

OFFICE OF POLICY PLANNING

**TASK FORCE REPORT ON
MEDICAL RADIATION PROTECTION**

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INTRODUCTION AND BACKGROUND

Medical radiation is regulated at the Federal level by the Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA). NRC and the 29 Agreement States regulate the use and users of byproduct materials for both therapeutic and diagnostic medical purposes. FDA regulates the safety and effectiveness of drugs, biologics, and medical devices, including those that utilize ionizing radiation, primarily at the manufacturing level. States have broad authority and responsibility for the protection of their citizens from a public health perspective, but as a practical matter, the implementation of individual State programs for medical use of ionizing radiation varies widely. The Conference of Radiation Control Program Directors (CRCPD) helps to coordinate State programs in this area and has developed suggested State regulations for the control of radiation (SSRCR) for all sources of radiation. Adoption of the SSRCR by the States is voluntary, and currently only 15 States have adopted these regulations. A summary of Federal and State regulatory controls regarding the medical uses of ionizing radiation is provided in Appendix A.

At the May 6, 1993, hearing before the Senate Committee on Governmental Affairs concerning the regulation of medical radiation, Senator Glenn, Committee Chairman, raised questions as to whether Federal and State regulations related to medical radiation provide an adequate margin of protection of public health and the rights of those who may be put at risk. Although this Committee has maintained an interest in the subject of medical radiation for a number of years, this particular hearing was triggered by a series of articles in the Cleveland Plain Dealer which primarily addressed patient deaths, injuries, and overexposures. He noted the Committee's longstanding interest in the role of Federal and State agencies that regulate medical radiation, and in that context, stated that medical radiation regulation is scattered, fragmented, and very inconsistent.

Testifying at the hearing on behalf of NRC, Chairman Selin noted that the bulk of the radiation therapy treatment in the country was subject to only discretionary and perhaps inconsistent regulation and suggested options to address issues of regulatory coverage. In response to Senator Glenn's request to speed up the NRC's consideration of these issues, Chairman Selin committed to provide the Senate Committee on Governmental Affairs a preliminary report in three months. This report is the result of the NRC Task Force effort to look at issues and options which address radiation protection of the public health and safety from all medical sources of ionizing radiation.

Staff Approach, Development of Issues, and Contacts

NRC formed a Task Force, including a representative from FDA, to examine these issue in response to the request from Senator Glenn. The members of the Task Force are listed in Appendix E. The Commission provided guidance to the Task Force in a Staff Requirements Memorandum (SRM) dated June 10, 1993, regarding the scope of this study. The Commission stated that the fundamental objectives for this effort should be to characterize the problem to the greatest extent possible based on currently available information and to identify options that should be closely evaluated, and the database necessary to allow a productive evaluation to be performed. The Commission also noted that the object of this effort was to develop a preliminary report on the issues but should not recommend final resolution of the issues. Such recommendations would be left to the independent review of the medical use program by National Academy of Sciences (NAS).

The Task Force viewed the central question addressing concerns raised by Senator Glenn to be: "Does the current allocation of authority and responsibility among Federal and State regulatory bodies meet the nationwide goal of ensuring adequate protection of the radiological health and safety of the public, including patients and health care workers, in the medical uses of ionizing radiation?" From this, a number of issues were identified which the Task Force felt needed to be addressed in order to respond to the central question. These issues, discussed in detail in Appendix B, are categorized as follows:

- Uniformity of requirements and regulatory oversight
- Database and health and safety implications
- Training and experience of radiation users and associated professional personnel
- Communication among Federal and State agencies

The allocation of regulatory responsibilities in medical radiation was discussed at a public meeting for the States on May 20, 1993. Input from that meeting, as well as guidance from the Commission, meetings with the NRC staff, review of the transcript of the May 6 hearing, and Task Force members' experience was used to help define the issues identified above.

Input on the question of whether these were, in fact, the issues that should be addressed, was sought from the States, the NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI), FDA, and NRC as well as selected Federal medical licensees, professional societies, medical equipment and radiopharmaceutical manufacturers, and a voluntary health organization. Appendix C

is a list of those contacted. The Task Force evaluated the comments received from the respondents to determine if the key issues had been appropriately identified and whether options for resolution of identified problems could be determined. The Task Force believes that all of these issues are important components of an effective regulatory framework concerned with medical radiation protection.

Discussion of Comments and Issues

Input was received from 22 States, CRCPD, four professional societies, three manufacturers, three Federal medical licensees, numerous FDA and NRC officials with responsibilities in this area, one voluntary health organization, and ACMUI. Most organizations provided written comments, while oral discussions were held with some respondents. This section of the report contains a summary discussion of the comments and issues based on the input received. Appendix D is a copy of the summary of the public meeting held by ACMUI on these issues. The bracketed listings indicate the sectors providing the stated comments.

