerns were not valid since NES had not performed any work under the auspices of its license. [redacted] acknowledged that there were a number of issues which were not examined in detail because NES was not working under the authorization of its license.

The Region I inspection at NES in July 1990 did not adequately address [redacted] allegations. This failure was due to inaccurate assumptions by Region I managers and inspectors as to the status of the NES license. Documents contained in the Region I docket file on NES contradicted the assurances made by the NES President to NRC inspectors.

Exhibits:

[redacted] O/S


20

OFFICIAL USE ONLY

OFFICE OF THE INSPECTOR GENERAL
REPORT OF INVESTIGATION

CONFLICT OF INTEREST INVOLVING NRC EMPLOYEES
AND NUCLEAR ENERGY SERVICES

CASE NO. 91-72A

[redacted]

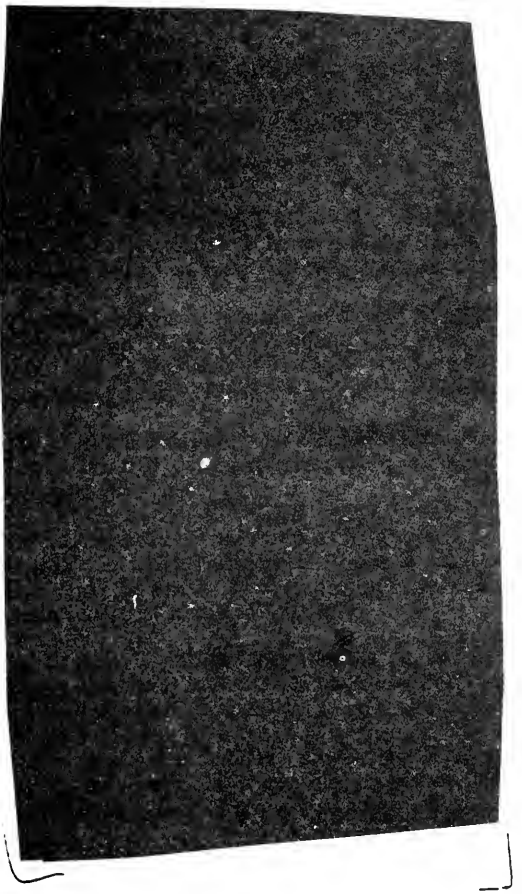
THIS REPORT IS THE PROPERTY OF THE OFFICE OF THE INSPECTOR GENERAL. IT MAY NOT BE PLACED IN THE PUBLIC DOCUMENT ROOM WITHOUT WRITTEN PERMISSION.

FREEDOM OF INFORMATION/PRIVACY ACT EXEMPTION (s)(5)(6)(7)(C)

OFFICIAL USE ONLY

TABLE OF CONTENTS

SUBJECTS



STATUTES AND REGULATIONS

18 USC 208
Conflict of Interest

10 CFR, Part O
Conduct of Employees

5 CFR, Part 2635.702
Government Ethics

Executive Order No. 11222
Section 201 (c) (2), Part II
Standards of Conduct

NRC Inspection Manual Chapter 1201
Conduct of Employees

EXECUTIVE SUMMARY

This investigation by the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC) was initiated based upon information provided by [redacted] Nuclear Energy Services. Nuclear Energy Services (NES) is a broad-based engineering and technical support service contractor in the nuclear industry. [redacted] advised OIG that during the period he worked for NES, the [redacted] NES expressed having received business referrals from NRC's Region III. [redacted] believed that NES [redacted] had developed a friendship with members of the Region III staff. [redacted] alleged that there was an improper relationship between NES and Region III staff.

The OIG investigation revealed that Region III [redacted] recommended NES to three licensees: Case Western Reserve University, Lafayette Clinic, and the University of Cincinnati. OIG obtained evidence that [redacted] recommended solely NES to the University of Cincinnati.

The investigation disclosed that [redacted] maintained continuous and substantial contact with NES, consequently establishing a familiar relationship with certain NES managers.

The investigation disclosed that most Region III inspectors routinely referred the names of certain consultants to licensees. Region III management was knowledgeable and encouraged this practice by instructing the regional staff to provide at least three recommendations as an unofficial policy.

The investigation disclosed that there was not an established system in place for the manner of referring consultants to licensees. There was no uniform list of consultants and most inspectors apparently relied on their own opinions. In addition, there were no criteria or guidance for making a judgement on what constituted a competent consultant. Further, there was no indication that Region III managers or inspectors considered whether the practice of recommending consultants might compromise the NRC's ability to conduct inspections of the work such consultants performed.

Further, the investigation revealed that on separate occasions [redacted] and [redacted] dined with [redacted] The employees stated that monies were given for their portion of the meals, however, the employees' testimonies were not consistent with [redacted] Weekly Business and Expense Reports submitted to NES for meals with the respective employees.

The investigation did not develop sufficient evidence to determine whether [redacted] Office of Nuclear Materials Safety and Safeguards, dined with [redacted] while [redacted] was an NES employee.

BACKGROUND

Nuclear Energy Services (NES) was developed by [redacted] in 1973 as a broad-based engineering and technical support service contractor to the nuclear industry. NES is headquartered in Danbury, Connecticut, with another office in Boston, Massachusetts. NES is a subsidiary of Penn Central Corporation located in Cincinnati, Ohio. Presently, NES has approximately 150 full-time employees. NES provides engineering and technical support services to nuclear utilities. Further, NES is involved in consulting services for radiological waste management and other NRC licensees.

In addition, NES maintains an NRC license to possess specified quantities of by-product material and source material. In 1985, the NRC issued NES a license authorizing use of materials for: (1) performing maintenance repair and/or decontamination of tools, equipment, and containers; (2) analyzing samples; (3) checking instruments; and (4) packaging and transporting of licensed materials. Use of the license is restricted to temporary job sites of the licensee anywhere in the United States where the NRC maintains jurisdiction for regulating the use of licensed material.

BASIS

This investigation by the Office of the Inspector General (OIG), U.S. Nuclear Regulatory Commission (NRC), was initiated based upon information provided by [redacted] Nuclear Energy Services. Nuclear Energy Services (NES) is a consulting firm to many NRC licensees. [redacted] advised OIG that during the period he worked for NES, the [redacted] NES alluded to receiving referrals from NRC's Region III. [redacted] alleged that there was an improper relationship between NES and the Region III staff.

DETAILS/ALLEGATION I

[redacted] Nuclear Energy Services, advised that there was an improper relationship between Region III staff and NES representatives. [redacted] stated that on at least two occasions during the period 1989-1990, NES [redacted] discussed at monthly management meetings surprise awards to the Plant Services Unit that were initiated by referrals from the Region III staff. On the two occasions, [redacted] believed the referrals concerned two NRC licensees in Ohio, Case Western Reserve University and the University of Cincinnati. [redacted] recalled that at one meeting [redacted] stated, "thank God for our friends at the NRC" and made the sign of the cross afterwards. [redacted] maintained that [redacted] never mentioned the name(s) of the NRC/Region III staff members who referred business to NES. [redacted] added that [redacted] at the time, was the contact between NES and Region III (Exhibit 1).

[redacted] stated that he did not have any documentation to support his belief of a "cozy relationship" between NES representatives and the Region III staff. However, [redacted] believed that internal NES correspondence produced during the period 1989-1990 contained information addressing this relationship between NES and Region III. Specifically, [redacted] suggested that OIG examine: (1) notes from the monthly staff meetings; (2) [redacted] monthly reports to NES' parent company; (3) the weekly marketing contact reports; and (4) the Sales Marketing Plan for the October-November 1989 timeframe. [redacted] related that the Sales Marketing Plan mentioned NES' close relationship with the Region III staff and how NES hoped to enhance it.

RECORDS OBTAINED FROM NES:

In response to an OIG subpoena, NES provided records pertaining to its business activities during the period from January 1988-December 1991. The following documents: (1) Plant Services Monthly Reports, dated June 2, 1988, September 28, 1988, December 1, 1988, February 7, 1989, April 20, 1989 and August 8, 1989 (Exhibits 2

thru 7); (2) Monthly Staff Meeting Minutes, dated September 11, 1989, March 14, 1989 and October 18, 1988 (Exhibits 8 thru 10); and (3) Telephone log of calls made by [redacted] via his AT&T Long Distance credit card during the period of 1988 to 1991 (Exhibit 11), indicate frequent contacts between NES and the Region III staff. The AT&T telephone log of [redacted] listed numerous calls to Region III inspectors.

Terminology used in the Plant Services Monthly Reports and Monthly Meeting Minutes implied a relationship between NES and Region III. Certain NES monthly reports and meeting minutes contained phrases such as "continue to foster relationship with NRC Region III" and "relations with NRC inspectors continues to be excellent with mutual trust exhibited towards NES." Further, the NES documents implied that Region III staff recommended NES to licensees. Included in the NES documents were the statements, "maintain contact with NRC headquarters," "foster NRC relationships for recommendations," and that NES received a verbal award to conduct an audit at the University of Cincinnati in response to Region III advice. The records provided by NES indicated Region III recommended NES to three licensees within Region III jurisdiction: Case Western Reserve University in Cleveland, Ohio; Lafayette Clinic in Detroit, Michigan; and the University of Cincinnati in Cincinnati, Ohio.

OIG requested that NES provide the personnel records and all documents pertaining to the business activities of [redacted] since 1978, resigned from the NRC in January 1989. [redacted] under the supervision of [redacted] Subsequent to [redacted] resignation, he was hired by NES in March 1989. Records provided by NES indicated [redacted] worked from his home in Chicago, Illinois and was responsible for marketing among by-product materials licensees of the NRC in the Region III area. Further, NES records indicated that one of [redacted] first projects with NES was the work conducted at the University of Cincinnati.

INTERVIEWS OF NRC LICENSEES INVOLVED WITH NES:

[redacted] Case Western Reserve University (CWRU), advised that failures within CWRU's radiation safety program prompted Region III inspections in 1987 and 1988. As a result of the 1987 inspection, CWRU was prohibited from continuing radiation research work. He advised that Region III inspectors informed CWRU that there were problems with the program, but the inspectors did not explain how CWRU could resolve the problems. [redacted] stated that the NRC requested that CWRU submit a proposal of how the university planned to fix the problems in addition to periodic progress reports (Exhibit 12).

[redacted] recalled that CWRU was "in a crisis" because the staff did not know how to solve its problems, and CWRU decided to hire a consultant for this purpose.

[redacted] advised that he and the radiation program staff called around to other facilities and colleagues for names of consulting firms that could assist with the development of their radiation program. Subsequently, NES was selected to assist CWRU with its radiation program. [redacted] did not know how or why NES was selected. He believed that a few firms were considered in addition to NES. [redacted] said he was not directly involved with the selection process, but was involved with the hiring of NES at the financial and policy level. According to [redacted] administered to the day-to-day responsibilities and managed all contacts and negotiations with the various competing consulting firms.

[redacted] believed that due to NES' immediate assistance CWRU was able to conduct research within a month after being shut down by the NRC, albeit on a probationary status. [redacted] recalled that [redacted] was CWRU's main contact at NES and performed most of NES' work. NES consulted with CWRU for approximately six months.

[redacted] of CWRU, recalled that Region III shut down CWRU's radiation program, requiring the university to resolve its programmatic problems. [redacted] maintained that he telephoned the region for advice regarding the hiring of a nuclear consultant to assist CWRU. [redacted] did not recall with whom he spoke, but believed it was an NRC official at the management level (Exhibit 13).

[redacted] stated that the Region III employee recommended three or four firms to him that could assist CWRU. [redacted] did not believe the Region III employee recommended any of the firms more strongly than the other. According to [redacted] the first firm he called was located in Cleveland, Ohio. He did not remember the name of the firm. [redacted] informed OIG that the Cleveland firm did not have the necessary resources to assist CWRU, so he contacted the next recommended firm on his list, NES. [redacted] said he spoke with [redacted] who claimed NES could begin immediately.

[redacted] advised that in December 1987, NES was hired as consultant to resolve CWRU's radiation program problems and assist with the development of the university's radiation program. [redacted] credited NES' prompt efforts for the reinstatement of CWRU's radiation research work. [redacted] did not observe a "cozy relationship" between NES and the Region III staff, but sensed that NES representatives knew and talked to the Region III staff. He explained that the NES staff knew the NRC regulations and requirements well enough to know what would be expected of the CWRU radiation program to pass inspection. [redacted] said that NES' familiarity with Region III staff and the inspection program was an advantage to CWRU. In February 1989, NES completed their work at CWRU.

[redacted] Lafayette Clinic, explained that in June 1988, there was a minor spill of radioactive material at the clinic. According to [redacted] Region III was notified that the clinic had some internal

problems with its radiation safety program, one of which was the June radiation spill, and was attempting to resolve these problems. Subsequent to the clinic notifying the NRC, a letter was received from Region III ordering the clinic to cease work within its radiation safety program. [redacted] advised that Region III shut down the clinic primarily because Lafayette Clinic had no RSO (Exhibit 14).

