AA73-1
PDR
B.20

January 18, 1985

Note to: REC

Thru: VLM

From: nlm

re: Part 35 Briefings held January 10, 1985

Summary: Most individuals are interested in completely eliminating misadministrations; there did not appear to be significant interest in current medical policy or the changes proposed in the paper. Comments from each individual follow.

Peter Crane (OGC lead on Part 35; Marty Malsch will assist): All he said in two hours was "I like this. You can read it and know what you have to do." He appeared to buy my "Let's look at the relative hazard in the hospital" argument for lessening our control of licensees.

Bill Parler (Zech) has had bad dealings with S. Carolina medical industry. Do not invoke "mature industry" thesis. Very interested in misadministrations.

Maria Lopez Ortin (Roberts) was mainly interested in misadministrations; she thought doctors should be required to inform patients. I said roughly 20% do based on my review of each report. Aron interrupted to say misadministration wording was carefully developed.

Joan Aron (OPE for intergovernmental affairs and some medical issues): "This paper should address more issues. Why aren't we regulating x-rays and NARM? Don't tell me we don't have staff. What will you do with saved man-hours?" My response: More issues in one paper would cloud and confuse. Concerning x-rays and NARM, this is not a "new frontiers" paper, but a consolidation of current requirements with no change in day-to-day operations. We don't have expert medical staff, and from what I hear we aren't getting any in the next few years; furthermore, FDA is the logical federal agency to regulate medical care. The saved man-hours calculation is tenuous and vociferously disputed by the Agreement State experts.

Clyde Jupiter (OPE lead on Part 35): The package is well written. Can we certify physician training programs? My response: We could, but it would be a whole new policy direction for the agency that should be dealt with separately.

I also stressed as frequently as possible: 1. Misadministrations are 0.01%, compared to 10% for physiologically active drugs. 2. Hospitals are dangerous to work in, and radiation is a minor hazard compared to chemicals, equipment, viruses, and emotional stress there. 3. This will not change a hospital's day-to-day operations. 4. This provides a uniform, nationwide standard.

5. This is not an item of compatibility, but the Agreement States think they may be pressured into the flexibility clause. 6. Everyone likes the regulatory text except for the dispute over the flexibility clause.

Briefing for Droggitis (Asselstine) is scheduled for Friday, January 25. Stoloff (Bernthal) and Polk (Palladino) wanted a briefing after they read the paper. Nothing scheduled as yet.

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sion products (crud) as the principal source of worker exposures at nuclear power plants. Man-rem exposure, plant down-time, and operating and maintenance costs may be substantially increased without appropriate exposure control of these depositional processes. The industry has been exploring methods of reducing occupational radiation exposures due to these sources. At such time in the future as information becomes sufficient to justify specific regulatory requirements in this area, rulemaking could achieve a specific annual radiation exposure design objective for control of occupational radiation exposures from crud buildup, analogous to 50.34a for effluent control. More immediately, it would appear desirable to conduct rulemaking surrounding the development of additional design criteria in Appendix A of Part 5 involving two separate considerations: (i) Crud formation, solution, and deposition, including design criteria for the primary coolant system for decontamination of crud; and (ii) aspects of plant layout and design to reduce occupational radiation exposure from this source in keeping with ALARA criteria in Regulatory Guide 8.8.

● *Generic radiological impact for normal LWR radionuclide releases*—Radiological impact estimates are currently prepared through an engineering evaluation of the radioactive waste treatment system that produces an inventory of radionuclides released to the environment, a calculation of the available atmospheric and hydrologic dilution, and a calculation of the dose to individual receptors in the immediate site environs and to the population within 50 miles of the site and the total United States. A generic treatment of these radiological impacts would be appropriate because: (1) There is a regulatory requirement that radioactive effluents result in calculated doses within 10 CFR Part 50, Appendix I, design objective values, and (2) technical specifications are imposed on nuclear plants which hold them to or below these values. This results in operating criteria that always limit the impact to a value below a specified value. The proposed rulemaking would be based, in part, on a survey of the calculated impacts in environmental statements to determine appropriate ranges of doses for categorizing radiological impacts from radionuclide releases. The upper end of this range of doses would be the Appendix I design objective values. An empirical study of the relation between observed and calculated impacts would establish a more reliable lower bound for radiological impacts than that presently calculated and would obviate the need for calculating radiological impacts of normal radionuclide releases for each individual licensing case.

● *Threshold limits for generic disposition of cooling tower effects*—The potential environmental and socioeconomic effects of cooling tower operation have raised contentions at a substantial number of case hearings. These issues include weather modification (increased rain, snow, fog, tornadoes and floods), deposition, interactions of cooling tower operation with other plant effluents (radiological and chemical), noise, and aesthetics. In a sizeable fraction of these cases a detailed examination of these issues in supplemental testimonies supports the conclusion that the impacts are of negligible societal importance. Accordingly, a useful objective of rulemaking would be to seek to establish threshold limits for each potential effect of cooling tower operation for a wide variety of designs and site-specific conditions which, if not exceeded, would be deemed to be inconsequential to societal interests. If these threshold limits were exceeded, then more detailed assessment would be required for the individual licensing action in lieu of generic disposition.

44 FR 8242
Published 2/9/79
Effective 2/9/79

Regulation of the Medical Uses of Radioisotopes; Statement of General Policy

AGENCY: Nuclear Regulatory Commission.

ACTION: Final Policy Statement.

SUMMARY: The Nuclear Regulatory Commission (NRC) has the following policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

EFFECTIVE DATE: February 9, 1979.

FOR FURTHER INFORMATION CONTACT:

Mr. Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5860).

SUPPLEMENTAL INFORMATION: The NRC has developed the following three part policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. On March 17, 1978, the three part policy statement was published in the FEDERAL REGISTER (43 FR 11208) for public comment. Copies of the policy statement were sent to all NRC medical licensees, the States and 25 professional societies, Federal agencies, and individuals. The comment period expired May 16, 1978. Twenty-two comments were received. Nine commenters favored all three parts of the policy statement, four commenters opposed one part of the policy statement and nine commenters addressed specific issues discussed in the March 17, 1978 FEDERAL REGISTER notice. The comments are discussed in Section II. Copies of the comments may be examined in the NRC Public Document Room at 1717 H Street, N.W., Washington, D.C.