Uniformity and Regulatory Oversight

Some level of national uniformity in regulations and standards, to avoid substantive differences in regulations on medical radiation among the 50 States, was identified as being desirable by all respondents. Suggestions on this issue included: (1) regulations that would cover all sources of ionizing radiation and both diagnostic and therapeutic procedures [Federal medical licensees, some States and professional associations, CRCPD, and the voluntary health organization]; (2) regulations that cover only radiation safety issues for all sources of radiation [ACMUI and some professional societies and States]; (3) regulations that are limited to activities involved in interstate commerce [some Federal regulators and manufacturers]; and (4) limiting regulations to the area encompassing teletherapy byproduct sources and machine radiation sources [some Federal medical licensees].

There were several suggestions offered on how such uniform regulations could be established. Most of these related to mandating national adoption of some existing radiation protection regulations or standards rather than the development of new regulations. The adoption of the CRCPD's SSRCR was often suggested as well as the many voluntary practice standards and guidelines established by the professional associations [some professional societies, States, and Federal regulators]. In addition, there were several reasons why these regulations should address the diagnostic area, including (1) an option for therapy

alone addresses only relatively low probability, high consequence events and ignores the greater population dose from diagnostic radiations; (2) the issue remains the application of standards with the most troublesome configuration being the diagnostic imaging device in the private office; (3) the Federal government should require that minimum standards be implemented for Medicare patients for all diagnostic and therapeutic procedures involving ionizing radiation, such as it has for mammography; and (4) the misadministration of x-rays could be extended to the ordering of unnecessary or non-beneficial exams [CRCPD and some professional associations and States].

In addition, there was agreement that there should be some regulatory structure, whether a single Federal agency, a pair of Federal agencies, or a network of Federal and State agencies, to be the focal regulatory authority for all types of ionizing radiation. A need for a single Federal agency to control the introduction of products containing ionizing radiation and their manufacture and distribution by the private sector was identified [some manufacturers, Federal regulators, and Federal medical licensees]. Implementation (licensing, inspection, and enforcement) was generally identified as a State responsibility but should allow for flexibility [some States, Federal regulators, professional societies, and manufacturers]. In the event where a State did not want this responsibility or sufficient funding was not available to the State, implementation could be accomplished by the NRC Regions [some Federal medical licensees, and manufacturers]. Suggestions on the organization that should be responsible for all regulatory oversight ranged from CRCPD, FDA, NRC, an entirely new Federal agency, or a combination of these.

Database and Health and Safety Implications

Since there is currently no database on the frequency of administration of ionizing radiation for diagnostic and therapeutic purposes or on the accuracy of delivery, many respondents were positive on the need to develop such a database in order to determine whether there is a problem in the regulation of the medical uses of ionizing radiation that requires additional regulatory oversight. The respondents also were in general agreement on the desirability of establishing common terminology for regulations and reporting for data analysis [all sectors]. The States, in general, as well as some respondents from other sectors did not see the need for collecting additional data and making health and safety comparisons because of the perceived current low frequency of occurrence of adverse events or because the cost of obtaining additional information could not be justified within budget constraints.

Comments on which comparisons should be made to identify important health and safety considerations fell into one of two fairly distinct groups. One group suggested that there is a need for comparison of the risk of the medical uses of ionizing radiation with other medical procedures. These comparisons were favored because (1) they could demonstrate that a public health and safety problem does not exist with respect to the medical use of ionizing radiation or (2) could identify an allocation of scarce Federal, State, and health care resources in accordance with actual patient deaths and injuries [some professional societies, some Federal regulators, and ACMUI]. The other group suggested that the usefulness of these comparisons may be of limited value because (1) modalities cannot be lumped together, (2) relative risk is like comparing "apples and oranges," (3) certain risks may be unacceptable regardless of other considerations, and (4) the public has clearly demonstrated a low tolerance for radiation related occurrences, [one professional society, one manufacturer, some Federal regulators, some Federal medical licensees, some States, and the voluntary health organization]. There was nearly unanimous consensus of the ACMUI that getting better data to characterize the problem should be the highest priority and should be done before the other issues are addressed (see Appendix D).

Additionally, of those respondents who commented on the safety goal, some responded positively and others recommended caution on the use of a safety goal because of the difficulty of defining what to measure, such as deaths, misadministrations, or serious injuries; and a potential undesirable outcome of a safety goal having a negative influence on the use of one medical technology over another [some professional societies and some Federal regulators].

Training and Experience

There was general agreement that minimum national standards were appropriate regarding the training and experience criteria of physicians, radiation safety officers, and associated professional personnel [all sectors]. There was also general agreement on the need to maintain qualifications and for periodic requalification by the certifying group or agency [some Federal regulators, professional societies, Federal medical licensees, and one manufacturer]. However, the States indicated that Federal regulations in this area could conflict with existing State statutes or regulations if they cover diagnostic and therapeutic x-ray machines. As in other areas, there are differences in the capabilities and resources of the States to pursue this issue, therefore, differing levels of Federal involvement may be warranted [some States]. ACMUI reiterated its belief that the focus of licensure for use of ionizing radiation in medicine should be radiation safety and that training and

experience criteria should be closely linked to the type of use and associated hazards.

Suggestions on who should develop the minimum national training and experience criteria included the professional organizations, the medical advisory groups of NRC and FDA, the States, Department of Health and Human Services, and NRC.