After Lafayette Clinic's radiation program was shut down, [redacted] was appointed as the [redacted]. He stated that after his appointment as [redacted], an inspection was conducted by Region III. He named [redacted] and [redacted] as some Region III members that he dealt with concerning the clinic's problems. According to [redacted] was very helpful in explaining how the clinic could get its radiation safety program "back on track." [redacted] advised that [redacted] suggested several sources the clinic could contact who were capable of providing assistance the clinic needed. [redacted] said [redacted] recommended three consulting firms, one of which was NES. He did not recall the names of the other two firms recommended by [redacted]. In [redacted] view, [redacted] was professional and very impartial when recommending the consulting firms.

[redacted] informed that Lafayette Clinic was under pressure to resolve its problems and return to its radiological work as soon as possible. Due to the exigent circumstances he decided on NES because of the immediate response from [redacted] when he was contacted by [redacted] recalled that almost immediately after NES began working, the clinic was able to perform radiation work again. He noted that NES reconstructed the clinic's radiation safety program, and due to NES' efforts the program was much improved and passed the Region III inspection.

[redacted] advised that throughout this period of time, he had direct contact with the Region III staff and there should not have been any NES contact with the region. He recalled that Region III inspectors visited the clinic the same time the NES staff was present. However, [redacted] did not believe that the Region III staff and NES representatives met with one another on these occasions. [redacted] stated that he did not get the impression there was an improper relationship between the NES staff and the Region III staff.

[redacted] University of Cincinnati (UC), advised that during 1989 a series of problems developed within UC's radiation safety program. He explained that technicians within the program had made serious allegations against the RSO and the radiation safety program. Due to the gravity of the accusations and his inability to ascertain the truth, [redacted] decided to hire an outside consultant to examine the allegations and conduct a thorough review of the university's radiation safety program (Exhibit 15).

[redacted] said he required assistance in identifying a consultant so he contacted [redacted] for suggestions. [redacted] advised that he knew [redacted] from prior UC

involvement with the Region III. According to [redacted] on August 3 or 4, 1989, he spoke with [redacted] about the need for assistance with the university's radiation safety program. [redacted] recalled that [redacted] specifically suggested [redacted] contact [redacted] and provided a telephone number for [redacted] at NES. [redacted] maintained that [redacted] claimed NES performed the type of service UC required, and NES would do a good job. [redacted] reiterated that [redacted] recommended only NES.

On August 12, 1989, NES began consulting for the university. [redacted] recalled that [redacted] and [redacted] were the principal NES representatives responsible for assisting UC with its radiation safety program problems. NES conducted a review of the radiation safety program and found many problems and possible NRC violations. As a result of the NES audit, the RSO was suspended and replaced. [redacted] said NES assisted the university with the placement of a new RSO. Subsequently, [redacted] was nominated for this position pending the approval of the NRC. [redacted] recalled that he and other UC faculty members joined [redacted] in meeting with the Region III staff concerning the appointment of [redacted] did not recall who attended the meeting on behalf of Region III. [redacted] said that [redacted] must have met the Region III staff before because he introduced UC faculty members to them.

[redacted] advised that NES consulted for UC for nearly a year. He maintained that as NES discovered safety problems, he immediately informed Region III of the problems. Consequently, Region III inspectors visited UC to examine the situation to formally document these safety problems. On those occasions Region III inspectors visited UC, [redacted] said he did not observe the inspectors meeting with the NES representatives. However, [redacted] advised that [redacted] was very friendly with the Region III inspectors. [redacted] opined that [redacted] relationship with the inspectors was normal considering that [redacted] was a former Region III inspector.

[redacted] UC, related that he interacted with NRC Region III staff during the 1989 inspection of the university's radiation safety program. [redacted] recalled being told that [redacted] desired a consulting firm to resolve some allegations and other problems associated with UC's program. He said [redacted] reported that he contacted Region III for recommendations of consulting firms and was provided NES' name. According to [redacted], the Region III staff recommended only NES. [redacted] could not recall who [redacted] spoke with at Region III (Exhibit 16).

[redacted] claimed that he thought it was "strange" that [redacted] only received a single recommendation from Region III, and believed this was against NRC rules. He explained that he was familiar with the NRC's rules and regulations from his past employment with the Atomic Energy Commission (AEC), NRC's predecessor. [redacted] noted that UC acquired NES's services on a sole source procurement basis and he wrote a letter explaining the circumstances to UC's procurement department (Exhibit 17).

[redacted] stated that he did not have any evidence to support that there was an improper relationship between NRC and NES, however, he believed there was an appearance of one. [redacted] speculated that there may have been a leak from Region III to [redacted] or someone else at NES. According to [redacted] knew of NRC results prior to the NRC informing the university of them. He recalled a message [redacted] left for him which referred to "unofficial information" (Exhibit 18). [redacted] said he had the impression that [redacted] and [redacted] had constant contact with the Region III staff. He surmised that [redacted] learned of certain information because of [redacted] past experience as an Region III inspector and knowledge of NRC regulations.

INTERVIEWS OF NES MANAGEMENT:

[redacted] NES, stated that during 1988-1991, NES conducted work in three main areas: Engineering, Technical and Waste Management. [redacted] explained that within NES' Engineering Division, procedures were written for nuclear plants that had recently started-up, and NES modified certain nuclear plant procedures that had become antiquated. NES also conducted in-service inspections and quality control work for nuclear plants under the Technical Division, in addition to radiological field work conducted by NES' Waste Management Division. Under the scope of these three areas, NES began marketing to commercial utilities (Exhibit 19).

[redacted] maintained that NES acquired its clients during 1988-1991 mainly through "word of mouth." [redacted] advised that NES had a reputation as a quality company in certain respects. In order to build upon its reputation, NES began to seek others within the nuclear industry to inform them of NES and the services it could provide. [redacted] stated that NES initially sought out Region I to assist NES in this effort. He explained that NES approached Region I because NES is headquartered in Region I. [redacted] related that NES attempted to meet with Region I to describe the company and its services and to obtain a published list of troubled licensees in Region I. However, the Region I staff rebuffed NES and claimed there was no such list of licensees.

[redacted] said he did not believe NES tried the same approach with any of the other NRC regions as it did with Region I. He believed that Region III recognized NES for the quality work NES had previously performed in the region. [redacted] stated that he had heard Region III compiled a list of quality firms, which included NES. [redacted] heard that the list was provided to Region III licensees requiring services the firms could provide. According to [redacted] the Region III staff never gave preference to any of the firms on the list. He added that he did not have direct knowledge of any licensee requesting assistance and Region III referring companies from the list.

[redacted] advised that NES has received referrals from Region III in the sense that NES was named among other companies that could provide certain services in a timely manner. [redacted] related that NES acquired work at CWRU by being named among

[redacted]

many firms by the Region III staff. He recalled the situation with CWRU because the university was in trouble and needed immediate assistance, which NES was able to provide. According to [redacted] he never considered Region III's referral procedure as providing NES with an improper advantage over competitors.

[redacted] said that he touted NES' success to his employees after NES received the CWRU consulting project. [redacted] recalled that he told the NES staff that good work can lead to more projects. According to [redacted] he did not credit Region III for this success, but the NES staff responsible for doing the quality work which led to the CWRU project. Regarding the alleged statement "Thank God for our friends at NRC," [redacted] doubted that he ever made such a statement. He added that he probably told his staff "...thank God we're doing good work" (Pg 18).

OIG asked [redacted] about the comments contained in the Plant Services Monthly Reports and Monthly Staff Meeting Minutes, which implied a relationship with Region III (Exhibits 2 thru 10). [redacted] stated that comments like "relationship with NRC,' what it means is that the quality of work permits NRC to look at us as somebody that's not a shoddy performer but somebody that's there to stand behind a good product" (Pg 22). [redacted] explained that proper interpretation of the Monthly Staff Meeting Minutes inferring a relationship between NES and Region III was that NES must continue to do good work to give the region reason to place NES on a reference list, if so inclined. [redacted] informed that NES did not ask the Region III to be placed on such a list. [redacted] maintained that if NES was recognized for the quality of its work, he would accept any recommendation and assume that it was done in a fair and proper manner by the NRC. [redacted] advised that he had no contact with the Region III staff and had not visited Region III.

Concerning NES' employment of [redacted] informed that [redacted] and [redacted] hired him. [redacted] stated that he met [redacted] prior to him being hired and he was aware [redacted] was a former inspector for Region III. [redacted] did not know whether NES approached [redacted] about employment at NES or [redacted] approached NES.

[redacted] NES, was interviewed by OIG. [redacted] recalled that sometime in 1985 NES' first encounter with the Region III staff was during consulting work the NES performed for the SOHIO Chemical Plant located in Lima, Ohio (Exhibit 20).

According to [redacted] NES maintained a continuous dialogue with the Region III inspectors while NES worked at SOHIO. He noted that the NES site manager at SOHIO called Region III [redacted] a few times to determine the acceptability of many issues. [redacted] said he personally dealt with [redacted] regarding certain projects [redacted] managed involving Region III. He explained

[redacted]

that discussions be had with Region III staff were of two types: (1) formal communications such as reports and letters to the region from the client were drafted by NES; and (2) informal communications with the region to ascertain the NRC requirements for a particular task.

[redacted] advised that subsequent to the SOHIO project, NES worked at other facilities in Region III that were the focus of NRC inspections, such as CWRU, Lafayette Clinic, and the University of Cincinnati (UC). [redacted] did not have direct knowledge that Region III recommended NES as a service consultant to these facilities. However, [redacted] said he was aware of a Region III practice of providing a list of several companies that did quality work to licensees in need of assistance. [redacted] stated that his impression was that Region III did not refer NES specifically to any facility.

[redacted] believed that NES was placed on the Region III list of quality companies because of their good performance record. In fact, [redacted] related that Region III's recognition of NES' strong performance was discussed numerous times in managers' meetings with [redacted] did not recall hearing [redacted] make the alleged statement, "Thank God for our friends at the NRC." He noted that "...we had absolutely no relationship with Region III that I know of other than on a purely professional basis..." (Pg 5). [redacted] said that NES had a very strong professional relationship with Region III.

With respect to NES' hiring of [redacted] stated that [redacted] was qualified for his position at NES and would have been hired whether there was a published vacancy or not. [redacted] did not believe there was a published announcement for [redacted] position. According to [redacted] hiring was not a surprise. He explained that when NES hired [redacted] the company was growing. [redacted] informed that other employees were hired during the time [redacted] was retained.

[redacted] NRC, advised that prior to being hired by the NRC he was employed by NES between 1982-1990. [redacted] was the [redacted] and later became [redacted] stated that NES began seeking decontamination projects. In this regard, [redacted] said he visited NRC headquarters to find out which licensees were in need of NES' services. According to [redacted] NRC headquarters staff informed him that the licensee information NES sought was handled by the individual regions (Exhibit 21).

[redacted] advised that NES eventually approached Regions I and III to acquaint the regional staff with NES. He said NES visited Regions I and III because NES was headquartered within Region I jurisdiction, and the majority of materials licensees were in Region III. [redacted] recalled that the regional staffs immediately told NES they did

not recommend consultants to licensees. However, [redacted] said Region III maintained that if a licensee had a problem and needed assistance, they would provide a list of firms, of which NES would be one. [redacted] recalled speaking to [redacted] concerning this matter.

[redacted] said he did not believe Region III ever referred NES as the only consultant to a licensee. [redacted] reiterated that he believed the Region III staff recommended several consulting firms to include NES to any licensee requesting assistance. [redacted] stated that through this referral system NES received the CWRU project. He did not know whether NES received the Lafayette Clinic and UC projects via the Region III referral system. In [redacted] view, the Region III staff was confident NES was doing a good job.

[redacted] advised that NES and the Region III staff developed a professional relationship and did not believe any NES representative was involved in an improper relationship with an NRC staff member. He acknowledged that he knew the late Lee ROUSE, an NRC headquarters employee, and considered him a friend. [redacted] stated that [redacted] frequently spoke with [redacted] but [redacted] did not consider the two to be friends.

Concerning NES' hiring of [redacted] was not sure how NES came to hire [redacted] believed that [redacted] or someone on [redacted] behalf approached [redacted] about a position with NES. [redacted] said he knew [redacted] wanted to leave the NRC. [redacted] believed that [redacted] had valuable experience which would be an asset to NES. [redacted] maintained that [redacted] was very familiar with NRC regulations and the Region III area.

[redacted] NES, was interviewed by OIG. [redacted] informed that during 1988-1991, he was the [redacted] reporting to [redacted] said his responsibilities were to develop business opportunities in the non-reactor decommissioning services market and with nuclear power plants. He added that NES was very much involved with fuel clean-up services during this timeframe (Exhibit 22).