I. STATEMENT OF GENERAL POLICY

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes.

It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States, and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following statement of general policy to guide its regulation of the medical uses of radioisotopes:[1]

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been

[1] NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term *byproduct material* means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term *source material* means (1) uranium, thorium or any combination thereof, in any physical or chemical form or (2) ores which contain by weight one-twentieth of one percent (0.05%) or more of (i) uranium, (ii) thorium or (iii) any combination thereof. Source material does not include special nuclear material. *Special nuclear material* means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235 or (2) any material artificially enriched by any of the foregoing, but does not include source material.

generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by AEC. During this period AEC regulated the radiation safety of workers and the general public *and* the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for * * * medical therapy * * *." Section 81 directs NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 35, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 *et seq.*) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question is a question of *policy* not *authority*, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of *authority*, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of *policy*, these limits depend upon how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.[3] This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with FDA's activities; is in harmony with regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals; and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. As noted before, NRC has the authority to regulate the radiation safety of patients.

The NAS-BEIR[4] report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

> In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgments. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to be a part of the practice of medicine. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

[3] The term general public in this statement specifically excludes patients.

[4] National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report. *The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. National Academy of Sciences—National Research Council*, Washington, D.C. (1972).

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A consequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For all therapeutic uses of radioactive drugs, and in certain diagnostic uses—for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical devices as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. The Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. Discussion of Public Comments

A. Comments on the Policy Statement

One commenter opposed the use of the general term "radioisotopes" in the first part of the policy statement. This commenter was concerned that, if taken out of the context of the footnote, it could be interpreted to include naturally occurring and accelerator produced radioisotopes.

The Commission believes that the general term "radioisotopes" is plain English and easily recognized by the public. It was properly footnoted in the policy statement to include the more cumbersome but specific terms: byproduct, source and special nuclear material and to exclude naturally occurring and accelerator produced radioactive material.

One commenter, in opposition to NRC's regulation of patient radiation safety, suggested that NRC limit its role to the radiation safety of the hospital staff and the general patient population. He believes that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter feels that NRC should first require adequate staffing, including a board certified physician or radiopharmacist and a radiation safety officer, and then essentially leave the institution alone regarding dosimetry, instrumentation, calibration, drug procurement or any other function considered to be the practice of medicine.

NRC does require the licensee to staff its operation with a radiation safety officer and a physician (not necessarily board certified) trained to administer radioactive material or radiation to patients. However, the Commission cannot limit its regulatory role to protecting the hospital staff and the general patient population and at the same time fulfill its congressional mandate to protect the health and safety of the public as regards source, byproduct and special nuclear material. The patient being treated or diagnosed with radioactive material, as well as the general public who may be exposed to radiation as a result of that treatment, are all members of the public to be protected by NRC.

Two commenters objected to NRC's regulation of patient radiation safety because they believe that NRC does not have the authority to regulate patient safety. They note that NRC's enabling legislation does not specifically mention the radiation safety of patients. They believe that patient safety is the responsibility of the physician, a responsibility that cannot be shared. They believe that the Commission is in error to equate patients with the public and to consider patients as users rather than recipients of radioactive material.

As noted in the analysis of the similar comment above, the NRC's overriding congressional mandate is to protect the health and safety of the public. The patient is a member of the public, notwithstanding the Commission's recognition of physicians' primary responsibility for protection of their patients. The policy statement and, indeed, all of the Commission's actions in regulating the medical uses of radioisotopes, acknowledge the secondary but necessary role of NRC in regulating the radiation safety of patients. The Commission also considers patients to be both users and recipients of radioactive material. However, the distinction between receipt and use of radioactive materials is not meaningful in this case because NRC regulates, among other things, receipt, possession, use and transfer of byproduct, source and special nuclear material in protecting the health and safety of the public.

B. Comments on Specific Issues

There were six comments on the question of reporting misadministrations of radioactive material. Three commenters opposed any misadministration reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in dealing with NRC's newly proposed misadministration reporting requirement that was published in the Federal Register for public comment on July 7, 1978 (43 FR 29297).

There were six comments on the specific issue of paramedical training. Three commenters believe that it is unnecessary for NRC to become involved in paramedical training because several organizations are already providing or developing minimum standards, guidelines or certification. One commenter believed that NRC should be involved in this area because the technologist, not the physician, does most of the work with radioisotopes. Two commenters believe that radiological physicists should be separated out from other paramedical personnel and one of these commenters offered a definition of radiological physicist.

As noted in the proposed policy statement, NRC is studying the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

There were five comments on the specific subject of nuclear pharmacies (radiopharmacies).

One commenter urged NRC to distinguish between radiopharmacists working in a hospital setting and those working in a retail environment (commercial nuclear pharmacy). This commenter also noted the complexity of the problem of definition when the hospital based radiopharmacy provides radiopharmaceuticals to other hospitals and practitioners in its area.

As noted in the proposed policy statement, the NRC will defer to the Food and Drug Administration (FDA) regarding a determination of those activities of nuclear pharmacies that will be considered manufacture and those activities that will be considered the ordinary practice of pharmacy (compounding and dispensing).

Four commenters objected to NRC's licensing nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radiopharmaceuticals or reagent kits. One commenter cited the practice of nuclear pharmacies supplying radiochemicals to researchers who use them on humans under their own FDA "Notice of Claimed Investigational Exemption for a New Drug" (IND). One commenter noted that FDA permits nuclear pharmacies to operate in the absence of a final determination of their status, providing they meet all State and local pharmaceutical regulations. The two other commenters characterized the NRC's restrictions on the distribution of radiopharmaceuticals by nuclear pharmacies as an unwarranted intrusion into the practice of pharmacy which is regulated by the States.

NRC licenses nuclear pharmacies to distribute radioactive drugs that have been approved by FDA. This includes radioactive drugs subject to an FDA-approved "New Drug Application" (NDA), or "Notice of Claimed Investigational Exemption for a New Drug" (IND). NRC relies on FDA approval of radioactive drugs because NRC has not regulated the safety and effectiveness of radioactive drugs since 1975. Also, there are not many States that are equipped to regulate radioactive drug safety and effectiveness.

Dated at Washington, D.C. this 1st day of February 1979.