Communications

It was generally indicated [all sectors] that better communication was needed and would serve both the regulators and the regulated. In fact, some commentors indicated that more regulations were not needed, but rather more cooperation and more communication were needed in carrying out existing regulations. Examples of ways to improve communications included having all States routinely report all extraordinary events to a central Federal agency and having that agency share the details of the causes of those events with all appropriate licensees, and establishing a formal written agreement between FDA and NRC.

TASK FORCE RESULTS

Findings

Based on a review of the comments and the regulatory experience of FDA, NRC, and the States with their medical programs, the Task Force has summarized its findings as follows:

- Since the regulation of medical radiation is implemented by two Federal government agencies and by the individual States, there are inconsistencies in requirements and implementation, as well as terminology and the focus of regulation, which result in an inability to determine the magnitude of the problem and have the potential to adversely affect the adequacy of protection of the public health and safety.
- There is not sufficient information currently available for all uses of ionizing radiation to determine if there is a health and safety problem, the magnitude of the problem if one exists, and the need to reallocate regulatory responsibility among Federal and State agencies. A national study of the issues in this area would be needed prior to making recommendations for the existing regulatory system.
- There has not been any independent evaluation of the risk from medical misadministrations of ionizing radiation relative to other treatment modalities.
- Improvements in protection of the public health and safety could be made within the existing regulatory framework.
- Enhancement of the communication and cooperation among all participants involved in the regulation of medical uses of ionizing radiation and development of national regulations for both training and experience criteria for those responsible for delivery would clearly be beneficial.
- A strong partnership among Federal and State regulatory agencies is necessary in the development of national radiation regulations and in their implementation.
- Despite the lack of definitive risk data and the opportunities for improvement in the current system, it is not clear that the current regulatory framework does not adequately protect the public health and safety. Federal and State programs in effect, combined with professional medical practices and voluntary professional standards, appear to have served the public health and safety.

- If legislation is warranted to reallocate regulatory responsibility, providing uniform regulatory oversight for all similar uses of radioactive materials (e.g., industrial, academic, research, and medical) would be beneficial.

Characterization of the Problem

The current framework for the regulation of medical radiation is not uniform, either at the Federal or the State level. NRC regulates the use of byproduct material at the user level while FDA regulates the safety and effectiveness of drugs, biologics, and medical devices, primarily at the manufacturer level. NRC has mandatory reporting of adverse events at the user level for its licensees. FDA has mandatory reporting requirements for device manufacturers and user facilities, and a system of voluntary reporting for health care providers and patients. At the State level, medical radiation safety programs may vary from State to State or within States for differing sources of radiation. Both the States and the Federal government have important roles; however, their approaches are not always uniform or consistent. The database necessary to determine if there is a health and safety problem does not currently exist and there is not a process in place for its generation. Finally, there are no comprehensive regulatory systems in place to ensure adequate training and experience of those health care professionals involved in the medical application of radiation or formal systems to ensure communication among Federal agencies and States on their respective responsibilities, and to share technical guidance, and event information. Therefore, the problem could be characterized as a lack of a fully coordinated regulatory effort as well as a lack of sufficient data to evaluate the effectiveness of this effort, across Federal and State agencies, to ensure adequate protection of the public health and safety in medical radiation.

Preliminary Options

Regulation of medical radiation is currently being provided by NRC, FDA, and the States. This has resulted in differing requirements based on the source of the radiation being administered and on where in the United States the administration takes place. Since the public health and safety is the principal goal of these regulatory programs, an important issue is an allocation of regulatory responsibility that would most effectively accomplish this goal.

The Task Force considered a broad range of options for the allocation of regulatory responsibility based their advantages

and disadvantages. As input to this process, we have considered the problems and issues as seen from the regulator's perspective and input from the States, Federal agencies, and the private sector. Other options have advantages which are attractive but, on balance, did not appear to the Task Force to be viable at this time. For example, an option where the Federal government would be totally responsible for regulations and implementation (without an Agreement State program for implementation) would likely be the most uniform approach. Conversely, having the Federal government be responsible for only basic radiation protection could save Federal resources but may not accomplish the goal of uniformity. Recognizing that there is a large number of possibilities, and with the short time available, we have selected for discussion those which received endorsement from commentors, were solutions to identified problems such as lack of uniformity, or were extensions of these.

Option 1 - Maintain the current framework for the regulation of medical ionizing radiation with recognition of planned and potential improvements.

This option would maintain the regulatory responsibility of FDA, NRC, and the States, recognizing that there are current initiatives, discussed below, which are intended to address certain of the identified problems. These initiatives would provide additional information to better understand the impacts of medical radiation on public health and safety. This option would not require new legislation, costs would not be substantially impacted by the new initiatives, and regulatory agencies continue in their current roles. Therefore, while this option would have the least short term effect on the issues that we have identified, its impact on resources and the inner workings of the current regulatory system would be minimal.

This option would also accommodate the significant initiatives being made to improve regulatory oversight in the existing regulatory programs. Additionally, new information gained through efforts to evaluate risks associated with medical misadministrations could provide a basis for determining whether the allocation of resources among Federal and State agencies should be changed. These program changes and studies are described below.