[redacted] stated that in 1985 while conducting work at the SOHIO facility, later known as BP Chemical, NES first encountered the NRC. [redacted] advised that regarding the SOHIO project, NES had to negotiate with NRC headquarters staff. [redacted] recalled dealing with Lee ROUSE at NRC and as a result, he became the principal NES contact to the NRC. [redacted] noted that the inspection of the SOHIO facility was conducted by Region III staff. During the Region III inspection of SOHIO, [redacted] said he met two inspectors, [redacted] and [redacted]

believed that NES was recognized by Region III after their excellent work at the SOHIO facility. stated that due to NES' efforts at SOHIO, Region III placed NES on an "unofficial list of qualified vendors," developed by of Region III (Exhibit 23) claimed that if a licensee with problems contacted Region III asking for the names of consultants, Region III provided the licensee with a minimum of three firms. added that when Region III provided the three names background on each firm was also provided advised that Region III licensees were given this assistance, however, those in other regions were not provided with NRC assistance. stated, "Of all the regions that you have, the one that is closer to your licensees is Region III..." (Exhibit 22 pg 8).

maintained that NES definitely did not solicit the Region III staff to be recommended to NRC licensees. reiterated his belief that NES' good performance was recognized by the Region III staff resulting in their referral of NES among other companies to licensees. According to NES received referrals to CWRU, Lafayette Clinic, UC and two others that NES did not accept. said he knew NES was recommended to the three aforementioned licensees by Region III staff because each representative told of this. noted that of CWRU, and with Lafayette Clinic; and of UC contacted him for their respective consulting needs. said he was positive that CWRU and Lafayette Clinic received the names of three companies from the Region III staff. However, was not certain of UC received three referrals. stated that he just assumed recommended three companies to because that was the normal procedure for Region III.

stated that NES' familiarity with the Region III staff did not provide an unfair competitive advantage for NES. He explained that any similar consulting firm could have gone to Region III and requested information on a licensee or ask to be recommended to licensees. said "I know that I can go and sit down with the following day and say, 'What's new? I've heard that we have problems in this kind of licensee. What's the status?'" (Pg 44). said he took pride in knowing how to deal with the Region III staff. He advised that NES' clients expected NES to interface with the region on their behalf. noted that the many telephone calls to Region by him were done on behalf of clients to find out if the Region III approved of certain efforts by a licensee. He maintained that a lot of issues were resolved by telephone. added that his calls were primarily to

Regarding NES' employment of advised that he hired him after he left Region III. speculated that received NES' name from his former supervisor, said he may have contacted about hiring because he recalled stating that was very good at health physics and a good writer. In view, it made sense to hire a person with such valuable experience. denied that was hired in exchange for providing NES as a sole referral. According to gave

NES insight on how Region III inspected licensees. He noted that [redacted] left NES because he did not wish to move to NES headquarters in Connecticut.

OIG discovered that [redacted] resigned from NES in 1992. OIG's efforts to locate [redacted] were to no avail. Consequently, [redacted] was not interviewed by OIG.

INTERVIEWS OF REGION III INSPECTORS:

[redacted] Nuclear Materials Safety Branch (NMSB), advised that he first became familiar with NES when [redacted] went to work for NES in 1989. He related that [redacted] was employed by NES during a Region III inspection at UC. [redacted] believed he met another NES representative, [redacted] during a meeting at Region III at approximately the same time (Exhibit 24).

[redacted] stated that he occasionally referred the names of firms to licensee when he was a Section Chief and Inspector. [redacted] noted that he provided a list of at least three names when asked for recommendations. He provided the names of companies that were listed in the Radiation Protection Professionals Directory and Handbook. According to [redacted] he normally recommended companies in the directory/handbook, companies he was familiar with, and/or companies he knew as good performers. He added that other Region staff members referred companies from their own lists. [redacted] stated that [redacted] also maintained a list of medical consultants. He added that there are many different lists held by the various sections of Region III.

[redacted] stated that the procedure of referring the names of consultants to licensees was an informal regional policy. He noted that the policy was shared within Region III by "word of mouth." According to [redacted] the Region III staff knew it was improper to recommend one company to a licensee. [redacted] acknowledged that a company would be unfairly advantaged if not on the list of recommended companies. He advised that so many companies are available that not all can be known to the regional staff.

[redacted] said that the issue of referring consultants concerned him. He said he was unsure whether it was the region's responsibility to assist licensees in finding a consultant to resolve their problems. However, if the region did not provide such assistance, the NRC might be ignoring safety concerns. [redacted] believed that Region III had a tendency to be problem-oriented and tried to help licensees. [redacted] noted that he has in the past discussed issues with consultants on behalf of the licensee to resolve problems, although most knowledgeable consultants did not contact the region.

[redacted] NMSB, informed that he joined the NRC in 1981 as a [redacted] stated that he first became aware of NES while

working on a decontamination project involving Chemetron in Cleveland, Ohio. He recalled that Chemetron's consultant, NES, employed [redacted] (Exhibit 25).

[redacted] said that he "probably recommended" NES along with four or five other consulting firms to various licensees. [redacted] advised that there was a list of consultants used for referrals, which had been prepared by [redacted] (Exhibit 23). According to [redacted] he was unaware of any written policy for NRC inspectors when providing licensees with the names of consulting firms. However, he said that Section Chiefs and Branch Chiefs routinely instructed Region III inspectors to provide at least three or four names and to never recommend any particular company. [redacted] added that he routinely communicated with consultants who requested guidance on behalf of the licensee.

[redacted] was generally unaware of any contact between NRC staff and [redacted] after he went to work for NES. However, [redacted] believed that [redacted] used Region III inspection information to develop a "package" that would be advantageous to gaining employment with NES. He explained that UC technicians had been sending allegations "left and right" to Region III, which were not being acted upon prior to [redacted] leaving NRC. He added that [redacted] was the [redacted] and should have been acting on (them)." [redacted] said that one of his recommendations to [redacted] and [redacted] for solving a UC safety concern was used by [redacted] as an NES promotional service to UC.

OIG interviewed seven other inspectors assigned to the Division of Radiation Safety and Safeguards (DRSS), Region III who were familiar with NES. The inspectors were familiar with NES as a consultant to various licensees in the Region III area. None of the inspectors claimed to know how NES acquired the work at CWRU, Lafayette Clinic or UC. The inspectors were familiar with NES' work at UC mostly due to [redacted] being part of NES' consulting team at UC (Exhibits 26 thru 32).

The inspectors concurred with [redacted] and [redacted] that there was no formal Region III policy regarding recommendations to licensees. The inspectors advised that licensees requesting recommendations were provided with the names of at least three consultants. The inspectors stated that there were different unofficial vendor lists used within the division (Exhibits 33 thru 35). The inspectors related that they were instructed not to give preference to any firm. The inspectors did not know of this procedure ever being compromised by a Region III inspector.

Further, the inspectors stated that no specific instructions were given for dealing with a licensee's consultant who made inquiries to the region. When this occurred, most inspectors said they would participate in discussions with the consultants. Certain inspectors noted they would not receive questions from a consultant and would refer to the licensee's management. However, the inspectors collectively agreed that consultants could not replace licensees at Region III meetings.

[redacted] Nuclear Material Safety Branch (NMSB), began his career with Region III in 1979. From 1981-1989, [redacted] was the [redacted] advised that in July 1989 he was reassigned as [redacted] to the Director of DRSS (Exhibit 36).

[redacted] stated that he first encountered NES in 1985 during an allegation review of SOHIO/BP Chemicals facility, where NES was a subcontractor. [redacted] commented that he was impressed with the quality of NES' work at SOHIO. [redacted] stated that NES subsequently requested a meeting with Region III management and inspection staff to introduce themselves and inform Region III of the services NES provided. [redacted] informed that [redacted] DRSS, approved the meeting. He did not remember when the meeting occurred. He recalled NES representatives, [redacted] and [redacted] being present. [redacted] maintained that he later interacted with NES at three facilities, CWRU, Lafayette Clinic and UC.

[redacted] recalled that CWRU was experiencing problems at some of its various laboratories which used radioactive materials. [redacted] informed that Region III [redacted] was sent to CWRU to conduct an inspection. Based on [redacted] findings, a Confirmatory Action Letter suspending the university's radiation activities was issued. Consequently, [redacted] said that he received a telephone call from [redacted] of CWRU. [redacted] stated that [redacted] wanted some assistance with developing CWRU's radiation safety program and asked for recommendations. [redacted] stated that he recommended [redacted] of Cleveland Hospital; Nuclear Medicine Associates in Cleveland, Ohio; NES; and Applied Health Physics, which was already conducting work at CWRU.

[redacted] stated that he was aware [redacted] contacted [redacted] at NES because [redacted] told him of this after receiving [redacted] call. [redacted] recalled that [redacted] telephoned him asking for a summary of CWRU's problems. [redacted] told [redacted] about the Confirmatory Action Letter and explained that CWRU needed an overhaul of their entire radiation program. He maintained that the information he provided [redacted] was public information available at the NRC's public document room.

[redacted] stated that he dealt with the NES staff at Lafayette Clinic in the same manner as he did at CWRU. [redacted] explained that Lafayette Clinic's RSO had resigned, leaving the clinic without a qualified person to manage the radiation safety program. [redacted] assigned [redacted] to inspect Lafayette Clinic. According to [redacted] contended there were a lot of regulatory problems at the clinic. Subsequently, Region III issued a Confirmatory Action Letter requesting the clinic to suspend its licensed activity and to appoint a new NRC-approved RSO. [redacted] said after the letter was issued, he received a telephone call from [redacted] and [redacted] of Lafayette Clinic.

[redacted] maintained that [redacted] and [redacted] asked him to suggest what they should do to put their program back into operation. According to [redacted] "I told them that if I was in their situation I would consider a third party audit of the entire radiation safety program" (Pg 16). [redacted] stated that he provided [redacted] and [redacted] three sources: [redacted] from Wayne State University; Medical Physics Consultants in Ann Arbor, Michigan; and NES.

[redacted] explained that following NES' work at Lafayette Clinic, the firm was contracted at UC. [redacted] maintained that UC was a problem facility for many years dating back to the early 1980s. According to [redacted], Region III had received numerous allegations concerning UC's radiation safety program. In April 1989, [redacted] prepared a memorandum concerning the recent allegations he had received (Exhibit 37). Subsequently, the region conducted an inspection at UC. [redacted] explained that he was not involved with the inspection at UC because he was transferred from NMSB to the [redacted] in July 1989.

[redacted] stated that he received a telephone call from [redacted] of UC after July 1989. He recalled that [redacted] wanted Region III to investigate the numerous allegations and resolve UC's safety problems. [redacted] told [redacted] that the NRC encourages licensees to identify and correct violations whenever possible, so UC should take the initiative. According to [redacted] asked him to recommend someone. [redacted] said he recommended [redacted] contact [redacted] with Applied Health Physics; [redacted] with Radiation Safety Services Incorporated; and [redacted] with NES. [redacted] remembered that he provided [redacted] with the telephone number of [redacted] at NES, but was not positive he gave him telephone numbers to the other firms.

[redacted] maintained that he did not recommend only NES to [redacted] He recalled that his telephone call with [redacted] was quite lengthy. [redacted] stated that he did not emphasize NES to [redacted] more than the other firms recommended. Although, [redacted] stated that he gave [redacted] a little background on NES and not the other companies. [redacted] said he told [redacted] of NES' good work at CWRU. According to [redacted] "...I would say because of my statement about Case Western that probably that was the thing that really made his [redacted] decision mentally" (Exhibit 36 pg 92).

[redacted] maintained that he has never recommended one firm to any licensee. [redacted] stated that he kept a list of consulting companies he recommended to licensees upon request. [redacted] prepared the list himself of companies he dealt with during past inspections based on their performance and geographic location (Exhibit 38). According to [redacted] other Region III inspectors recommended consulting firms to licensees. He stated that recommending three companies was standard practice within the region. [redacted] recommended three companies so that he could not be accused of favoritism to any one of them. He added that he tried not to recommend the same companies repeatedly.

[redacted] advised that there was no written policy concerning the recommendations of outside consultants to licensees. [redacted] acknowledged that it was not his responsibility for assisting the licensees with finding a consultant, but he did so as a courtesy. According to [redacted], "Public health and safety is the number one thing and by turning your back on them (licensees) and telling them that's your problem not mine, you get it fixed, that is sort of a bureaucratic cavalier approach that I would never take" (Exhibit 36 pg 31).

[redacted] explained that he had frequent contact with licensees and their consultants. He informed that much of his contact was answering licensees' questions via the telephone. [redacted] said that he treated licensees' contractors the same as he did the licensees. For example, [redacted] noted that he interacted with NES regarding their work at Lafayette Clinic, CWRU, and to some extent UC.

[redacted] stated that his interaction with NES did not create a unique or cozy relationship. According to [redacted] he treated NES as he would any other consulting firm. He explained that his dealings with NES and any other consulting firm was to assure that the licensees had programs in place that were in compliance with NRC rules and which provided a safe and healthy environment.

Regarding Region III inspector [redacted] recalled talking to [redacted] about [redacted] stated that after [redacted] resigned from Region III, he mentioned to [redacted] that he may want to consider hiring [redacted] and provided [redacted] his telephone number. [redacted] told [redacted] that [redacted] did a thorough job on inspections and investigations. Subsequently, [redacted] said he learned that [redacted] was hired by NES.