44 FR 8276
Published 2/9/79
Comment period extended to 3/14/79

GENERIC RULEMAKING TO IMPROVE NUCLEAR POWER PLANT LICENSING

Interim Policy Statement, Extension of Comment Period

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Extension of comment period.

SUMMARY: The Nuclear Regulatory Commission is extending the public comment period on its Interim Policy Statement regarding Generic Rulemaking to Improve Nuclear Power Plant Licensing for an additional 30 days. The Interim Policy Statement was published on December 14, 1978 (43 FR 58377). The original comment period would have expired February 12, 1979. Further information regarding generic rulemaking issues and staff deliberations is found in NUREG-0499, "Preliminary Statement on General Policy for Rulemaking to Improve Nuclear Power Plant Licensing". Supplement No. 1 to NUREG-0499 contains information on "General Considerations and Issues of Significance on the Evaluation of Alternative Sites for Nuclear Generating Stations Under NEPA". Copies of these documents are available by writing to the Distribution Services Branch, Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

DATE: New comment period expires: March 14, 1979.

ADDRESSES: Written comments or suggestions for consideration in connection with the proposed Interim Statement on Rulemaking Policy should be submitted to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch.

FOR FURTHER INFORMATION CONTACT:

Dr. Miller B. Spangler, Office of Nuclear Reactor Regulation, Division of Site Safety and Environmental Analysis, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, telephone 301/492-7305.

44 FR 59686
Published 10/16/79
Comment period expires 10/16/79

Proposed Agency Policy and Procedures for Differing Professional Opinions; Request for Comments

The Nuclear Regulatory Commission (NRC) has developed a statement of policy on differing professional opinions and the general procedures for implementing this policy within the agency. The NRC requests comments upon the proposed policy and the procedures, and also any additional recommendations or experiences regarding policy objectives, procedures, or other provisions that the Commission should consider before proceeding to adopt the proposed policy and procedures.

The proposed statement of policy clarifies the responsibilities of both NRC employees and NRC management regarding the expression and resolution of differing professional opinions. Moreover, the policy assures all employes the opportunity to have differing professional opinions heard and considered by NRC management free from retaliation in any form.

The proposed system for implementing this policy on differing professional opinions within the agency is described in a set of thirteen detailed procedures. These procedures provide, for example, alternate channels for the submission of differing professional opinions, accountability for all actions taken on a differing professional opinion, resolution of all differing professional opinions submitted in accordance with these procedures, and assurance against retaliation for the submission of a differing professional opinion. Also included are provisions for follow-up and evaluation of these procedures to ensure that implementation accomplishes the stated objectives and to recommend changes, as appropriate.

Single copies of the proposed policy and procedures can be obtained by writing to the U.S. Nuclear Regulatory Commission, Office of Management and Program Analysis, Washington, D.C. 20555. In addition, a single copy of the proposed policy and procedures is available, and may be inspected and copied, in the Commission's Public Document Room at 1717 H Street, N.W., Washington, D.C. Copies of comments received are also available for inspection at the Washington, D.C.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
Secretary of the Commission.

[FR Doc. 78-7167 Filed 3-16-78; 8:45 am]

[7590-01]

[10 CFR Part 35]

REGULATION OF THE MEDICAL USES OF RADIOISOTOPES

Proposed Policy Statement

AGENCY: Nuclear Regulatory Commission.

ACTION: Advanced notice of proposed rulemaking.

SUMMARY: The Nuclear Regulatory Commission (NRC) has under consideration the following proposed policy statement regarding NRC's future role in regulating the medical uses of radioisotopes. This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC activities in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

DATE: Comments are due on or before May 16, 1978.

ADDRESSES: Send comments and suggestions to: Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch. Copies of comments may be examined in the: Nuclear Regulatory Commission Public Document Room, 1717 H Street NW., Washington, D.C.

FOR FURTHER INFORMATION CONTACT:

Mr. Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, 301-443-6910.

SUPPLEMENTAL INFORMATION:

In 1976, NRC, with a view to possible changes, began reviewing its regulations regarding the medical uses of radioisotopes, originally promulgated by the Atomic Energy Commission (AEC). On April 21, 1977, NRC published a meeting notice in the FEDERAL REGISTER (42 FR 20691), inviting the public to comment on NRC's regulations concerning medical practices. The FEDERAL REGISTER notice and related public announcements stated that the purpose of the public meetings was to receive written and oral comments that the Commission could use in deciding future NRC policy in regulating the medical uses of radioisotopes and to provide a basis for possible future rulemaking. The notice requested comments on specific issues as follows:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material? Areas of possible regulatory involvement by NRC in this area include:

1. Evaluation of physician's clinical qualifications,
2. Selection of patients for diagnostic or therapeutic procedures,
3. Selection of instruments to be used in performing diagnostic or therapeutic procedures,
4. Selection of radioactive drugs or devices to be used,
5. Selection of procedures to be performed,
6. Selection of dose level (quantity of radioactive material or radiation dose) to be used,
7. Proper measurements of the dose the patient receives,
8. Calibration of diagnostic equipment and dose-measuring instrumentation,
9. Qualifications of paramedical personnel, such as technologists, nurses, radiopharmacists and radiological physicists, and
10. Reporting to NRC, the patient and/or the patient's physician, misadministration of radioactive material or radiation from devices incorporating radioactive material.

In addition to the FEDERAL REGISTER notice and other public announcements, NRC directly contacted more than 30 physician groups, professional societies, public interest groups, and Federal agencies, the 25 NRC Agreement States and several non-Agreement States.

The meetings of NRC staff with the public and the Advisory Committee on Medical Uses of Isotopes were held on May 6, 1977, in Silver Spring, Maryland. The meeting record was held open for 70 days following the meeting for the receipt of written comments. Over 90 people participated in the public meetings and 33 comments were received for the record. Transcripts of the meetings and copies of the comments may be examined in the NRC Public Document Room at 1717 H Street NW., Washington, D.C.

I. PROPOSED POLICY STATEMENT

This NRC policy statement is intended to inform NRC licensees, other Federal and State agencies and the public of the Commission's general intention regarding the regulation of the medical uses of radioisotopes. It is expected that future NRC acitivites in the medical area, such as promulgation of new regulations and development of cooperative relationships with other Federal agencies, will follow this statement of NRC policy.