- A senior management review of the NRC program has been completed and the results of that review will be combined with other initiatives into a comprehensive plan to improve the NRC's medical regulatory program. Planned action items include new and revised inspection and licensing guidance, a comprehensive revision to Part 35, review of the enforcement policy, and continuing research efforts to evaluate risks

associated with therapy procedures, and the human error component of misadministrations.

- NRC is pursuing a study by NAS for a comprehensive review and evaluation of the adequacy of the NRC's regulatory program for protecting public health and safety from undue risk attendant to the medical use of byproduct material. The statement of work for this study specifically identifies interest in an examination of the broad policy issues which underlie the regulation of medical uses of radioisotopes, the overall risk context associated with the use of ionizing radiation in medicine, and the current framework for the regulation of medical uses of byproduct material. Information from this study will be essential to determining what database would be required to fully understand the scope of the problem, if one exists, in the regulation of radiation medicine.
- An MOU, between NRC and FDA, provides for increased sharing of information between the two agencies. It addresses coordination in the areas of notification of product complaints, misadministrations or emergency situations, coordination of investigational activities, information exchange, and the NRC licensee and Agreement State Notifications.
- FDA has included, in its pending Medical Device Reporting regulation for user facilities and manufacturers, criteria for a "reportable radiation therapy device event." The reporting criteria are consistent with those used in the NRC's misadministration definition in Part 35. While the revision of the reporting criteria and its extension to user facilities improve on the information to be reported, reporting is still limited to events resulting from device problems and does not include those resulting from user errors alone. Also, there is no reporting requirement for errors involving the use of naturally occurring and accelerator-produced radioactive material (NARM) radiopharmaceuticals.

Even with the improvements identified above, this option does not address the fragmentation and inconsistencies of State regulatory programs for non-Atomic Energy Act (AEA) sources of radiation. In the current framework, the NRC-Agreement State program provides a substantial degree of consistency in the regulation of AEA material between NRC and each of the 29 Agreement States. The Agreement States generally look favorably on this program. However, there is some lag in adoption by the States of the NRC requirements, and variation in implementation (licensing, inspection and enforcement) from State to State. Further, questions have been raised as to differences between

Agreement State and the NRC regional program implementation. NRC staff is developing a program to provide more consistent oversight of its regional offices and the Agreement States.

Option 2 - The Federal government develops and implements regulations for all sources of ionizing radiation used in medical therapy.

Under this option a Federal agency (or agencies) would develop and implement the regulations for ionizing radiation therapy with all States developing and implementing regulations for medical diagnostic uses. The Federal agency would have the authority to establish an Agreement State-like program for implementation of the medical therapy regulations.

This option would ensure a high degree of uniformity and consistency in the regulation of ionizing radiation therapy and avoid gaps in the application of these regulations. It also would eliminate any regulatory advantage of one radiation treatment modality over another. Also, it concentrates efforts and resources in the area that has the greatest potential for causing harm to the patient. One advantage of this option is that individual users would only have to deal with one regulatory authority regarding implementation of medical ionizing radiation therapy. Each State would have flexibility to meet their unique interests and to be innovative in their programs to achieve public health and safety for diagnostic medical ionizing radiation.

On the other hand, such expanded Federal authority would be costly, and therefore, unlikely to gain acceptance in times of budget cutbacks. The extension of Federal authority, even to this limited area of medical therapy, would likely be met with opposition from the States who now have authority for NARM and machine sources. Thus, the goal of uniformity in implementation in all probability would not be achieved. Funding to ensure the States' ability to implement the regulations could be a problem in times of tight budgets. Further, any change in legislation may be difficult to support in the absence of a definitive safety problem. Therefore, completion of some of the studies discussed in Option 1 may be required to make a case for the new legislation required by this option. Also, differences in program implementation in this area may still occur from State to State in the diagnostic area unless there was some group to help maintain uniformity.

Option 3 - The Federal government develops and implements regulations for all sources of ionizing radiation used in medical diagnosis and therapy.

Under this option, a Federal agency (or agencies) would develop and implement the regulations for ionizing radiation used in diagnosis and therapy. The Federal agency would have the authority to establish an Agreement State-like program for implementation of the regulations.

This option would ensure increased uniformity and consistency and avoid gaps in the application of the regulations. Also, this option would eliminate any regulatory advantage of one radiation treatment modality over another. Another advantage is that individual users would only have to deal with one regulatory authority.

As with Option 2, this approach would likely be met with opposition from the States who now have authority for non-AEA sources. Also, such expanded Federal authority over all uses, including the large number of diagnostic applications, would be very costly and therefore, unlikely to gain acceptance in times of budget cutbacks. Further, any change in legislation may be difficult to support in the absence of a compelling safety problem. Therefore, completion of some of the studies discussed in Option 1 may be required to make a case for the new legislation required for this option.

Option 4 - The Federal government develops regulations for all sources of ionizing radiation used in medical therapy with States responsible for implementation.

This option would provide a high degree of uniformity in radiation therapy regulations and would eliminate any regulatory advantage of one radiation treatment modality over another. Regulations for non-AEA materials, which are similar in scope to the NRC regulations for AEA materials, would need to be promulgated.