[redacted] informed that not long after [redacted] was hired by NES, he saw him at the regional office. According to [redacted] telephoned him to explain that [redacted] was going to represent NES at the UC project. [redacted] told [redacted] that he did not anticipate a problem with [redacted] working at the university. [redacted] did not check with his superiors concerning the accuracy of the information he provided to [redacted]. After [redacted] left Region III, [redacted] said he spoke with him on only two other occasions. He continued that on one of these occasions [redacted] telephoned to elicit [redacted] opinion of the report NES wrote concerning UC after the UC problems had been resolved. The second occasion [redacted] met with [redacted] and [redacted] at the regional office. [redacted] advised that NES had developed a health physics computer application training program and demonstrated the program to [redacted] said that he did not have the decision making authority concerning training equipment, but met with [redacted] and [redacted] because he was personally interested in the computer program.

INTERVIEWS OF REGION III MANAGEMENT:

[redacted] Region II, advised that he was [redacted] Region III from 1987-1990. [redacted] informed that he was familiar with NES as a consulting firm. [redacted] first encounter with NES occurred when NES decommissioned the SOHIO/BP Chemical facility. [redacted] noted that he became aware of NES again when NES worked for CWRU, a facility Region III discovered to have had many safety concerns. According to [redacted] the last time he heard of NES was during the firm's involvement with UC. [redacted] could only recall NES serving as a consultant to three facilities: BP Chemicals; CWRU; and UC (Exhibit 39).

[redacted] recalled a questionable incident regarding the recommendation of NES to a licensee. He did not remember which licensee was involved, but informed that [redacted] was implicated. [redacted] explained that a question was raised of whether or not [redacted] solely recommend NES to a licensee. [redacted] discussed the situation with [redacted], but did not recall the details of the conversation. He did not recall whether [redacted] was officially counseled about the incident. [redacted] surmised that since the matter was not officially pursued in the region, [redacted] explanation of the situation must have been satisfactory to him [redacted]. Although [redacted] concluded the situation was not significant, he believed he probably discussed the matter with Division Director [redacted]

[redacted] acknowledged that some employees in his branch referred companies to licensees and in fact there was a list maintained by Region III of firms to be referred. [redacted] informed that as Materials Licensing Section Chief he kept a list and when asked he would recommend companies from his list (Exhibit 40). He explained that there were often licensees with safety concerns who would call the Region III for help. [redacted] advised that the Region III staff provided the names of all companies they could think of in the region. [redacted] stated that his specific instructions concerning recommendations was to always provide a licensee with the names of more than one consultant, and if possible, to refrain from recommending any firm. According to [redacted] he cautioned against recommending one company because he did not want anyone to be accused of favoritism. [redacted] noted that the procedure of recommending more than one consultant was not a written policy, but it has been an informal Region III policy for some time. To [redacted] knowledge, the Regional Counsel was never advised of or queried concerning this unofficial policy.

With respect to [redacted] policy on working with licensees and their consultants, he advised that licensees were to be dealt with directly. He stated that licensees were always recognized as the first line of contact for the Region III staff. [redacted] recalled that often licensees' consultants called the region requesting information, meetings and approval status on issues. [redacted] advised his staff not to deal with the licensees' consultants on these types of issues. [redacted] maintained that telephone

calls had to be answered, of course, but the staff was instructed not to answer specific questions. [redacted] said that he made his instructions known to the region's section chiefs and expected the information to be disseminated to the inspectors.

Regarding [redacted] stated that [redacted] worked in [redacted] section and the two were close friends professionally. [redacted] did not know of a relationship outside the office. He informed that [redacted] resigned from the NRC in 1989, after the NRC learned of inappropriate conduct by [redacted].

[redacted] Region III, told OIG that NES was known to him as a consulting firm, which had represented several Region III licensees. His personal dealings with NES staff was limited to a couple of meetings at Region III, in which NES representative [redacted] was a participant. [redacted] recalled a situation in which [redacted] recommended NES solely to UC. According to [redacted] the situation arose during an enforcement conference when a UC representative maintained that [redacted] solely recommended NES as the consultant to resolve UC's program deficiencies (Exhibit 41).

Following the enforcement conference, [redacted] said he discussed the matter with [redacted] who claimed he provided the names of three or four consulting firms to UC. However, [redacted] related that [redacted] acknowledged having told UC, "you should get NES" or "they (NES) are the best." [redacted] counseled [redacted] that the NRC was not in the business of recommending a specific consultant to a licensee. According to [redacted] acknowledged that doing so was poor judgement on his part. [redacted] advised that [redacted] action did not warrant a personal reprimand, but he decided to forward the matter to OIG (Exhibit 42).

With respect to providing referrals to licensees, [redacted] stated there was general knowledge "by some within the business," that when licensees so requested, Region III provided the names of three or four consultants without recommending a particular one. He explained that licensees were typically at a loss to resolve their inspection problems without outside assistance, so the Region III provided a selection of consultants. [redacted] advised that he knew of no written procedure, but he strongly suspected that other NRC regions followed the unofficial procedure of providing several consultants to a requesting licensee. [redacted] was unaware of an unofficial vendor list and did not believe such a list existed. He stated that his personal instruction to subordinate staff was that the NRC was not in the consulting business and should not attempt to resolve problems for licensees. However, if outside consultants were needed, Region III inspectors could help licensees learn which companies might be available to them.

[redacted] stated that he was not familiar with NES until [redacted] went to work at NES. Subsequent to [redacted] leaving the NRC for

employment with NES, [redacted] was asked to provide guidance on how to treat [redacted] and any other former NRC employee who works for a licensee or contractor. [redacted] believed [redacted] requested the counselling session. [redacted] recalled informing [redacted] branch that former NRC employees were to be treated as a member of the public and not to provide them any privileged information (Exhibit 43).

[redacted] advised that he was aware inspectors provided lists of consulting firms to licensees who requested assistance in finding a consultant. [redacted] stated that he was not aware of an inspector recommending only one consulting firm to a licensee. He explained that recommending three or more companies to a licensee was allowed, although this procedure was not a written policy. [redacted] informed that he neither had knowledge of the list of recommended firms nor that the recommendations actually occurred. [redacted] said there may have been some discussion regarding the inspectors providing recommendations and he vaguely remembered pursuing the point with the Office of the General Counsel (OGC).

[redacted] had some concern with the recommending of three or more consulting firms when there are several others available from which to choose. He stated that the recommendations posed a fairness question since companies not recommended or listed are placed at a disadvantage. According to [redacted] recommending three or more firms was a possible conflict of interest because preference was given to the firms recommended. [redacted] opined that the "best scenario would be to give whomever the list and say choose from the list without ever providing three names." [redacted] did not know how the other regions operated with respect to this informal procedure.

FINDINGS/ALLEGATION 1

The OIG investigation revealed that [redacted] referred NES among other companies to Case Western Reserve University and Lafayette Clinic. Although there is conflicting testimony about [redacted] recommending only NES to the University of Cincinnati, it is clear that [redacted] recommendation of NES to the University of Cincinnati was interpreted as an endorsement of NES' services.

[redacted] as well as other Region III staff made referrals to licensees. Region III management was knowledgeable and encouraged this practice by instructing the staff to provide at least three referrals. By memorandum of February 23, 1993, NRC General Counsel advised that it would be a violation of government regulations "for a NRC employee to recommend the services of a particular entity for a particular project, which is subject to NRC's regulatory jurisdiction."

The investigation disclosed that [redacted] maintained continuous and substantial contact with NES, consequently establishing a familiar relationship with certain NES employees. [redacted] had repeated interaction with NES via telephone calls,

meetings and with former Region III inspector [redacted] admitted recommending [redacted] to NES as a potential employee.

The investigation disclosed that there was not a fair system in place for the manner of referring consultants to licensees. There was no uniform list of consultants, and most inspectors apparently relied on their own opinions. Further, there were no procedures established to ensure fairness and to avoid charges of favoritism.

DETAILS/ALLEGATION II

As previously mentioned in this report, NES provided OIG documents pertinent to its business activities in response to an OIG subpoena. Upon review of these documents, OIG discovered expense accounts of two NES representatives that indicated meals were bought for NRC employees. The two NES representatives, [redacted] and [redacted] reported on their expense accounts dining with NRC employees, [redacted] and [redacted] In addition, [redacted] expense account indicated that he bought a meal for [redacted] after [redacted] became an NRC employee. The meals occurred on the following dates: October 17, 1988; February 8, 1989; March 23, 1989; April 4, 1989; and July 21, 1991.

MONDAY, OCTOBER 17, 1988 AND THURSDAY, MARCH 23, 1989 MEALS WITH [redacted]

[redacted] Advisory Committee on Nuclear Waste (ACNW) was a [redacted] with NES until 1990. [redacted] Weekly Business & Expense Report indicated that on October 17, 1988, he had a business dinner with [redacted] and L.C. ROUSE at Dominique's in Baltimore, Maryland (Exhibit 44). [redacted] reported on the expense account that the cost for the dinner was $56.70. Another expense report of [redacted] indicated that on March 23, 1989, [redacted] had breakfast with L. ROUSE and [redacted] at The Golden Bull in Gaithersburg, Maryland (Exhibit 45) and (Exhibit 21).

[redacted] said that he probably had meals with some of the NRC staff and assumed he paid for them. [redacted] explained that he often visited an NRC employee, Lee ROUSE, who was an old friend from when [redacted] worked for the Atomic Energy Commission. ROUSE is now deceased. [redacted] continued that when he visited ROUSE, other NRC employees were usually present and all would go out to dine together. [redacted] did not recall what was discussed on the two occasions he dined with [redacted] and ROUSE.

[redacted] stated that "if I bought lunch for [redacted] I would hope that nothing happens to [redacted] because I probably said don't worry about it, I'll take care of it or you can pay me back the next time or something" (Exhibit 21 pg 56). [redacted] acknowledged that his lunches with the NRC employees may have given the appearance

of a conflict of interest, but he did not believe there was a conflict with the situation. In [redacted] view, the recipients of the inexpensive lunches did not feel [redacted] as an NES representative, was trying to "buy" them.

[redacted] Office of Nuclear Materials Safety and Safeguards (NMSS), stated that he was introduced to [redacted] during [redacted] visit to NRC headquarters. [redacted] informed that [redacted] was visiting [redacted] supervisor, Lee ROUSE, Chief, Field Cycle Safety Branch. According to [redacted] visited ROUSE on several occasions, sometimes unannounced. [redacted] had the impression that [redacted] visited to renew acquaintances and to gain information that might be useful to NES. He recalled two occasions that [redacted] visited at NRC for business meetings (Exhibit 46).

[redacted] denied having any meals with [redacted]. He maintained that he consistently brought a brown bag lunch to work and ate at his desk. [redacted] informed that he was neither familiar with nor had been to Dominique's Restaurant in Baltimore, Maryland. [redacted] had heard of The Golden Bull in Gaithersburg, Maryland, but claimed "I certainly wasn't there with [redacted] and Lee ROUSE" (Pg 7). [redacted] categorically denied ever going to the restaurants mentioned above with [redacted].

WEDNESDAY, FEBRUARY 8, 1989 MEAL WITH [redacted]

[redacted] NES was interviewed [redacted] Weekly Business & Expense Report indicated that on February 8, 1989, he had dinner with [redacted] at Top of the Town in Cleveland, Ohio. [redacted] reported on his expense account that the cost of the dinner was $85.67 (Exhibit 47).

[redacted] stated that he and [redacted] and [redacted] were at Case Western Reserve University (CWRU) on the above date. According to [redacted] he invited [redacted] and [redacted] to dinner with him. He recalled that [redacted] elected not to go because he had friends or relatives in the area he wanted to visit. [redacted] advised that the dinner was at a restaurant on top of a building. He did not recall the name of the restaurant (Exhibit 22).

[redacted] stated that during the dinner he and [redacted] discussed quality and performance factors and the current misadministration problems at some facilities. According to [redacted] he paid for the meal with his credit card, and [redacted] reimbursed him with cash for his meal. [redacted] explained that the reason the money [redacted] paid was not reflected on the expense report was due to NES' difficult accounting process. He claimed that a cash advance form would have to have been completed in order to reflect cash received during a trip. [redacted] continued that "We are very loose sometimes on other meals, so sometimes what I remember in some cases I am not that specific but I may have used his [redacted] money to put the tip and

then to balance I just expense it against other things and it didn't show up in the end" (Pg 30).

[redacted] acknowledged that upon [redacted] request in May 1992, he later wrote on his expense account that [redacted] paid cash for his meal. [redacted] said that [redacted] trusted him and did not believe [redacted] was concerned with the manner in which he prepared his expense report.