Based on past experience and the comments and advice of the public, other Federal agencies, the States and NRC's Advisory Committee on the Medical Uses of Isotopes, the Commission has developed the following policy statement to guide its regulation of the medical uses of radioisotopes:[1]

1. The NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.

2. The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

3. The NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine.

II. RATIONALE

The NRC and its predecessor the Atomic Energy Commission have regulated the medical uses of radioisotopes since 1946. AEC recognized that physicians have the primary responsibility for the protection of their patients and designed its regulations accordingly. The physicians were required to be licensed by the State, and their applicable training and experience were evaluated in consultation with the Advisory Committee on the Medical Uses of Isotopes. This regulation has been generally oriented toward assisting qualified physicians in discharging their responsibilities to patients. However, regulation by AEC/NRC has at one time or another encompassed nearly every aspect of the delivery of radioisotope medical services to patients. The broadest regulation occurred between 1962 and 1975, when the Food and Drug Administration (FDA) exempted from its requirements for new drugs all radiopharmaceuticals regulated by

[1] The NRC licenses radioisotopes in three categories: byproduct, source and special nuclear material. The NRC does not regulate naturally occurring or accelerator produced radioisotopes. The term byproduct material means any radioactive material (except special nuclear material) yielded in or made radioactive by exposure to the radiation incident to the process of producing or utilizing special nuclear material. The term source material means (1) uranium, thorium, or any combination thereof, in any physical or chemical form, or (2) ores which contain by weight one-twentieth of one percent (0.05 percent) or more of (i) uranium, (ii) thorium, or (iii) any combination thereof. Source material does not include special nuclear material. Special nuclear material means (1) plutonium, uranium 233, uranium enriched in the isotope 233 or in the isotope 235, or (2) any material artificially enriched by any of the foregoing, but does not include source material.

AEC. During this period AEC regulated the radiation safety of workers and the general public and the safety and efficacy of radioactive drugs and devices with respect to patients. AEC regulation included production of the radioisotope, manufacture of the final radioactive drug product or device, distribution, use and disposal of the products. In 1975, the FDA terminated the exemption for radiopharmaceuticals, stating that it would now regulate the safety and efficacy of radioactive drugs with respect to patients. (As noted later in this statement, FDA does not regulate the physician's routine use of radiopharmaceuticals.) At the same time, NRC withdrew from regulating radioactive drug safety and efficacy, stating that it would regulate the radiation safety of the workers and the public. The 1976 Medical Device Amendments to the Food, Drug and Cosmetic act extended FDA's authority over medical devices (including devices containing radioactive materials) in a way similar to its authority over drugs.

NRC's authority to regulate domestically the medical uses of byproduct material is found in the Atomic Energy Act of 1954, as amended. For example, section 81 of that Act authorizes NRC "to issue general or specific licenses to applicants seeking to use byproduct material for * * * medical therapy * * *." Section 81 directs NRC to regulate the manufacture, production, transfer, receipt in interstate commerce, acquisition, ownership, possession, import and export of byproduct material. Finally, Section 81 also directs that:

> The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission.

Commission regulations, for the most part set forth in 10 CFR Parts 30 through 36, were promulgated to carry out the broad regulatory scheme envisaged by section 81. For example, Part 35 establishes regulations specific to human uses of byproduct material. FDA's statutory authority (Federal Food, Drug and Cosmetic Act, as amended, 21 U.S.C. 301 et seq.) does not diminish NRC's authority. Where NRC's and FDA's authorities overlap, the respective authorities can be harmonized by interagency agreement.

The central question in the April 21, 1977, FEDERAL REGISTER notice is a question of policy not authority, namely:

To what extent should the protection of the patient be considered in NRC's regulation of the medical use of byproduct material?

From the standpoint of authority, it is clear that NRC can regulate the medical uses of byproduct material to protect the health and safety of users of this material, for instance, patients. In licensing the possession and use of byproduct material, NRC establishes limits within which physicians exercise professional discretion. From the standpoint of policy, these limits depend upon how NRC views the potential hazard to the patient's health and safety in the uses of the byproduct material. The greater the potential hazard to a patient from the byproduct material or its use by a physician, the more NRC may elect to circumscribe areas that might otherwise be regarded as within the discretion of the physician.

The first part of NRC's policy statement indicates that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers and the general public.[1]

This is the traditional regulatory function of NRC for all uses of byproduct, source and special nuclear material. It is a regulatory role that was not questioned by any of the commenters but, rather, it was consistently recognized as a necessary role in the medical uses of radioisotopes.

NRC's regulation of the radiation safety of workers and the general public in the medical uses of radioisotopes is relinquished by NRC to Agreement States; does not overlap with FDA's activities; is in harmony with regulation by the Department of Transportation, Social Security Administration and the Joint Commission on Accreditation of Hospitals; and dovetails with Occupational Safety and Health Administration regulation of the work-place for the use of naturally-occurring and accelerator-produced radioactive materials.

The second part of NRC's policy statement indicates that NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate. As noted before, NRC has the authority to regulate the radiation safety of patients.

The NAS-BEIR[2] report discusses limiting the exposure of the population to medical applications of ionizing radiation. That report, which includes all medical uses of ionizing radiation, shows an average dose rate from radiopharmaceuticals of 1 mrem/year and an average dose rate from diagnostic radiology of 72 mrem/year in 1970.

The following quotation is from the NAS-BEIR report:

> In the foreseeable future, the major contributors to radiation exposure of the population will continue to be natural background with an average whole body dose of about 100 mrem/year, and medical applications which now contribute comparable exposures to various tissues of the body. Medical exposures are not under control or guidance by regulation or law at present. The use of ionizing radiation in medicine is of tremendous value but it is essential to reduce exposures since this can be accomplished without loss of benefit and at relatively low cost. The aim is not only to reduce the radiation exposure to the individual but also to have procedures carried out with maximum efficiency so that there can be a continuing increase in medical benefits accompanied by a minimum radiation exposure.