An advantage of this option is that individual users would only have to deal with their State regarding the implementation of the regulations in diagnostic and therapeutic uses of ionizing radiation. Each State would have flexibility to meet its unique interests and to be innovative in their programs to achieve public health and safety.

States currently exercise control over the public health and safety for NARM and machine-produced ionizing radiation therapy, and it is only because of Federal preemption over byproduct materials that control in this one area was given to the Federal government, with a provision subsequently to relinquish certain

authority back to the States. Thus, the extension of Federal authority, even to this limited area of medical therapy, would likely be met with opposition from the States who now have authority for NARM and machine sources. Thus, the goal of uniformity in implementation in all probability would not be achieved. Funding to ensure the States' ability to implement the regulations could be a problem in times of tight budgets.

Differences in program implementation may still occur from State to State unless there was some group to help maintain uniformity. Additionally, an issue that would have to be addressed is who would have authority to take action should a State choose not to implement the regulatory program or operate at a level which raises serious questions as to the protection of public health and safety. Thus, the goal of uniformity in implementation in all probability would not be achieved. Further, any change in legislation may be difficult to support in the absence of a compelling safety problem. Therefore, completion of some of the studies discussed in Option 1 may be required to make a case for the new legislation required by this option.

Option 5 - The Federal government develops regulations for all sources of ionizing radiation used in medical diagnosis and therapy with States responsible for implementation.

This option would give a Federal agency authority to promulgate regulations for all sources of ionizing radiation used in diagnosis and therapy with all States assuming responsibility for implementation. Regulations for non-AEA materials, which are similar in scope to the NRC regulations for AEA materials, would need to be promulgated. This option would ensure a high degree of uniformity and consistency in the regulations for ionizing radiation and would eliminate any regulatory advantage of one medical treatment over another. An additional advantage of this option is that individual users would only have to deal with their State regarding the implementation of the regulations for diagnostic and therapeutic uses of ionizing radiation. Each State would have flexibility to meet their unique interests and to be innovative in their programs to achieve public health and safety.

Differences in program implementation may still occur from State to State unless there was some group to help maintain uniformity. An additional issue which would have to be addressed is who would have authority to take action should a State choose not to implement the regulatory program or operate at a level which would raise serious questions as to the protection of public health and safety. Funding to ensure the States' ability to implement the regulations could be a problem in times of tight budgets. Fragmentation and inconsistencies among State

regulatory programs would be viewed negatively by manufacturers and suppliers who do business in multiple States. Further, any change in legislation may be difficult to support in the absence of a compelling safety problem. Therefore, completion of some of the studies discussed in Option 1 may be required to make a case for the new legislation required by this option.

CONCLUSIONS

The Task Force concludes that Option 1, along with initiatives currently being pursued by FDA and NRC, provide substantial progress in addressing the effectiveness of regulation of medical radiation through gathering of information, improved regulatory oversight, and plans for a study of this area. This option also requires the smallest additional commitment of resources and minimum impact on the stakeholders while the study by the NAS is being conducted.

The Task Force also considered the database necessary to allow a productive evaluation of the options to be performed. Item (2) in Appendix B delineates the database characteristics we felt to be important and there was little disagreement from the respondents. Common definitions for administration, misadministration, and serious injury would be needed to provide a consistent framework for the following data set:

- the number of misadministrations for each source of ionizing radiation in relation to the number of administrations
- the number of adverse incidents involving medical devices in relation to the incidence of use
- the frequency of occurrence of serious injury relative to the use of each source of ionizing radiation and to other treatment modalities

Upon completion of the collection and analysis of the information sufficient to determine if there is a health and safety problem, the Task Force recommends that Options 2 and 3 be closely evaluated.

Therefore, we conclude that the regulatory framework currently in effect for ionizing medical radiation should be maintained until current initiatives produce results and more definitive data on the magnitude of the problem are available.

APPENDIX A

FEDERAL & STATE CONTROL OVER MEDICAL RADIATION USES

At the Federal level, regulatory control is exercised by the Nuclear Regulatory Commission (NRC) over medical use of byproduct material, including the adequacy of the radiation safety properties of sources, devices, and radiopharmaceuticals used in medicine, and by the Food and Drug Administration (FDA) over the safety and effectiveness of drugs and devices. The NRC oversight is limited to the use of byproduct, source and special nuclear material, which represents only about 25% of the total radiation sources which are used in medical radiation. NRC is also proposing to amend relevant regulations to allow properly qualified nuclear pharmacists and physicians greater discretion in preparing radioactive drugs containing byproduct material. The FDA oversight for radiation therapy devices is not limited by the source of radiation.