[redacted] Nuclear Materials Safety Branch (NMSB), stated that he met with [redacted] to discuss the Lafayette Clinic "Get Well Program" over dinner. [redacted] informed that the dinner with [redacted] occurred on February 8, 1989, during a visit to CWRU in Cleveland, OHIO. [redacted] explained that he and [redacted] NMSB were at CWRU concerning some administration problems the university was experiencing. He added that [redacted] was the NES representative responsible for assisting CWRU with their radiation safety program. [redacted] recalled that [redacted] wanted him to review some documents he [redacted] had concerning Lafayette Clinic. [redacted] told [redacted] that his schedule was full with CWRU's issues so [redacted] suggested they have dinner to discuss the documents (Exhibit 36).

[redacted] recalled that he had a fish dinner with one scotch and water drink and maybe had some coffee, which cost approximately $12-$14. He informed that he did not see the actual bill. According to [redacted] "When the bill arrived, I asked Mr. [redacted] what is my portion and his comment was, oh, don't worry about it, and I said, no, I'm not able to accept a meal from a licensee or anyone who represents a licensee" (Pg 37), and [redacted] gave [redacted] $25. [redacted] stated that he assumed that the $25 was adequate to cover his meal and drink. He noted that [redacted] paid the bill with his American Express credit card.

[redacted] said the dinner with [redacted] lasted for approximately two hours. [redacted] informed that during the dinner he reviewed documents [redacted] presented to him. [redacted] noted that the documents pertained to the corrective action for violations identified by Region III during the past inspection of Lafayette Clinic. He explained that [redacted] brought the documents to him for review because they were going to be submitted to the Region III and [redacted] wanted to make sure the documents would be acceptable. [redacted] added that the review of these draft documents by NRC personnel prior to the documents being submitted to the NRC was permissible and done often. He stated that at the conclusion of the dinner [redacted] drove him to his hotel.

[redacted] stated that he was aware of NRC policies on employee conduct and conflict of interest. He noted that he kept a special file of the NRC announcements on conflict of interest and other documents pertaining to employee conduct regulations.

OFFICIAL USE ONLY

[redacted] did not believe having a meal with [redacted] in which he paid for his portion was a problem. In [redacted] view, his meal with [redacted] did not violate any conflict of interest rules. However, [redacted] maintained if he were placed in the situation again he would not dine with [redacted]

TUESDAY, APRIL 4, 1989 MEAL WITH [redacted] AND [redacted]

[redacted] Weekly Business & Expense Report indicated that on April 4, 1989, he had dinner with [redacted] and [redacted] at the Holiday Inn in Detroit, Michigan. [redacted] reported that the cost for the dinner was $56.56 (Exhibit 48).

[redacted] recalled that [redacted] and [redacted] were in Detroit conducting an inspection at Lafayette Clinic. [redacted] advised that he and the two inspectors temporarily resided at the same hotel and met for dinner in the hotel restaurant. During the dinner, [redacted] believed they discussed the current violations at Lafayette Clinic and the progress of [redacted] training. According to [redacted] and [redacted] paid him cash for their meals. He did not recall how much each inspector paid (Exhibit 22).

With respect to [redacted] expense account not reflecting the monies provided to him by the inspectors, [redacted] gave the same explanation as he did for his dinner with [redacted] reiterated that the NES accounting process for cash received was complicated and cumbersome. [redacted] emphasized that [redacted] was not concerned with the amount of money he spent on a trip, but with the success of his trip.

[redacted] NMSB, Region III, stated that he was familiar with NES as a health physics consulting firm to some NRC licensees. [redacted] was aware that NES was involved with two NRC licensees, Lafayette Clinic and University of Cincinnati. [redacted] stated that he came in contact with NES while conducting an inspection at Lafayette Clinic in April 1989 (Exhibit 31).

On April 4, 1989, [redacted] recalled dining with NES representative, [redacted]. He maintained that the dinner with [redacted] occurred after work hours. [redacted] explained that he and [redacted] a trainee inspector were sitting in the Holiday Inn Hotel restaurant when [redacted] approached him and [redacted] and asked if he could join them. [redacted] believed that [redacted] was staying at the same hotel as he and [redacted]. According to [redacted] while the three ate dinner they discussed the radiation protection industry.

[redacted] stated that each person paid for their meal, and he and [redacted] paid cash. According to [redacted] "My general practice is to pay for the meal myself using my own cash as opposed to giving the money to someone else and letting them pay" (Pg 11). He claimed that he did not allow [redacted] to pay for the meal.

OFFICIAL USE ONLY

[redacted] did not believe there was anything improper about he and [redacted] dining with [redacted] including the appearance of any impropriety. [redacted] stated that he and [redacted] were well aware that inspectors could not accept any meals, gratuities, or gifts from licensees or contractors. He added that as an inspector he was taught to decline meals with licensees or contractors. However, [redacted] informed that he did not decline [redacted] request because he "did not feel there was any problem with him joining us for a casual dinner" (Pg 15).

[redacted] Division of Radiation Safety and Safeguards (DRSS), Region II, began his career with Region III in 1989. Upon graduating from college [redacted] was hired as a [redacted] in NMSB. [redacted] informed that his initial supervisor was [redacted] (Exhibit 32).

One of [redacted] first inspection trips was to Lafayette Clinic with [redacted] in April 1989 [redacted] advised that he accompanied [redacted] in a training capacity and was not intimately acquainted with the issues of the inspection. [redacted] believed NES was the consultant to Lafayette Clinic, but was not positive of NES' role.

[redacted] acknowledged that on April 4, 1989, he and [redacted] had dinner with [redacted] explained that he and [redacted] happened to meet [redacted] in the lobby of the hotel, where all three were staying. [redacted] continued that after meeting [redacted] in the hotel lobby, they all went to the hotel restaurant and sat at the same table. He did not recall anyone asking whether the other wanted to eat with one another. [redacted] reiterated that he, [redacted] and [redacted] happened to meet and sit down together at the same table.

[redacted] maintained that each person paid for their meal. He did not recall how much he paid, but suggested $10, $12 or $15 in cash. [redacted] did not recall what was discussed at the dinner, although, he stated that information concerning the inspection at the clinic was not discussed. [redacted] believed that each person had a separate bill. [redacted] did not recall specifically requesting a separate bill, but maintained that he typically did so.

[redacted] did not believe that he had been formally advised of the conflict of interest rules at this point in his career. According to [redacted] "...it was probably more or less I was running off common sense type stuff" (Pg 16). [redacted] stated that he did not think there was a conflict of interest problem if a dinner with a consultant concerned business.

SUNDAY, JULY 21, 1991 MEAL WITH [redacted]

The Weekly Business & Expense Report of [redacted] indicated that on July 21, 1991, he had lunch with [redacted] at a restaurant (name unknown) in Washington, D.C. [redacted] reported that the cost for the lunch was $64.54 (Exhibit 49).

[redacted] told OIG that he and his wife had brunch with [redacted] and his wife in Annapolis, Maryland, instead of Washington, D.C. He advised that the brunch was purely a social event. According to [redacted] he and his wife attended a Health Physics show in Washington, D.C. and stopped by to visit the [redacted] He informed that the foursome went to brunch at a restaurant on the waterfront in Annapolis (Exhibit 22).

[redacted] did not recall whether [redacted] paid for their meal. However, [redacted] stated that he did not mind paying for [redacted] because he believed a brunch was the least he could do for [redacted] explained that [redacted] was his [redacted] at NES for many years, and they had developed a good friendship. [redacted] did not believe his friendship with [redacted] posed a problem to the NRC because [redacted] work at the NRC did not relate to NES.

[redacted] stated that subsequent to his being hired by the NRC in February 1990, he dined with [redacted] informed that he has known [redacted] for approximately 11 years, having worked with him at NES. [redacted] recalled one occasion when [redacted] and his wife visited [redacted] and his wife. According to [redacted] the [redacted] were in the Maryland area visiting the Annapolis Naval Academy in anticipation of their son's future enrollment at the academy. [redacted] noted that he and his wife took the [redacted] to brunch at the Middleton Tavern and later gave them a tour of the naval academy. [redacted] did not recall the date of the brunch, but believed it occurred on a Sunday during the warm weather season. [redacted] did not recall who paid for brunch (Exhibit 21).

[redacted] stated that he was aware of the NRC's policies on conflict of interest and employee conduct codes, but did not believe he violated any rules. In [redacted] view, there was not a problem with his brunch with [redacted] because they had a friendship that was established prior to [redacted] working at the NRC. He noted that his work at the NRC did not effect NES in any manner. [redacted] added that neither the business of the NRC nor NES was discussed at the brunch.

INTERVIEW OF NES' [redacted] REGARDING THE MEALS WITH REGION III:

[redacted] NES, stated that NES had a practice of not paying for government employees' meals because his employees knew it was against the government's regulations. [redacted] advised that he did not implement this practice as a written policy. [redacted] believed that all NES employees understood that government

employees were not to be taken out and entertained. However, [redacted] maintained that sitting down and splitting the cost of a meal with a government employee was acceptable (Exhibit 19).

[redacted] stated that upon receipt of an OIG subpoena for NES documents on May 1992, he noticed [redacted] expense accounts reported meals with NRC/Region III inspectors. [redacted] advised that he questioned [redacted] regarding the meals and believed him when [redacted] said the Region III inspectors paid cash for their meals. [redacted] noted that there were not many occurrences of meals with Region III inspectors, and [redacted] had been very scrupulous in the past so he believed him. [redacted] explained that he probably gave a cursory examination of [redacted] expense account and left the accounting particulars to the NES' Accounting Department.

[redacted] stated that NES worked on the honor system. He acknowledged that he would have preferred that [redacted] reduce the amount the inspectors paid him for the meals. He added that [redacted] should not have "pocketed" any money paid to him by the inspectors. [redacted] concluded that if [redacted] received money from the inspectors and did not account for it on his expense reports then it was wrong. [redacted] stated that he was not overly concerned about the disparities in [redacted] expense report because he was primarily interested in the how productive his employees' business trips were for NES.

INTERVIEWS OF NRC/REGION III MANAGEMENT REGARDING THE MEALS WITH NES:

[redacted] DRSS, stated that he was not aware any inspector had dined with NES representatives. [redacted] advised that approximately a week prior to his interview with OIG, [redacted] told him that he had gone out to dinner with an NES representative on one occasion. [redacted] noted that [redacted] insisted he paid for his portion of the meal. He added that [redacted] provided this information unsolicited (Exhibit 50).

[redacted] stated that "Conflict of Interest" training for Region III inspectors began in 1989 and continues. He informed that the inspectors were given scenarios that were applicable to avoiding meals or engaging in social activities with licensees or licensees' contractors. Further, [redacted] stated that after the various scenarios were discussed the inspectors were queried for the correct response to ensure that they were cognizant of appropriate conduct by NRC employees. [redacted] added that NRC/Region III inspectors were trained and quizzed on Title 10 Code of Federal Regulations (CFR) 50 Part 0. Certification of such training is documented by having each inspector initial and date his Training Qualification Card periodically.

[redacted] DRSS, Region II, advised that he was not aware of any Region III inspector having a meal with NES during his tenure as a Region III

[redacted] indicated had he known an inspector had dinner with a consultant, whether the inspector paid for the meal or not, [redacted] would have counseled the individual. [redacted] believed that a meal with licensees and/or consultants posed an appearance of a conflict of interest. Further, [redacted] stated that there was a more serious problem with [redacted] dining with a consultant because as a [redacted] had power to make decisions affecting the licensee (Exhibit 39).

[redacted] said that he cautioned his inspectors not to have lunch with licensees. According to [redacted] each inspector was given a Training Qualifications Journal upon being hired in the region, which provided instruction concerning conduct codes for inspectors. [redacted] continued that after receiving the appropriate instructions, an inspector must sign the journal certifying that instructions were given. [redacted] recalled that at least once a year during his tenure he had meetings or discussions regarding conflict of interest rules.

[redacted] advised that as part of his responsibilities as [redacted] he reviewed the "Conduct of Employees," Part O of the Code of Federal Regulations (CFR) with all new Region III employees. [redacted] said he explained to the employees that meals should not be taken and to be discrete about pre-existing friendships. In addition, [redacted] reviewed the Fundamentals of Inspection with all new inspectors to Region III. [redacted] noted that the region has received the conflict of interest announcements generated by NRC headquarters throughout the years. According to [redacted] Region III employees, especially the inspectors are well versed in conflict of interest rules (Exhibit 43).

In addition to the NRC's period announcements and regulations contained in CFR Part O, Region III inspectors were provided guidance in the NRC Inspection Manual, Chapter 1201, "Conduct of Employees." The NRC Inspection Manual, 1201-07 (b) Meals,, states: "Employees shall not go to places of entertainment or out to eat with an employee of a licensee or its contractors when the NRC employee is normally assigned to work on, or is responsible for, matters directly affecting that licensee or contractor. This restriction applies even though the NRC employee pays his or her own way" (Exhibit 51). The manual further instructed employees to discuss with their immediate supervisor all cases of actual or potential conflicts of interest or situations which might lead to the appearance of a conflict of interest.