NRC will act to help ensure that radiation exposure to patients is as low as is reasonably achievable, consistent with competent medical care and with minimal intrusion into medical judgments. NRC will not exercise regulatory control in those areas where, upon careful examination, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Wherever possible, NRC will work closely with Federal and State agencies and professional groups in designing new voluntary guidance for practitioners to limit unnecessary patient radiation exposure. However, there are specific areas discussed in Section III of this policy statement where NRC will regulate the radiation safety of patients to help minimize unnecessary patient exposure.

The third part of NRC's policy statement indicates that NRC will minimize its intrusion into medical judgments affecting the patient and into other areas traditionally considered to be a part of the practice of medicine. The Commission recognizes that physicians have the primary responsibility for the protection of their patients. The Commission believes that basic decisions concerning the diagnosis and treatment of disease are a part of the physician-patient relationship and are traditionally considered to be a part of the practice of medicine. NRC regulations are predicated on the assumption that properly trained and adequately informed physicians will make decisions in the best interest of their patients.

The regulations try to find a balance between adequate controls and avoidance of undue interference in medical judgments. A consequence of too much regulation could be poorer health care delivery to patients. A con-

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[1] The term general public in this statement specifically excludes patients.

[2] National Academy of Sciences Advisory Committee on the Biological Effects of Ionizing Radiations (NAS-BEIR) report. The Effects on Populations of Exposure to Low Levels of Ionizing Radiation. National Academy of Sciences—National Research Council, Washington, D.C. (1972).

sequence of leaving to physicians the majority of the decisions concerning their patients is that the physicians will make mistakes. The tightest regulation of physicians' decisions by Federal, State and professional groups will not be able to prevent future incidents in the medical uses of radioisotopes.

The Commission recognizes that FDA regulates the manufacture and interstate distribution of drugs, including those that are radioactive. FDA also regulates the investigational and research uses of drugs as well as the specific guidance on doses and procedures found in the product labeling. However, FDA does not have the authority to restrict the routine use of drugs to procedures (described in the product labeling) FDA has approved as safe and effective. Indeed, NRC is the only Federal Agency that is currently authorized to regulate the routine use of radioactive drugs from the standpoint of reducing unnecessary radiation exposure to patients.

The Commission believes that the diagnostic use of radioactive drugs is, in most cases, clearly an area of low radiation risk to patients. Therefore, NRC will not control physician's prerogatives on patient selection, instrument selection, procedure selection, drug selection and dose level for most diagnostic uses of radioisotopes. For some therapeutic uses of radioactive drugs, and in certain diagnostic uses—for example, the use of phosphorus-32 for localization of eye tumors—the risk to patients is not low. The risk of tissue or organ damage (or even death) is inherent in the use of therapeutic levels of radioactive drugs. NRC will continue to restrict the uses of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physicians' prerogatives on patient selection and instrument selection for therapy procedures, because these procedures are so specialized and patient specific.

Congress recently gave FDA authority to regulate medical devices, similar to FDA's authority to regulate drugs, but with additional authority to restrict the routine use of medical devices as may be necessary to provide reasonable assurance of their safety and effectiveness. FDA has not yet had sufficient time to implement its full authority to regulate medical devices containing byproduct, source or special nuclear material. Therefore, NRC will continue to restrict physician's uses of these medical devices, both for diagnosis and therapy, to those procedures that NRC has determined (in consultation with its Advisory Committee on the Medical Uses of Isotopes) to be safe and effective.

The Commission does not consider equipment calibration, qualifications of paramedical personnel or reporting to NRC misadministrations of radioactive material to be exclusively the practice of medicine or a part of physician-patient relationships. As described in detail in Section III, the Commission intends to regulate these areas of patient radiation safety where justified by the risk to patients and where voluntary standards, or compliance with these standards, are inadequate.

III. NRC Position on Specific Issues

The following represent the Commission's position on the specific issues raised in the April 21, 1977, Federal Register announcement (42 FR 20691):

1. Evaluation of Physicians' Clinical Qualifications

NRC has always required that licensees be qualified by training and experience in the handling of radioactive material from the standpoint of radiation safety of workers and the general public.

The Commission believes that it is necessary to continue to evaluate physicians' clinical qualifications prior to issuance of NRC licenses. At this time there is no alternative method of determining if a physician, not certified by the American Board of Nuclear Medicine or the American Board of Radiology, is competent to use byproduct material. However, the Commission also believes that, as this field of medicine continues to mature, other alternatives will replace the NRC evaluation of clinical qualifications.

NRC has for several years accepted certification by the American Board of Nuclear Medicine and the American Board of Radiology as sufficient evidence of clinical competence in the fields of nuclear medicine and radiation therapy, respectively. It has recently determined that certification by the American Board of Radiology in Diagnostic Radiology, with Special Competence in Nuclear Radiology, is sufficient evidence of clinical competence in nuclear imaging procedures.

Based on specific assessments in consultation with its Advisory Committee on the Medical Uses of Isotopes, NRC will continue to expand its use of the various board certifications as satisfactory evidence of adequate clinical training and experience for the medical uses or radioisotopes. NRC will also work closely with the professional societies to assist them in developing suitable permanent alternatives to NRC's evaluation of physicians' clinical qualifications.

2. Selection of Patients for Diagnostic or Therapeutic Procedures

NRC currently evaluates a physician's clinical qualifications to use radioisotopes on humans. One NRC requirement is that the physician's training include "supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed."

The Commission recognizes that the selection of patients for diagnostic or therapeutic procedures is basically a matter of medical judgment. Diagnostic procedures have a low patient risk and therapeutic procedures are specialized and patient specific. Radioactive drug manufacturers provide guidance on patient selection and contraindications in the product labeling. Supplemental voluntary guidelines on limiting patient radiation exposure, including the standpoint of patient selection, are available in the literature. The contribution to unnecessary patient exposure from improper selection of patients is believed to be small. Therefore the Commission does not anticipate the need to limit, to any major extent, the physician's discretion in selection of patients. Because the NRC does not evaluate physician qualifications for the general license, the Commission will continue its minor restriction in the general medical license [10 CFR 35.31(c)(4)] prohibiting administrations of radiopharmaceuticals to a woman with confirmed pregnancy or to persons under 18 years of age. This restriction does not affect specific licensees.

3. Selection of Instruments to Be Used in Performing Diagnostic or Therapeutic Procedures

NRC evaluation of a physician's qualifications includes an evaluation of training in radiation physics and instrumentation.

