STATEMENT SUBMITTED BY

UNITED STATES NUCLEAR REGULATORY COMMISSION

TO THE

COMMITTEE ON GOVERNMENTAL AFFAIRS

UNITED STATES SENATE

CONCERNING

MEDICAL RADIATION PROTECTION

PRESENTED BY

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CHAIRMAN

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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 2000 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 4500 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 implement 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 long-standing 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.