FINDINGS/ALLEGATION II

The OIG investigation disclosed that NRC employees, [redacted] and [redacted] dined with NES representative, [redacted] on different occasions. However, the investigation did not conclusively determine whether the NRC employees received a gratuity in the form of meals from [redacted] The employees stated they paid cash for their portion of the meals,

however, the employees' testimonies were not consistent with [redacted] Weekly Business and Expense Reports.

The investigation disclosed that on three separate occasions [redacted] submitted expense reports reflecting that he incurred the full cost of the NRC employees' meals. [redacted] testimony did not adequately address his claims represented on his expense reports. Either [redacted] submitted false expense reports to NES or was untruthful to OIG. In either situation, the perception exists that the government employees received free meals from [redacted]

The investigation revealed that [redacted] and [redacted] were not sufficiently sensitive to their responsibility to avoid actions that might result in or create the appearance of a conflict of interest. As [redacted] and [redacted] were directly involved with the regulatory activities that affected NES, as a contractor. These inspectors should have been aware of the restriction for accepting meals with a licensee or its contractor, including meals that were paid for by them.

The investigation did not develop sufficient evidence to determine that [redacted] dined with [redacted] when [redacted] was an NES employee. [redacted] stated that he dined with [redacted] on two occasions, in which [redacted] Weekly Business and Expense Reports reflect the two occasions. [redacted] categorically denied having a meal with [redacted] on either occasion.

Exhibits:

[redacted]

American College of Medical Physics

1891 Preston White Drive • Reston, Virginia 22091
(703) 648-8966 • (703) 648-9176 FAX

June 2, 1993

The Honorable Senator John Glenn
United States Senate
Washington, D.C. 20510

Dear Senator Glenn,

On behalf of the American College on Medical Physics, I wish to thank you for the opportunity to provide testimony to the Senate Committee on Governmental Affairs hearing on federal regulation of medical radiation uses. Enclosed you will find a copy of our testimony to be included in the official records of this hearing.

Certainly, The American College of Medical Physics is willing and anxious to provide to your Committee any additional information which you require. Thank you again for the opportunity to submit this testimony.

Best Wishes,

Michael T. Gillin, Ph.D
Associate Professor

MG/keo

Statement to the Senate Governmental Affairs Committee

by the American College of Medical Physics, May, 1993

The American College of Medical Physics(ACMP) appreciates the opportunity to express to the Senate Governmental Affairs Committee its positions on federal and state regulations on "Medical Radiation Protection' and associated topics. The ACMP is an organization of senior, clinically experienced medical physicists in the United States who are especially interested in the contributions their professional expertise can provide toward patient care and safety. Medical physicists are the board certified, non physician, medical specialists who bear the responsibility for ensuring the specific quantity, quality, and placement of radiation doses in any medical imaging or therapeutic procedure involving ionizing radiation. The ACMP agrees with the concerns expressed by Senator Glenn relative to the scattered, fragmented, and inconsistent regulations on the medical use of radiation. In addition, the ACMP is concerned that future cost containment pressures may result in the reduction of the existing standards with a subsequent increase in risks to the public health.

The risks to the public health from the use of ionizing radiation have been well studied. The National Council on Radiation Protection and Measurements (NCRP), an organization chartered by the U.S. Congress, and its predecessor national committees have been involved with this topic since 1929. The NCRP has published over 100 reports which contain detailed recommendations on medical and non-medical uses of ionizing radiation. There have been multiple reports of the Advisory Committee on the Biological Effects of Ionizing Radiations (BIER) of the National Academy of Sciences. From the public health perspective, the diagnostic use of ionizing radiation exposes a much larger portion of the population than does the therapeutic use of ionizing radiation. To avoid the fragmented situation noted by Senator Glenn, the ACMP recommends that any federal initiative address both diagnostic and therapeutic uses of ionizing radiation. To focus on the one thousand linear accelerators in the U. S. and to ignore the hundreds of thousands of diagnostic x-ray tubes would indeed be inconsistent. In April, 1992, the ACMP held a symposium entitled Current Regulatory Issues in Medical Physics. The symposium addressed the following topics:

1. Suggested State Regulations for Radiation Therapy
2. Suggested State Regulations for Diagnostic Radiology
3. Licensure of Medical Physicists
4. The NRC Quality Management Program and Misadministrations
5. The New 10CFR20 Radiation Exposure Limits for Personnel and the Public
6. Mammography Equipment Performance Requirements
7. Equipment and Software Requirements for Radiation Oncology.

(A copy of that symposium accompanies this report.)

Regulatory issues and public health concerns and patient health concerns have been addressed by numerous scientific, professional, educational private and public organizations. The ACMP urges the Committee to review the recommendations of the various organizations while considering the drafting of any new legislation.

The American College of Medical Physics has passed several resolutions which speak directly to the concerns raised by Senator Glenn. One resolution "urges that federal regulatory responsibilities for medical devices including the use of ionizing radiation be consolidated into one agency which by virtue of its comprehensive regulatory position will be in a better position to protect the public health and insure patient safety and will be better positioned to coordinate with the individual states to implement their oversight responsibilities, and that this agency be the Food and Drug Administration" (adopted March, 1993). The FDA through the Center for Devices and Radiological Health (CDRH) has a long and basically successful history in protecting the public health from both diagnostic and therapeutic medical applications using ionizing radiation. They have developed good working relationships with the states, with industry, and with users. The Nuclear Regulatory Commission, on the other hand, spends less than 5% of its budget to regulate less than 2% of the medical uses of ionizing radiation. They have been very slow in dealing with new technology, such as remote afterloading devices. The relationship between the NRC and others, including the states and the NRC licensees, tends to be more legalistic than constructive. Chairman Ivan Selin of the U. S. Nuclear Regulatory Commission in his statement to this Committee acknowledged that there are areas where improvement is needed in the NRC's medical use program. Certainly, the weaknesses of the NRC's programs have been long apparent to those being regulated by this agency. It must be noted that the NRC's Advisory Committee on the Medical Use of Isotopes met directly with the Commissioners for the first time ever in 1992. One question which should be faced by the Committee on Governmental Affairs is can the NRC cast off its history of isolation and refocus itself from "detailed compliance with NRC requirements" to "overall radiation safety performance" in the medical environment, as was suggested by Chairman Selin.

Another ACMP resolution "recommends that the Radiation Safety Officer (RSO) named on the license for each medical institution should be independent of the direct clinical use of the radiation producing equipment and the radioactive material, and should report directly to the institution's management for the purposes of radiation safety". As part of the same resolution, the ACMP has also stated that "the institution's management must assure that the RSO named possesses appropriate and sufficient training in radiation safety for the responsibilities imposed by the type of medical procedures being performed and has the necessary experience in radiation safety in the medical environment to manage the radiation safety program in a safe and efficient manner" (adopted March, 1993). The current practice in many institutions is to name a physician who is an authorized user for the medical use of radiation producing equipment and radioactive material as the radiation safety officer or the chairman of the

oversite committee to which this officer reports and this results in the user being the evaluator of the radiation safety program. Title 10 CFR Part 35.21, 22, and 23 and 35.900 (copies attached) contain the pertinent details of the NRC's requirements for the RSO and permit this real or perceived appearance of this conflict of interest in the supervision of the radiation safety program.

Another ACMP resolution "urges the USNRC and appropriate state licensing agencies that appropriately trained and experienced medical physicists be named on the license for each use of radioactive materials, including afterloading units, and that such individuals be charged with the responsibility of insuring patient safety for the treatments delivered with such units". (adopted March, 1993). The NRC in Part 35.961 (copy attached) lists the training for a teletherapy physicist. The NRC has yet to develop any regulations describing the minimum training requirements for any aspect of brachytherapy including remote afterloading devices. As recent tragic events have indicated, it is prudent and wise to supplement the medical focus of the physician with the safety focus of the physicist. The failure to address staffing and training needs for brachytherapy procedures must be corrected soon.

It must be noted that the Nuclear Regulatory Commission currently requires a license for an individual to handle teletherapy sources. A NCR license is also required to calibrate a Geiger counter, to calibrate a nuclear medicine dose calibrator, and to possess the sources used in such calibrations. All of these licenses are granted by the Nuclear Regulatory Commission or an agreement state. In the 1980's the NRC required that the teletherapy physicist be named on the license. Why has the NRC chosen not to require licenses to calibrate cobalt teletherapy units or sealed sources used in brachytherapy? Both of these applications of radioactive material have been used for decades. Apparently it required the Indiana, Pennsylvania accident with a high activity source used in a remote afterloading device to force the NRC to address issues associated with this new technology.

The American Association of Physicists in Medicine Report 45 states that a medical radiation oncology physicist should be on-site during operational hours of a radiation therapy clinic. The Report of the Inter-Society Council for Radiation Oncology, Radiation Oncology in Integrated Cancer Management, November 1986, contains the following description of medical radiation physics activities:

> The ultimate objective of the medical radiation physics activities is to insure the delivery of high quality treatment. This requires quality control of the physical components of treatment. Necessary surveillance includes:
>
> 1. equipment functioning and safety
> 2. treatment planning
> 3. treatment application
> 4. dosimetry
> 5. personnel radiation safety.

From the information gathered on the high dose rate remote afterloading accident in Indiana, Pennsylvania, it appears that the institution did not have a full time, on-site physicist. Perhaps one reason why there was no qualified medical radiation oncology physicist present is related to recent changes in the HCFA reimbursement policies for physics services, namely that for free standing centers the global fee for medical physics services is paid to the physician. The absence of federal and state regulations requiring that qualified medical radiation oncology physicists be on-site during operational hours and the difficulties associated with institutions being appropriately reimbursed for physics services has partially lead to the current concerns expressed by Senator Glenn and others. Qualifications, staffing, and appropriate reimbursement are all issues which the Committee should explore.

In the diagnostic area, HHS has published regulations specifying the qualifications of physicists who can calibrate mammography units. This is the only such requirement for the calibration of diagnostic ionizing radiation devices. The JCAHO does require annual calibration of diagnostic units for those institutions who seek their accrediation. The appropriate calibration of the tens of thousands of x-ray units in private offices is substantially less certain.

The question of appropriate qualifications for individuals who are given the responsibility for insuring the public health with respect to the use of ionizing radiation is a very important one. Two different specialty boards currently certify the minimum qualifications of most medical physicists in the United States, namely the American Board of Medical Physics and the American Board of Radiology. There are now over 1,000 board certified medical physicists in the United States. Licensure of medical physicists is now required in the State of Texas. There is movement towards licensure in some other states.

The NCRP has published a definition of a qualified expert for several decades which is based upon board certification. The American College of Medical Physics has adopted the following definition for a qualified medical physicist:

A qualified medical physicist is an individual who is competent to practice independently in one or more of the subfields of medical physics.

1. At the present time, the subfields of medical physics are:

a) Therapeutic Radiological Physics is that branch of medical physics which deals with (1) the therapeutic applications of roentgen rays, of gamma rays, of electron and charged particle beams, of neutrons, and of radiation from sealed radionuclide sources, and (2) the equipment associated with their production and use.

b) Diagnostic Radiological Physics is that branch of medical physics which deals with (1) the diagnostic applications of roentgen rays, of gamma rays from sealed sources, of ultrasonic radiation, of radiofrequency radiation, and (2) the equipment associated with their production and use.

c) Medical Nuclear Physics is that branch of medical physics which deals with (1) the therapeutic and diagnostic applications of radionuclides (except those used in sealed sources for therapeutic purposes), and (2) the equipment associated with their production and use.

d) Medical Health Physics is that branch of medical physics which deals with the safe use of roentgen rays, of gamma rays, of electron and other charged particle beams, of neutrons, of radionuclides, and of therapeutic purposes, and (2) the instrumentation required to perform appropriate radiation surveys.

Additional subfields may be added as required.

2. An individual will be considered competent to practice one or more of the subfields of Medical Physics if that individual is certified or licensed in that field by any of the following organizations:

a) The American Board of Medical Physics.
b) The American Board of Radiology.
c) The American Board of Health Physics.
d) The American Board of Science in Nuclear Medicine.
e) The Canadian College of Physicists in Medicine.

Additional certifying organizations may be added as they are recognized.

3. It is expected that an individual will not hold him/herself out to be qualified in a subfield for which he/she has not established competency according to the requirements of paragraph 2 above.

4. The American College of Medical Physics regards board certification, in the appropriate medical physics subfield, and state licensure, in those states in which licensure exists, as the appropriate qualification for the designation of a Qualified Medical Physicist (adopted July 17, 1986; revised May 1, 1993).

The specification of the minimum training and experience of the regulators has never been comprehensively addressed. Thus in some inspection situations the high school graduate inspector is evaluating the work of the physician and the Ph.D. physicist. The substantially greater expertise of those being inspected diminishes the inspection process.

In summary, the ACMP salutes Senator Glenn and other members of the Senate Governmental Affairs Committee for the identification of problems in the area of medical radiation protection. The ACMP shares Senator Glenn's concerns about the current regulatory situation, which is not only scattered, fragmented, and inconsistent, but is also very expensive. The American College of Medical Physics wishes to emphasize the following points:

1. The entire spectrum of the medical uses of ionizing radiation should be reviewed to adequately address all public health concerns.