The selection of instruments for performing diagnostic or therapeutic procedures is, like patient selection, basically a matter of medical judgment. There are also voluntary guidelines available on the selection, calibration and maintenance of instrumentation. Again, diagnostic procedures have low patient risk and therapeutic procedures are specialized and patient specific. NRC does not currently restrict selection of instruments and does not anticipate the need for doing so in the future. The Commission recognizes that FDA will regulate the investigational and research uses of medical devices under its new legislation, the Medical Device Amendments of 1976 (Pub. L. 94-295). The Commission also recognizes that these amendments give FDA new authority to restrict the routine use of medical devices under such conditions as may be necessary to provide reasonable assurance of their safety and effectiveness.

4. Selection of Radioactive Drugs or Devices to Be Used

The NRC now restricts a physician's selection of radioactive drugs by limit-

ing the distribution of the radioactive drugs to those products meeting FDA requirements. The physician is thus restricted to using radioactive drugs subject to an FDA-approved "Notice of Claimed Investigational Exemption for a New Drug" (IND) or an FDA-approved "New Drug Application" (NDA). NRC regulates the manufacture and installation of teletherapy devices as well as the integrity testing of these and other radioactive medical devices during use. However, NRC does not now require that medical devices containing radioactive material meet FDA requirements.

The Commission believes that it is necessary to continue its restrictions on the availability of radioactive drugs to those that meet FDA requirements. NRC will study and assess with FDA the necessity for a similar NRC requirement for radioactive medical devices.

In those cases where several radiopharmaceuticals have been approved by FDA for the same procedure, the Commission does not plan to restrict a physician's decision regarding which agent to use. The Commission considers the basic decision on drug or device selection to be a traditional part of medical practice.

The Food, Drug and Cosmetic Act differentiates between pharmacy and manufacture. However, no clean line has been established to determine when a nuclear pharmacy has gone beyond the ordinary practice of pharmacy (compounding and dispensing) and has become a manufacturer. The FDA is drafting guidelines that will define all of those operations (of nuclear pharmacies) connected with the preparation of radioactive drugs which will be regarded as manufacture (and, therefore, subject to FDA new drug requirements) and not part of the practice of pharmacy. In the absence of FDA guidelines, the NRC licenses nuclear pharmacies to distribute only those products that they have prepared from FDA-approved radio- pharmaceuticals or reagent kits.

5. SELECTION OF PROCEDURES TO BE PERFORMED

NRC evaluates a physician's clinical qualifications. His training includes studies, under a preceptor, of case histories to establish the most appropriate diagnostic or therapeutic procedures, limitations, contraindications, and so forth.

The Commission recognizes that the selection of procedures is basically a matter of medical judgment. The Commission does not anticipate the need to limit, to any major extent, the physician's discretion in the selection of clinical procedures.

The Commission recognizes that FDA does not restrict the routine use of NDA-approved drugs to those procedures for which there is substantial evidence of safety and effectiveness, that is, to those procedures approved in the drug labeling. According to FDA's statement on drug labeling:

> The FDA Commissioner clearly recognizes that the labeling of a marketed drug does not always contain all the most current information available to physicians relating to the proper use of the drug in good medical practice. Advances in medical knowledge and practice inevitably precede labeling revision by the manufacturer and formal labeling approval by the Food and Drug Administration.
>
> Good medical practice and patient interests thus require that physicians be free to use drugs according to their best knowledge and judgment. Certainly, when a physican uses a drug for a use not in the approved labeling, he has the responsibility to be well-informed about the drug and to base such use on firm scientific rationale or sound medical evidence, and to maintain adequate medical records of the drugs use and effects, but such usage in the practice of medicine is not in violation of the Federal Food, Drug and Cosmetic Act.

Basically, NRC issues two types of licenses to medical institutions for the human uses of byproduct material, the medical license of broad scope and the medical license of limited scope.

Broad medical licenses authorize multiple quantities and types of byproduct material for unspecified uses and are issued to institutions that (1) have had previous experience operating under a limited medical license and (2) are engaged in medical research as well as routine diagnosis and therapy using radioisotopes. The programs under the broad medical license operate under the supervision of a medical isotopes committee. No physicians are named as individual users on the license, nor are radioisotopes limited to specific clinical procedures.

Limited medical licenses specify the radioisotopes and the clinical procedures that may be performed by physicians named on the license. Under limited medical licenses the institutional licensee must have a medical isotopes committee and the physicians named on the institution's license conduct their programs with the approval of that committee. Under limited medical license the authorized diagnostic and therapeutic radioactive drugs and the authorized clinical procedures are listed in the NRC regulation 10 CFR § 35.100, "Schedule A—Groups of medical uses of byproduct material."[4]

The authorized clinical procedures listed in the groups are procedures approved by FDA in the drug labeling. Since FDA does not restrict the physician to clinical procedures listed in the labeling, NRC regulations are more restrictive than FDA regulations.

Elsewhere in this issue of the FEDERAL REGISTER is a proposed rule that would delete the specification of the clinical procedure from the lists of the diagnostic radioactive drugs in § 35.100. However, this proposed rule would place limitations on a drug's use for procedures not specified in the package insert.

As noted in Section II of this policy statement, the radiation risk[5] to the patient from most diagnostic nuclear medicine procedures is low, while the risk is significant from misuse of therapeutic levels of radioactive drugs. Those few diagnostic procedures where the risk to the patient is high are not listed in K 35.100 but are the subject of specific license authorizations and will continue to have the clinical procedure specified.

6. SELECTION OF DOSE LEVEL (QUANTITY OF RADIOACTIVE MATERIAL OR RADIATION DOSE) TO BE USED

As noted in Item 2, selection of patients, the physician's training must include supervised experience in recommending proper dosages for specific patients.

The Commission recognizes the selection of dose level is basically a matter of medical judgment. The package inserts for radioactive drugs include the recommended usual dose and usual dosage range. Because of the many variables that determine the most effective dosage for both the diagnostic and therapeutic use of radioisotopes, the NRC does not now regulate, nor does it anticipate the necessity of restricting in the future, the physician's selection of dose level.