These agencies have maintained close communication over the years, although prior to this time, there has not been formal documentation, such as a Memorandum of Understanding (MOU), to scope out the extent of this communication. A general description of the Federal and State regulatory programs is set forth below.*

The principal statutes under which NRC regulates byproduct, source, and special nuclear material are the Atomic Energy Act (AEA) of 1954, as amended, and the Energy Reorganization Act of 1974. Within the scope of its coverage, the NRC has broad regulatory authority, and carries out an active program of

* Detailed information on the NRC responsibilities and interfaces regarding medical uses are set forth in an April 15, 1992, memorandum from the Office of the General Counsel (OGC) to the Commission titled "Regulation of Nuclear Medicine," a September 10, 1992, memorandum from OGC to the Commission titled "Response to SRM Dated June 23, 1992 RE: Practice of Medicine," and a February 10, 1993, memorandum from OGC to the Commission titled "The Effect of the Safe Medical Device Act on NRC Jurisdiction Regarding NRC Review of Source Devices Used in Medicine." A description of the FDA's regulatory responsibility for the safety and effectiveness of medical devices, particularly radiation therapy devices, is given in D. Bruce Burlington's testimony at the May 6, 1993, Senate Governmental Affairs Committee.

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licensing the uses of materials for medical use, inspecting users, requiring reports of radiation safety problems and medical misadministrations and taking enforcement action for regulatory violations.

Within FDA, regulatory control over the safety and effectiveness of drugs and device uses is carried out by the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), and the Center for Biological Evaluation and Research (CBER). The principal statute under which FDA/CDRH regulates devices is the Food, Drug, and Cosmetic Act as amended by the Medical Device Amendments of 1976, the Safe Medical Devices Act of 1990, and the Medical Devices Act of 1992. The principal statute under which FDA/CDER regulates drugs for human use is the Food, Drug, and Cosmetic Act, as amended. FDA/CBER regulates all biological products. They are either drugs or devices, and are regulated under both the Food, Drug, and Cosmetic Act and the Public Health Service Act. The FDA regulatory programs have focussed on the approval of devices or drugs for clinical use, review of voluntary or mandatory problem reports, enforcement actions including product removal and recall, and prosecution and civil penalties against manufacturers.

States have broad regulatory authority over the general public health and safety of their residents. This includes authority over the use of all sources of ionizing radiation except for that which is preempted by the Federal government -- byproduct, source, and special nuclear material which is controlled by NRC. However, NRC has signed agreements with 29 States, as provided for in Section 274 of the AEA, in which it has formally relinquished its regulatory authority to those States. NRC has a program in which it periodically assesses the Agreement States' programs to assure adequacy and compatibility with the NRC program. Agreement States have three years to update certain designated regulations promulgated by NRC to maintain compatibility. One of these regulations is the requirement to report misadministrations to NRC.

The degree to which States exercise control over all medical radiation uses varies from State to State. The Agreement States normally apply the standards which they have developed for the NRC materials to other sources of radiation within their States, although there is no requirement that they do so. In addition, there is no requirement that non-Agreement States regulate other sources of radiation by applying the standards for the NRC materials. This has led to inconsistencies in the regulation of other sources of radiation in these States. Further, FDA has

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also contracted with certain States to perform inspections of diagnostic x-ray machines within their States.

The regulatory scheme described above has resulted in inconsistencies and voids in the control and reporting requirements as related to the medical uses of radiation. As noted above, NRC is limited in that its jurisdiction extends only to byproduct, source, and special nuclear material. NRC requires the reporting of misadministrations by the user. The FDA jurisdiction extends to all sources; however, the FDA's statutory program regulates the safety and effectiveness of drugs and devices. NRC requires the reporting of misadministrations by the end user. FDA will be requiring the reporting by user facilities and manufacturers of deaths, serious injuries, and with the implementation of its pending Medical Device Reporting regulation, reportable radiation therapy device events that deviate from planned treatment by specific criteria. The Agreement States' requirements are compatible with NRC, but there may be a time lag in the adoption of similar regulations. In areas other than those covered by the NRC's Agreement State program, there is no requirement for a consistent program for oversight of medical radiation uses within the States.

APPENDIX B

ISSUES RELATIVE TO RADIATION SAFETY IN THE MEDICAL USES OF IONIZING RADIATION

The central question: Does the present allocation of authority and responsibility among Federal and State regulatory bodies meet the nationwide goal of ensuring adequate protection of the radiation health and safety of the public, including patients and health care workers in the medical uses of ionizing radiation?

Set forth below is a list of issues which require further study or resolution prior to making recommendations on the central question. These issues have been grouped into four broad categories.

(1) Uniformity of Requirements and Regulatory Oversight

- (a) need for national uniformity in regulations (including reporting requirements) and their implementation (including effective enforcement) for each source of ionizing radiation (i.e., byproduct, naturally occurring and accelerator-produced radioactive material (NARM), and machine produced)
- (b) need for one national regulatory authority to ensure uniformity in areas that are now handled by multiple agencies (e.g., certification of sealed sources and devices and notification of referring physicians and patients of a misadministration and the likely consequences)
- (c) need for a national program to monitor uses of ionizing radiation (including emerging technologies and new trends) and identify radiation safety issues that need new or additional regulatory oversight
- (d) need to identify source of funding for regulation development and implementation

(2) Database and Health and Safety Implications

- (a) need to develop common terminology and definitions of administration, misadministration, and serious injury for each source of ionizing radiation