2. The Center for Devices and Radiological Health of the Food and Drug Administration be the appropriate federal agency in which to center all federal activities involving the medical use of ionizing radiation.

3. There should be both federal and state regulations which define a qualified medical physicist and which require a qualified medical radiation oncology physicist to be on-site during operational hours for radiation oncology clinics.

4. HCFA should be requested to develop appropriate reimbursement regulations which insure that adequate funds are available to support all medical physics activities and that such funds are only paid when there are appropriately qualified medical physicists associated with the services provided to the Medicare patient.

5. The NRC be instructed to:
   A. License medical radiation oncology physicists to calibrate Co-60 teletherapy units and brachytherapy sealed sources.
   B. Name medical physicists on the license of each institution who wishes to perform brachytherapy procedures.
   C. Develop regulations to require that the radiation safety officers at medical institutions be independent of direct, clinical responsibilities

6. The Department of Health and Human Services be instructed to issue regulations that require all diagnostic radiology units, which image Medicare patients, and not just mammography units be calibrated by a qualified medical physicist.

The American College of Medical Physics will be pleased to provide the Committee with any additional information which the Committee would require and is grateful to the Committee for the opportunity to express its opinions.

American College of Medical Physics

April 16, 1993

The Honorable Senator John Glenn
Chairman
Government Affairs Committee
United States Senate

Dear Senator Glenn,

The American College of Medical Physics, a professional organization consisting of the senior medical physicists in the United States, has recently adopted three resolutions pertaining to regulatory aspects of the use of ionizing radiation for medical purposes. Enclosed find copies of those resolutions. It is my request that they be included in the record of the hearings which the Governmental Affairs Committee is going to conduct next week with representatives of the U. S. Nuclear Regulatory Commission.

Thank you very much for considering this request. Clearly, I would be happy to expand in these issues with you or a member of your staff. It is my hope that your hearings go well.

Best Wishes,

Michael T. Gillin, Ph.D
Chairman, ACMP

MG/keo

1891 Preston White Drive, Reston, Virginia 22091
(703) 648-8966

Whereas,

Radiation safety is an important aspect of every medical application which uses ionizing radiations in patient diagnosis or treatment, and

Whereas

the public, medical personnel, and the patient have a right to be safeguarded from the mis-use of ionizing radiations whether produced from equipment or from radioactive materials, and

Whereas

The current practice of medical institutions is to name aphysician who is an authorized user for the medical use of radiation producing equipment and radioactive material as the radiation safety officer (RSO) or the chairman of the oversite committee to which this officer reports and this results in the user being the evaluator of the radiation safety program,

Whereas

It is necessary to avoid real or perceived appearances of any conflict of interest in the supervision of the radiation safety program, and

Whereas

Assuring that appropriate trained and experienced staff necessary for the proper performance of the duties of a radiation safety officer is the responsibility of the medical instituion's administration, therefore

Be It Resolved that the American College of Medical Physics recommends that the Radiation Safety Officer named on the license for each medical institution should be independent of the direct clinical use of the radiation producing equipment and the radioactive material, and should report directly to the institution's management for the purposes of radiation safety. Be it further resolved that the institution's management must assure that the RSO named possesses appropriate and sufficient training in radiation safety for the responsibilities imposed by the type of medical procedures being performed and has the necessary experience in radiation safety in the medical environment to manage the radiation safety program in a safe and efficient manner.

Whereas

The duplicative efforts and oversight functions of the various federal, state, and local regulatory agencies or departments pertaining to the medical use of ionizing radiation are costly, wasteful, and a dilution of the limited, specialized talent contained within these various agencies or departments

Whereas

One federal agency by virute of its comprehensive regulatory position will be in a better position to protect the public health and insure patient safety and will be better positioned to coordinate with the individual states to implement their oversight responsibilities

Be It Resolved that the American College of Medical Physics urges that federal regulatory responsibilities for medical devices including the use of ionizing radiation be consolidated into one agency who by virtue of their comprehensive regulatory position will be in a better position to protect the public health and insure patient safety and will be better positioned to coordinate with the individual states to implement their oversight responsibilities and that this agency be the Food and Drug Administration.

Whereas,

High dose rate, remote afterloading units are inherently complex electro-mechanical devices which contain high activity radioactive sources that are transported by mechanical means into and from the patient

Whereas,

Recent events have demonstrated the potential for great harm to patients from these devices,

Be It Resolved that the American College of Medical Physics urges the USNRC and appropriate state licensing agencies that appropriately trained and experienced medical physicists be named on the license for each use of radioactive materials, including afterloading devices, and radiation beams, as is currently done for Co-60 units, and such individuals be charged with the responsibility of insuring patient safety for the treatments delivered with such units.

ACNP
1101 Connecticut Avenue, N.W. • Suite 700 • Washington, D.C. 20036
(202) 429-5120 Fax (202) 223-4579
American College of Nuclear Physicians
SNM
The Society of Nuclear Medicine

STATEMENT SUBMITTED TO THE

U.S. SENATE GOVERNMENTAL AFFAIRS COMMITTEE

Regarding

MEDICAL RADIATION PROTECTION

On Behalf of

The American College of Nuclear Physicians

and

The Society of Nuclear Medicine

May 13, 1993

For More Information Contact:
Kristen D.W. Morris
ACNP/SNM Director of Government Relations
(202)429-5120

The American College of Nuclear Physicians (ACNP) and the Society of Nuclear Medicine (SNM) are submitting the following comments to the Senate Committee on Government Affairs to describe the medical practice of nuclear medicine and to clarify the distinction between it and radiation therapy. We will discuss the inherent safety of the radioactive tracer materials used in nuclear medicine, the counterproductive nature of duplicative regulation, and the burden of increasingly costly regulation which we believe will not significantly improve medical care or radiation safety.

As the two largest voluntary health care organizations dedicated solely to the practice of nuclear medicine, we will always support reasonable efforts to improve the safety and quality of medical care provided to patients. It is unfortunate when public attention to medical care involving the use of radioactive materials is communicated by the media in a sensationalistic or confusing manner, or in a way that is not fully informative. We have concerns that this kind of reporting may in some cases cause patients to delay or even avoid necessary medical testing for lifesaving treatments.

We appreciate the opportunity to provide information which will put into perspective the relatively few, unacceptable, untoward medical events involving radiation in nuclear medicine. In contrast, approximately 10 million properly performed diagnostic and/or therapeutic procedures each year in nuclear medicine have individually and collectively improved health care in a cost-effective, safe manner.

Specialty Background

The College (ACNP) and the Society (SNM) have approximately 15,000 physician, pharmacist, scientist, and technologist members dedicated to the specialty of nuclear medicine. There is a separate medical Board certification for physicians (American Board of Nuclear Medicine), as well as independent Board certification for nuclear pharmacists (American Board of Nuclear Pharmacy), for nuclear medicine scientists (American Board of Science in Nuclear Medicine), and for nuclear medicine technologists (Nuclear Medicine

Technology Certification Board). Prior to the establishment of these Boards, members have completed approved training programs meeting strict standards.

Nuclear Medicine is a medical specialty in which tracer amounts of radioactive drugs are used to diagnose a large variety of illnesses in patients being evaluated by practitioners in primary care and most of the medical and surgical specialties and subspecialties. Examples of the types of medical or surgical conditions diagnosed include coronary artery disease, infections, metastatic prostate and breast cancer, sports "shin splints" or stress fracture injuries and gallbladder disease. Nuclear medicine physicians administer a lesser number of treatments to patients using larger amounts of radioactive drugs for cancerous and serious, non-cancerous medical conditions. Thyroid cancer, painful cancerous bone metastases from prostate cancer, life threatening blood disorders and hyperthyroidism are a few of the disorders which often are eliminated or improved as a result of treatment with radioactive medicines.

Nuclear Medicine is distinguished from other medical specialties by the expertise in using radioactive drugs which are "unsealed sources." That is, radioactive drugs which are usually injected, swallowed, or inhaled and concentrate in specific organ tissues or abnormalities such as tumors. This differs from other medical specialties using radiation such as diagnostic radiology or radiation oncology which use sealed sources of radioactive material or radiation producing machines.

Approximately 10 to 11 million patient procedures are performed in nuclear medicine each year. Additionally, about 100 million tests analyzing body fluids by "radioimmunoassay" (RIA) are performed each year using tracer amounts of radioactivity. In these RIA tests the radiation has no contact with the patient. Most of us know someone who has benefited from a pregnancy test (beta-hCG), prostate cancer tumor marker PSA, ovarian cancer tumor marker CA-125, thyroid function tests, etc. Most of these tests have involved the use of radioactive materials in radioimmunoassay.

While the Senate hearing on May 6, 1993, very clearly described the difference between nuclear medicine and other specialties, the definition was lost on other members of the public. Following the hearing several stories appeared in the media which perpetuated a misunderstanding regarding nuclear medicine[1] [2]. Our specialty has suffered due to the assumption that nuclear medicine is a generic term for all medical radiation procedures. We hope that as Congress continues to review this issue that this distinction in nomenclature is maintained.

Safety Aspects

It is estimated that the average citizen in the United States receives about 300 mrem per year of background radiation. This compares favorably with the small amount of radiation received by patients from a diagnostic nuclear medicine procedure. The National Council for Radiation Protection and Measurement (NCRP) has indicated that this average effective radiation dose for a nuclear medicine imaging test is 440 mrem per year. To put this small patient radiation discussion into perspective, please consider the NRC (Nuclear Regulatory Commission) guidelines allowing a radiation worker to receive up to 5000 mrem per year or ten times more than a patient receives from the nuclear medicine test. Radioactive drugs used in nuclear medicine tests are used in such minute amounts that it is truly rare for a patient to experience any allergic reaction, side effect, or untoward results. In fact, a pregnant woman with chest pain or shortness of breath who is thought to have a significant risk of life-threatening blood clots in the lungs (pulmonary emboli) is deliberately sent to a nuclear medicine physician for testing with radioactive drugs.

About 200 million Americans have benefitted from these radioactive drugs during the past half century. A testimony to the cost-effective, medical benefit and safety of the procedures is exemplified by the increased utilization and reliance on nuclear medicine procedures by physicians expert in other medical specialties such as primary care, cardiology, surgery, urology, etc. A recent publication in CA: A Cancer Journal for Clinicians the highlights from the National Cancer Data Base: 1993 were discussed [3]. This article indicates that

bone scans in men with prostate cancer increased from 21.5% in 1974 to 73% in 1990. Treatment for these men depends in significant part on information proved by these tests.

Commitment to Quality

Our members have a strong commitment to quality in the nuclear medicine profession. Annually for the last 40 years the Society (SNM) has held a national education meeting to advance the quality practice of nuclear medicine. A monthly scientific journal for nuclear medicine professionals is published by the SNM. The ACNP has a mature, peer review practice certification program to foster the delivery of safe, quality nuclear medicine services in hospitals and clinics in the United States. These voluntary peer-review inspections are growing in number and we hope that more practitioners will participate in the future.

We are encouraged by the stated willingness of the NRC to consider accepting peer review, nuclear medicine practice certification programs to be an alternative to NRC inspections of the quality management aspects of a practice. We also support the recently instituted NRC Visiting Medical Fellow Program which included a nuclear medicine physician and a nuclear pharmacist at NRC for the first time in NRC's history. The pending NRC contract with the National Academy of Sciences or Institute of Medicine, which would study the role of NRC in the medical use of byproduct material, should provide excellent, independent insight into present problems. We look forward to the swift initiation of this much needed project.

Regulation

Nuclear Medicine is more regulated than any other medical specialty. In addition to the normal medical regulatory controls, inspections, and paperwork (from the Health Care Financing Administration, the Joint Commission on Accreditation of Healthcare Organizations, the Occupational Safety and Health Administration, etc.), multiple Federal agencies have a responsibility for oversight of some aspect of the activity in nuclear medicine. NRC regulates radiation safety, the Food and Drug Administration (FDA)

regulates radiopharmaceuticals, the Environmental Protection Agency (EPA) regulates radiation in relation to the environment, the Department of Transportation (DOT) regulates transportation of radiopharmaceuticals across State lines, and the Federal Trade Commission (FTC) regulates by preventing us from restricting practice to Board Certified individuals.

At a time when the cost of health care is critical to the public, there is no significant effort on the part of these agencies to control or reduce costly paperwork. There is not enough interagency cooperation to reduce overlapping or duplicate regulation. There is no practical requirement for agencies to prove the significant benefit of a regulation in relationship to outcome and cost of the regulation.

It is understandable that agencies make an effort to carry out legal mandates. Many of these agencies are beginning to charge "users" for "services." This is becoming a significant burden to the public as part of the cost of health care.