7. PROPER MEASUREMENT OF THE DOSE THE PATIENT RECEIVES

The Commission believes that proper measurement of the radioactive drug dosage, or radiation dose in the case of therapy, helps to ensure that the patient receives what the physician has prescribed and thus helps minimize unnecessary radiation exposure to patients. NRC now requires most licensees, particularly those who prepare radioactive drugs from radioisotope generators or reagent kits, to measure the dosage prior to administration. This requirement is now imposed through a license condition. NRC will study the merits of amending its regulations to require measurement of all diagnostic and therapeutic doses of radio- pharmaceuticals, regardless of origin.

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[4] Radioactive materials in § 35.100 are divided into six groups, each group having similar requirements for user training and experience, facilities and equipment, and radiation safety procedures.

[5] The risk to a patient from a false positive or a false negative diagnosis through the use of a drug for a purpose not fully investigated and specified on the label would be expected to be greater than it is for a labeled use but this risk is difficult to quantify.

NRC currently has under consideration a proposed rule (42 FR 25743) that would require annual calibration and monthly checks of teletherapy units. This rule has received many public comments; the comments will be analyzed and the rule modified, if warranted. Based on the disposition of this proposed rule on teletherapy calibration, NRC may propose a similar rule for the periodic calibration of brachytherapy sources.

8. CALIBRATION OF DIAGNOSTIC EQUIPMENT AND DOSE MEASURING INSTRUMENTATION

The Commission believes that the calibration of diagnostic equipment and dosage measuring devices helps ensure that the patient receives what the physician prescribes and thus helps minimize unnecessary radiation exposure to patients. NRC presently requires licensees who prepare radioactive drugs from radioisotope generators and reagent kits to describe in the license applications a method for calibration of their dose measuring devices. NRC also provides an acceptable method for calibrating dose calibrators in "A Guide for Preparation of Applications for Medical Programs" (NUREG-0338 Rev. 1 November 1977) that can be obtained by writing to the Radioisotopes Licensing Branch, Division of Fuel Cycle and Material Safety, Nuclear Regulatory Commission, Washington, D.C. 20555.

NRC presently does not have any requirements concerning the calibration of diagnostic equipment. Because of the extensive experience of FDA's Bureau of Radiological Health and the new authority of FDA's Bureau of Medical Devices, NRC will collaborate with them in their development of voluntary guidelines for the routine calibration of diagnostic equipment. At the same time, NRC will study the merits of proposing mandatory requirements.

9. QUALIFICATIONS OF PARAMEDICAL PERSONNEL, SUCH AS TECHNOLOGISTS, NURSES, RADIOPHARMACISTS AND RADIOLOGICAL PHYSICISTS

On March 9, 1973, AEC published (38 FR 6399) a proposed amendment to its regulations in 10 CFR Part 35 that would (1) define the activities that may be delegated by physicians and those that may not, (2) require physicians to determine that paramedical personnel have been properly trained, and (3) require medical licensees to report to the Commission and to the patient misadministrations of radioactive material.

The Commission recognizes that there are several organizations currently involved in developing or providing minimum standards, guidelines or certification for technician training. These programs are administered by State, Federal and private agencies including: the Health Services Administration (Medicare and Medicaid DHEW), the Bureau of Radiological Health (FDA/DHEW), the Joint Commission on Accreditation of Hospitals (JCAH), the American Registry of Radiological Technologists (ARRT), the Registry of Medical Technologists (RMT) and the new certification board by the Technologists Section of the Society of Nuclear Medicine.

The Commission also recognizes that the majority of paramedical (allied health) personnel using radioactive material are not covered by these programs. Rather they are trained on-the-job, are not certified; and many do not have their training documented. However, the introduction of a relatively less comprehensive NRC program, such as that in the 1973 AEC proposal, could undermine the efforts of voluntary organizations or those Federal or State agencies relying on more comprehensive guidelines.

In the near future, NRC will publish a FEDERAL REGISTER announcement withdrawing the 1973 AEC proposal and substituting an NRC proposed misadministration reporting requirement. That future announcement will discuss more thoroughly the reasons for withdrawal of the AEC proposal and substitution of the NRC proposal. NRC is studying the various allied health certification programs currently in effect or being drafted by other Federal, State and professional groups. If the coverage provided by these programs is not adequate to protect the patient from unnecessary radiation exposure, NRC will work with these groups to develop a new NRC proposed rule for the training of allied health personnel.

10. REPORTING OF MISADMINISTRATION OF RADIOACTIVE MATERIAL OR RADIATION FROM DEVICES INCORPORATING RADIOACTIVE MATERIAL

As describe in Item 9, in 1973 AEC published a proposed rule that would require licensees to report misadministrations of radiopharmaceuticals or radiation from byproduct material to the Commission and to the patient or a responsible relative whenever the misadminsitration could cause a "demonstrably adverse effect on the patient." Ninety-eight comment letters were received, most objecting to the proposal for reporting to the patient. Reasons given for objection to the requirement for reporting misadministrations to the patient were: (1) such reports would constitute self-incrimination, (2) such reports would invite or increase unwarranted malpractice suits, (3) this would place the government as a third party in the physician-patient relationship, (4) this is a matter of medical ethics, and (5) there are no comparable requirements for any other drug or physicians in any other field of medicine.

The purpose of a misadministration reporting requirement is to allow NRC to investigate the incident, evaluate the corrective action taken by the licensee to minimize the chance for recurrence, and, if other licensees could make the same errors, begin generic corrective action which would, as a minimum, inform other licensees of the potential problem.

As also noted in Item 9, in the near future NRC plans to publish, in the FEDERAL REGISTER a new proposed rule for misadministration reporting. The new NRC proposal will address: (1) the types of misadministrations to be reported, (2) the substance and timing of the reports, and (3) the recipients of misadministration reports, for example, the referring physician and possibly the patient or a responsible relative, as well as NRC.

IV. PUBLIC AND ADVISORY COMMITTEE COMMENTS

The NRC staff met with the public on the morning of May 6, 1977, and with its Advisory Committee on the Medical Uses of Isotopes in an afternoon public meeting on the same day. The members of the Advisory Committee were the chairman, Mr. Richard E. Cunningham, Deputy Director of the Division of Fuel Cycle and Material Safety of NRC's Office of Nuclear Material Safety and Safeguards; Dr. James Quinn from Northwestern Memorial Hospital; Dr. Joseph Workman from Duke University Medical Center; Dr. David Kuhl from the University of California, Los Angeles; Dr. Henry Wagner from John Hopkins Medical Institution; Dr. Edward Webster from Massachusetts General Hospital; and Dr. Frank DeLand from the University of Kentucky. Two consultants to NRC, Captain William Briner from Duke University Hospital and Dr. Peter Almond from the M. D. Anderson Hospital, also attended.