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- (b) need to determine the number of administrations and misadministrations for each source of ionizing radiation (e.g., drugs, devices) and the uncertainty in each estimate
- (c) need to determine the number of misadministrations for each source of ionizing radiation and the uncertainty in each estimate
- (d) need to determine the frequency of occurrence of serious injury related to the use of each source of ionizing radiation and the uncertainty in each estimate
- (e) need to compare the individual frequencies of occurrence developed in (a) above, and compare the frequency of occurrence of serious injury related to all ionizing radiation therapy procedures versus other individual cancer therapy procedures (e.g., surgery, chemotherapy)
- (f) need to compare frequency of occurrence of adverse outcomes from misadministration versus properly conducted administrations for each source of ionizing radiation
- (g) need to establish a safety goal for the medical uses of ionizing radiation

(3) Training and Experience

(a) Physicians

- need to have a regulatory authority establish training and experience criteria for physician authorized users for each source of ionizing radiation
- need to have a regulatory authority implement physician authorized user training and experience criteria, including history of regulatory and legal compliance
- need to have a regulatory authority periodically reassess the qualifications of each physician authorized user

Task Force Report on Medical Radiation Protection

(b) Associated Professional Personnel

- need to have a mandatory licensing or certification program for activities utilizing each source of ionizing radiation
- need to have a regulatory authority establish and implement the training and experience criteria for associated professional personnel
- need to have a regulatory authority periodically reassess the qualifications of associated professional personnel

(c) Radiation Safety Officer

- need to have a regulatory authority establish the duties, responsibilities, and authorities to include each source of ionizing radiation
- need to have a regulatory authority establish and implement minimum training and experience requirements to include each source of ionizing radiation
- need to have a regulatory authority periodically reassess the qualifications of each radiation safety officer

(4) Communication

(a) among Federal agencies (primarily in this case, the Nuclear Regulatory Commission (NRC) and the Food and Drug Administration (FDA))

- need to clarify respective responsibilities
- need to coordinate device reviews
- need to coordinate regulations for the manufacture and distribution, compounding, and use of radiopharmaceuticals and radiolabelled biologics, and the manufacture and use of radiation therapy devices
- need to share information on events and incident reports and coordinate the responses

- (b) among States and between each State and the Federal government
 - need to share information on topics including event reports, proposed and final regulations, regulatory guides, information notices, enforcement cases, and product recalls

APPENDIX C

CONTACT LIST

All 50 States (22 responded)

Advisory Committee on the Medical
Uses of Isotopes

Food and Drug Administration

Society of Nuclear Medicine (SNM) /
American College of Nuclear Physicians (ACNP)

American Association of Physicists in Medicine (AAPM)
Professional Council

American College of Medical Physics (ACMP)

American College of Radiology (ACR)

DuPont Merck Pharmaceutical Company

Varian Associates

Nucletron Corporation

Johns Hopkins Medical Institution (declined to respond)

American Cancer Society

Department of Veteran Affairs

Department of the Air Force

Department of the Navy




UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MEMORANDUM FOR: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Barry A. Siegel, M.D., Chairman
Advisory Committee on the Medical
Uses of Isotopes

SUBJECT: CERTIFICATION OF THE SUMMARY REPORT OF THE
JULY 8, 1993, TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

I hereby certify that to the best of my knowledge and belief, the enclosed Summary Report for the July 8, 1993, teleconference meeting are an accurate record of the proceedings for that meeting.



Barry A. Siegel, M.D., Chairman
21 July 1993

(Date)

Enclosure:
As stated



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

MEMORANDUM FOR: Carl J. Paperiello, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

FROM: Barry A. Siegel, M.D., Chairman
Advisory Committee on the Medical
Uses of Isotopes

SUBJECT: SUMMARY REPORT - MEETING OF THE ADVISORY COMMITTEE ON
THE MEDICAL USES OF ISOTOPES, JULY 8, 1993

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held a special teleconference meeting on July 8, 1993.

Committee members who took part via telephone included:

Barry A. Siegel, M.D., Chairman
Peter R. Almond, Ph.D.
Judith I. Brown
Melvin L. Griem, M.D.
Joan A. McKeown
Carol S. Marcus, Ph.D., M.D.

For FDA:

David H. Woodbury, M.D., FDA [via telephone]
Donald R. Hamilton [present]

Present were: John E. Glenn, Ph.D., Nuclear Regulatory Commission (NRC), (Designated Federal Official for the panel), and Larry W. Camper, Section Leader, Medical and Academic Section, NRC, and Richard Vollmer, Director of Policy and Planning, NRC.

John E. Glenn, Ph.D., opened the meeting at 11:40 a.m.

Richard Vollmer of the NRC's Office of Policy and Planning initiated the discussion and provided background information to the ACMUI. He indicated that the Senate Committee on Governmental Affairs met on May 6, 1993, to consider the allocation of regulatory responsibility for the medical uses of ionizing radiation. This Committee requested a report from the Commission that would delineate the options for improving the current regulatory program. Chairman Selin committed to provide a preliminary report by August 6, 1993. Accordingly, a task force consisting chiefly of NRC staff, but including liaison representation from FDA, was convened to develop this report for the Commission. The task force was charged by the Commission with the principal objective of characterizing the problem, to the fullest extent possible, based on currently available information. The task force also was asked to identify those legislative and regulatory options worthy of careful evaluation and to identify the data base that would be necessary for a critical evaluation of

those options. Mr. Vollmer further indicated that the object of this preliminary effort was not to recommend specific, final solutions to any perceived problems. Rather, the Commission had instructed that recommendation of solutions should be delayed until completion of the independent assessment of the medical use program to be performed by the National Academy of Sciences.