Summary

The ACNP and SNM believe that nuclear medicine is being practiced safely and with quality by the vast majority of practitioners. Distinctions exist between us and other medical specialties, in terms of quantities of radiation used and the relative risks. Our organizations will continue to work with practitioners to minimize the relatively few, unacceptable untoward medical events involving radiation in medicine. We do not believe that new regulation will add to the safety or quality of nuclear medicine practices. In fact, efforts to reduce or coordinate the regulation of different Federal agencies allows practitioners more time to care for patients, and thereby increase quality.

Recommendations

1. The NRC is apparently evaluating its Agreement State Program. We welcome efforts to give States more authority to manage and monitor radiation safety in medicine just

as State Medical boards monitor medical practices.

2. Congress should consider ways to reduce health care costs by the coordination of overlapping and duplicative regulation by Federal agencies.

3. Congress should consider urging the President to appoint to the NRC a physician to the NRC Commission. This person should be Board certified in nuclear medicine or a specialty expert in the use of radiation in medicine.

4. Congress should consider ways to require a review of existing regulation in order to eliminate those that do not contribute to the public health and safety.

Thank you for the opportunity to comment on this most critical subject. We are available as a resource and hope to work with the Committee to address the issues presented during this hearing.

---

1. ABC Evening News, May 6, 1993.

2. "Nuclear Medicine's Risks Unreported, Most Patients Not Warned of Radiation Overdoses", Associated Press; Washington Post: Health Section, May 11, 1993, page 8.

3. Mettlin C. Jones GW, and Murphy GP: Trends in prostate cancer care in the United States, 1974-1990: Observations from the patient care evaluation studies of the American College of Surgeons Commission on cancer, In Murphy GP. CA: Cancer Journal for Clinicians 43:83-91, March/April, 1993.

RECENT AGREEMENT STATE REVIEWS
REGIONAL RESULTS

REGION	# AGREEMENT STATES	# A & C	# A	#FW
I	5	2	2	1
II	8	5	2	1
III	2	1		1
IV	9	5	3	1
V	5	2	2	1
TOTAL	29	15	9	5

Note: Data Current as of 5/20/93. A&C - Adequate and Compatible, A - Adequate, C- Compatible, FW - Finding Withheld

EXPLANATORY INFORMATION ON RECENT AGREEMENT STATE REVIEWS REGIONAL RESULTS CHART ADEQUACY AND COMPATIBILITY FINDINGS[1]

REGION I - 5 Agreement States

States found to be both adequate and compatible - 2

Maine (1992) — Maine became an Agreement State in April 1992. The first review was conducted April 26-30, 1993. The report documenting the results of that review has not been completed at this time.

Rhode Island (1991) — The last review was completed in November 1991 and the next review is scheduled for November 1993.

States for which a finding of compatibility was withheld - 2

Maryland (1991) — The last review was completed in April 1991 and the next review is schedule for August 1993.

Regulations overdue (and date due):

Waste disposal requirements	(1/86)
Transportation safety requirements	(9/86)
Waste classification standards	(12/86)
Waste shipment & manifest requirements	(12/86)
Remove exemption glass enamel & freud	(9/87)
Industrial radiography surveys & audits	(7/89)
Notification of filing for bankruptcy	(2/90)
Well logging safety requirements	(7/90)
Medical misadministration reporting	(4/90)
Certification of dosimetry processors	(2/91)
Funding of decommissioning plans	(7/91)

STATUS - A review visit was conducted of the State on June 9-10, 1992. The visit revealed that the State regulations continued to be seriously out-dated. In view of this, the results of the visit were sent to the State in a letter dated September 16, 1992 in order to bring this issue to the State's attention.

---

[1] The Office of State Programs' Director, upon signing of the letter documenting the results of the review, routinely calls the Agreement State management. During this call, the Director indicates the results of the review with emphasis being placed on areas needing improvement.

New York (1992)

The review of the New York radiation control programs was completed in November 1992 and the next review will be scheduled for November 1994.

Regulations overdue (and date due):

New York Department of Environmental Conservation

The regulations regarding low-level waste were determined to be compatible with NRC regulations. However, a finding of compatibility cannot be offered until the regulations become effective.

New York State Department of Health

Funding of decommissioning plans	(7/91)

New York City Health Department

Certification of dosimetry processors	(2/91)
Notification of filing for bankruptcy	(2/90)
Funding of decommissioning plans	(7/91)

New York Department of Labor

Funding of decommissioning plans	(7/91)

State for which findings of both adequacy and compatibility were withheld - 1

New Hampshire (1992)

The New Hampshire review was complete in June 1992 and the next review will be scheduled for June 1994.

Regulations overdue (and date due):

Funding of decommissioning plans	(7/91)

STATUS - The radiation control program (RCP) is in the drafting stage of the rule adoption procedure. Adequacy was withheld for two reasons. First, legal opinions were issued that indicated the RCP did not have the authority to (A) require licensees to clean-up contaminated facilities or (B) impound sources of radiation when necessary to protect public health and safety. Secondly, the RCP indicated it would need to relax its inspection effort in order to reduce a backlog of licensing actions. Efforts to resolve these issues are proceeding. These efforts have included assistance by the NRC and the Conference of Radiation Control Program Directors, Inc, (CRCPD) in reviewing licensing actions. This has allowed the State to reduce its backlog of licensing actions.

REGION II - 8 Agreement States

States found to be both adequate and compatible - 5

Florida (1993) — The review was completed on February 26, 1993 and the next review will be scheduled for February 1995.

Georgia (1991) — Next review October 1993

North Carolina (1991) — Next review December 1993

South Carolina (1993) — The last review was completed on March 24, 1993 and the next review will be scheduled for March 1995. The State of South Carolina has continued to have a strong radiation control program since it became an Agreement State on September 15, 1969. The program has undergone nineteen reviews by NRC, and has remained adequate and compatible during this period.

Mississippi (1991) — Next review September 1993

States for which a finding of compatibility was withheld - 2

Alabama (1991) — The last review Alabama was completed in June 1991 and the next review is scheduled for July 12-16, 1993.

Regulations overdue (and date due):

Certification of dosimetry processors (2/91)

STATUS - The rule was inadvertently omitted during the last rules update and a proposed rule is in the adoption process.

Kentucky (1992) — The last review of Kentucky was conducted in April 1992.

Regulations overdue (and date due):

Funding of decommissioning plans (7/91)

STATUS - A proposed rule is in the adoption process.

State for which findings of both adequacy and compatibility were withheld - 1

Tennessee (1992)

The Tennessee follow-up review was completed in September 1992.

Regulations overdue (and date due):

Well logging safety requirements (7/90)

STATUS - The well logging rules were adopted effective in November of 1992. **Note:** There is a slight difference between the NRC decommissioning rule and the equivalent Tennessee rule. The question of the compatibility of this rule is on hold pending a Commission determination of the "compatibility" issue. Adequacy was withheld due to a serious shortage of trained staff combined with a large backlog of overdue inspections.

REGION III - 2 Agreement States

State found to be both adequate and compatible - 1

Illinois (1992)

The Illinois review was completed in January 1992. However, the finding of compatibility is contingent on the Commission's evaluation of the State's regulations involving 1 millirem per year dose limit at the boundary of a low-level radioactive waste disposal facility, financial surety requirements for site reclamation and medical misadministrations.

STATUS - The compatibility issues with Illinois are still under consideration by the NRC. The 1 millirem issue is being discussed at the Commission level. A NRC and Illinois management meeting is scheduled for June 1993 to discuss the other compatibility issues.

State for which findings of both adequacy and compatibility were withheld - 1

Iowa (1993)

A follow-up review of the Iowa radiation control program was conducted in February 1993.

STATUS: Both adequacy and compatibility were withheld because the overall program was deficient due to management and programmatic deficiencies, which included: maintenance of adequate staffing levels; completion of technical training for inspectors/reviewers; and quality assurance reviews of licensees and reports by management. Corrective actions are underway, with reports from the RCP to NRC monthly. As the State has not yet reestablished an adequate and compatible program, the NRC has offerred continued short-term assistance to the State. This assistance has included licensing and inspection training, accompaniments of inspectors and the review of licensing case work.

REGION IV - 9 Agreement States

<u>States found to be both adequate and compatible</u> - 5

Arkansas (1991)

The 1993 review has been completed and the report will be issued shortly.

Colorado (1993)

The last review was completed on April 9, 1993 and the next review will be scheduled for April 1995.

North Dakota (1991)

A review is scheduled for June 21-25, 1993.

Utah (1992)

The last review of the Utah program was completed during the week of April 13-17, 1992. The findings of adequacy and compatible were contingent upon a satisfactory resolution of the technical quality of the licensing actions taken by State for the Envirocare low-level radioactive waste disposal license including the exemption of land ownership. The next review of the State will be scheduled in April 1994.

STATUS - The land ownership exemption issue is currently under review at the Commission level.

Texas (1993)

A follow-up review was conducted in January 1993. The last routine review was conducted in March 1992 and the next routine review will be scheduled for March 1994.

STATUS - On March 1, 1992, the Texas radiation control program was reorganized whereby the primary regulatory responsibility for the disposal of uranium mill tailings and low-level waste was statutorily assigned to the Texas Water Commission (TWC). This authority was previously assigned to the Texas Department of Health (TDH). In view of this reorganization, a follow-up review was conducted the week of January 25, 1993 to evaluate the transfer of authorities to the TWC. Although the follow-up review revealed that the program was adequate and compatible, the review disclosed that TDH was proposing the deletions of those sections in its regulations that pertain to the disposal of radioactive waste; thus, the TWC would have to adopt these same sections of the regulations, concurrently, in order to have continuously effective radioactive waste disposal regulations in the state of Texas. We recommend to the State that a coordinated effort between TWC and TDH be

established to ensure the continuance of the appropriate regulations for the disposal of radioactive waste in Texas.

States for which a finding of compatibility was withheld - 3

Kansas (1993)

The Kansas review was completed in February 1993 and the next review will be scheduled for February 1995.

Regulations overdue (and date due):

Funding of decommissioning plans	(7/91)
Industrial Radiography surveys & audits	(7/89)
Notification of filing for bankruptcy	(2/90)
Well logging safety requirements	(7/90)
Certification of dosimetry processors	(2/91)
Medical misadministration reporting	(4/90)

STATUS - The Kansas RCP has proposed rules to adopt the above; these proposed rules are currently undergoing legal review by the State Attorney General. In addition, a special visit was made to the State on May 4, 1993 by NRC management to encourage the expeditious adoption of regulations by the State. A commitment was made by Kansas' management to have all regulations promulgated within the next 30 to 60 days.

Louisiana (1991)

The last review of Louisiana was completed in August 1991 and the next review is scheduled for August 1993.

Regulations overdue (and date due):

Well logging safety requirements	(7/90)
Medical misadministration reporting	(4/90)
Funding of decommissioning plans	(7/91)

STATUS - The State completed the adoption of these rules in January 1992.

New Mexico (1992)

The last review of the New Mexico program was conducted in August 1992 and the next review will be scheduled in August 1994.

Regulations overdue (and date due):

Industrial radiography surveys & audits	(7/89)
Notification of filing for bankruptcy	(2/90)
Well logging safety requirements	(7/90)
Certification of dosimetry processors	(2/91)
Funding of decommissioning plans	(7/91)

STATUS - In letter dated November 16, 1992, we urged the State to take actions to adopt the above indicated rules. The State has hired a contractor to develop its rulemaing packages. All of the above indicated regulations are scheduled for adoption by January 1994.

State for which findings of both adequacy and compatibility were withheld - 1

Nebraska (1992)

Regulations overdue (and date due):

Funding of decommissioning plans (7/91)

STATUS - A proposed rule is in the adoption process. Adequacy was withheld due to a significant backlog of overdue inspections combined with a staff shortage. The Office of State Programs' management hand delivered the report to Nebraska to emphasize the need for corrective actions. The new Health Officer committed to turn the program around.

REGION V - 5 Agreement States

States found to be both adequate and compatible - 2

Oregon (1993)

The Oregon review was completed on April 2, 1993 and the next review will be scheduled in April 1995.

Washington (1992)

The Washington review was completed on July 17, 1992 and the next review will be scheduled for July 1994.

States for which a finding of compatibility was withheld - 2

Arizona (1992)

Regulations overdue (and date due):

Funding of decommissioning plans (7/91)

STATUS - A proposed rule is in the draft stage.

Nevada (1993)

A review of the Nevada program was completed in March 1993.

Regulations overdue (and date due):

Funding of decommissioning plans (7/91)

STATUS - The State is in the process of adopting this regulation.

State for which findings of both adequacy and compatibility were withheld - 1

California
January (1993)

The review of the California program was completed in 1993.

Regulations overdue (and date due):

Funding of decommissioning plans (7/91)

STATUS - Adequacy was held because of backlog of inspections (over 50% of inspection frequency) of byproduct material inspections in priorities 1, 2 and 3. In addition, some escalated enforcement was not adequately handled. In view of these deficiencies, upon dispatching the report to California, a special management meeting was held with the State on May 24, 1993.

ISBN 0-16-044575-2