Mr. Vollmer stated that what the task force seeks from the ACMUI is its views on the characterization of the issues as presented in the task force's draft document, entitled "Issues Relative to Radiation Safety in the Medical Uses of Ionizing Radiation."

During the ensuing discussion, the ACMUI did not provide commentary on each and every item in the draft list of issues compiled by the task force. Rather, the ACMUI focused its attention on the following issues.

The Health and Safety Implications of Radiation use in Medicine, and Data Base Needed to Assess These Implications.

It was the nearly unanimous consensus of the ACMUI that the wisest thing the task force could recommend would be a critical scientific evaluation of adverse events in all areas of medicine in order to determine whether adverse events associated with uses of ionizing radiation in medicine warrant more regulation, less regulation, or about the same level of regulation for nuclear medicine and radiation oncology as for the rest of medicine. Getting better data to characterize the problem should be the highest priority and should be done before the other issues are addressed. The ACMUI recommended that the National Academy of Sciences would be the best organization to perform such a study, which should be accomplished independently of any particular Federal agency.

Ms. Brown, while agreeing with the need for better data, cautioned that getting such data would be difficult given the wide variability in data collection by the states. Accordingly, she favored requiring that the reporting by the Agreement States of misadministrations in a form compatible with NRC regulations should be accomplished before 1995. Dr. Almond noted that the evaluation of the problem does not require every bit of data from both NRC-regulated and Agreement states; sampling methods are available that will allow for statistically reliable conclusions without access to all data. Ms. Brown further dissented by indicating her concern that comparing outcome and injuries in nuclear medicine and radiation oncology with those occurring in other areas of medical practice does not seem a useful exercise; the goal of regulatory agencies should be to achieve high quality in all areas of medical care. Other Committee members retorted that the regulatory approach cannot ignore costs and, thus, comparative data were appropriate to insure wise allocation of the nation's limited resources for healthcare.

Uniformity

The ACMUI expressed the general consensus that uniform national standards for radiation protection were appropriate, but uniform prescriptive regulations

governing medical practice were unnecessary and would limit medical flexibility. There also was consensus that, if there were uniformity by way of a single national regulatory authority, such authority should be vested within a department or agency that has responsibility for regulation of all medicine and not within an agency that has "tunnel vision" as a consequence of its narrowly constructed responsibilities for radiation safety. Lack of a global medical perspective has the potential to result in increasing and inappropriate over-regulation of nuclear medicine and radiation oncology without clear benefit to the general public welfare.

Ms. Brown dissented and advocated the need for a single national regulatory authority in order to allow for concentration of the highest level of expertise within a single organization and to allow for easiest access of the general public to such expertise.

Training and Experience


The ACMUI recommended that the task force study the minutes and transcript of the Committee's May, 1993 meeting. At that meeting, the ACMUI discussed the need for a "paradigm shift" in the approach to establishing training and experience criteria for licensure and in validating the training and experience of authorized users. The Committee reiterated its belief that the focus of the NRC and States with respect to licensure for use of ionizing radiation in medicine should be radiation safety, and that training and experience criteria should be closely linked to the type of use of ionizing radiation and hazard posed by such use to patients, occupational workers, and members of the general public.

Communication

The Committee agreed that the task force had identified the appropriate issues in this area, and that it would be hard to argue against the need for improved communication.

Written comments submitted to Dr. Siegel by several ACMUI members prior to the teleconference were accepted into the record. Dr. Glenn invited other Committee members to submit supplementary written comments.

Dr. Glenn declared that the meeting was closed at 1:15 p.m.



Barry A. Siegel, M.D., Chairman
21 July 1993

(Date)

APPENDIX E

Members of the Task Force

*Richard H. Vollmer, Director
Office of Policy Planning*

*Lloyd A. Bolling, Health Physicist
State Agreements Program
Office of State Programs*

*Donald R. Hamilton, Radiation Policy Advisor
Office of Health Physics
Center for Devices and Radiological Health
Food and Drug Administration*

*Janet A. Lambert, Senior Technical Assistant
Office of Policy Planning*

*Darrel A Nash, Senior Policy Analyst
Office of Policy Planning*

*Charles E. Norelius, Director
Division of Radiation Safety & Safeguards
Region III*

*Josephine M. Piccone, Section Leader
Commercial Section
Medical, Academic & Commercial Use Branch
Office of Nuclear Material Safety & Safeguards*

*Maria E. Schwartz, Attorney
Rulemaking and Fuel Cycle Section
Office of the General Counsel*

*John L. Telford, Chief
Rulemaking Section
Regulation Development Branch
Office of Nuclear Regulatory Research*