The comments from members of the public can be classified broadly in two categories. In the first category, the physicians, physicians' groups, pharmacists' groups and industry comments range from statements that "present regulations are sufficient" to the "the NRC should not regulate the use of radioisotopes in medicine at all." Many of the comments in this category stated that FDA regulates the safety and efficacy of drugs and that NRC should withdraw from this area and regulate only the radiation safety of workers and the general public.

In the second category, NRC Agreement and non-Agreement State radiation control agencies' comments range from statements that "present regulations are sufficient" to "much stronger regulation is necessary."

Many of the comments in this category note that FDA does not regulate the routine uses of drugs and devices and, therefore, NRC should regulate to ensure that the patient is protected from unnecessary radiation exposure.

In the area of NRC's evaluation of a physician's clinical qualifications, both categories of commenters recommend greater use by NRC of board certifications. Physicians and the industry in general appear to be interested in maintaining NRC evaluation as a means of entry into the field. They feel that if NRC withdrew from evaluating physician's clinical qualifications, the institutions or States would require specialty board certification. They state that there are not enough board certified physicians to fill the demand for services and that board certification is not necessary for many of the radioisotope procedures. The State radiation control agencies believe that NRC's evaluation of physician clinical qualifications is necessary to protect the patient. They feel that if NRC withdraws there will be a regulatory gap. Some States suggest that a physician's qualifications should be reviewed periodically, for example, every five years, to determine that he is keeping abreast of this rapidly changing field.

The general sense of NRC's Advisory Committee on the Medical Uses of Isotopes was that NRC should continue, at least for the immediate future, to examine physicians' clinical qualifications and should make greater use of the various types of board certification or registration, as evidence of adequate qualifications to practice in the areas of nuclear medicine and radiation therapy.

On the question of selection of patients, instruments, radioactive drugs or devices, procedures and dose level, the State radiation control agencies believes that NRC should not regulate the selection of patients or instruments. However, the States believe that licenses should specify the permitted radioactive materials and procedures and should require adherence to instructions and dose schedules in FDA-approved package inserts. The physicians and the industry believe that decisions on selection of patients, instruments, radioactive drugs or devices, procedures and dose levels are medical decisions and traditionally a part of the practice of medicine. They commented that NRC should not regulate these areas. Some argued that NRC has no authority to regulate in these areas since Congress gave FDA the authority to regulate the safety and efficacy of all drugs and medical devices.

The Advisory Committee on the Medical Uses of Isotopes does not have a consensus on this issue. The majority of the committee feels that NRC should not restrict the physician to those diagnostic procedures that have been approved by FDA in the labeling. One member believes that NRC should continue this restriction or that some arrangement should be made similar to the in-house institution committee review under an NRC Broad Medical License.

Regarding proper measurement of the dose the patient receives, the States urge NRC to expand the present licensing requirement for measurement of doses of radioactive drugs prepared from radionuclide generators, to cover all doses of radioactive drugs regardless of how they are prepared. On the related question of the calibration of diagnostic equipment and dose measuring instrumentation, the States favor NRC activity aimed at limiting patients exposures but recommend that NRC coordinate its activities with FDA's Bureau of Radiological Health and other professional and scientific groups.

The category of physicians, physician groups, and so on, varies in its comments regarding measurement of dose and calibration of diagnostic instrumentation and dose-measuring instrumentation. Several commenters state emphatically that NRC has no business regulating in this area. Many of them state as their reason the new authority of FDA's Bureau of Medical Devices and the recent activities of FDA's Bureau of Radiological Health in developing voluntary quality control guidelines. Several other commenters state that NRC activities in this area are both welcome and necessary to limit unnecessary patient exposures. Similar to the States' comments, some of these latter commenters recommend NRC cooperation with FDA's Bureau of Radiological Health and other professional and scientific groups active in developing guidelines for dose measurement and instrument calibration.

The consensus of the Advisory Committee on the Medical Uses of Isotopes is that NRC would do well to concentrate its activities on assurances that the patient receives the proper dose prescribed by the physician. The Advisory Committee can see no reason why radioactive drug doses should not be measured by well-calibrated instrumentation prior to administration to the patient. On the other hand, the Advisory Committee is not enthusiastic about the idea of NRC requiring the calibration of diagnostic instrumentation. The existence of guidelines in this area and the market pressures on manufacturers to provide quality instrumentation are two examples that it discussed.

On the question of the qualifications of paramedical personnel, the physician-industry category is virtually unanimous in its opposition to NRC requirements. The pharmacy, radiopharmacist and technologist groups are particularly against NRC granting credentials to paramedical personnel citing the numerous certifications and activities of other Federal and State agencies, as well as claiming lack of NRC authority to regulate in this area. The physician groups cite the fear that the number of certified technologists will fall far short of the need for these personnel.

The sense of the Advisory Committee is that existing certifications cover paramedical qualifications and hospitals look rather carefully at these. They feel that, in the final analysis, physicians are responsible for their patients and, therefore, are responsible for the qualifications of paramedical personnel working under their direction in caring for patients. With the exception of physicist's qualifications for calibration of radiation therapy, the Advisory Committee does not recommend that NRC become involved in regulating the qualifications of paramedical personnel.

The States consider misadministration reporting necessary in order to limit unnecessary radiation exposure to patients. They point out that with reports of misadministrations of byproduct material or radiation from byproduct material, NRC will be able to investigate the incident, determine if the corrective action is adequate and, if the problem could occur at other institutions, notify other licensees.

Physicians and physician groups are, in general, opposed to NRC requiring reports of misadministrations. They cite the low number of misadministrations of radioactive material to date combined with the fear of malpractice suits and the already high insurance premiums as the principal reasons for opposing misadministration reporting. They point out that most misadministrations of diagnostic levels of radiopharmaceuticals do not harm the patient and are similar to misadministrations of other drugs. They state that medical institutions and the medical profession have procedures for dealing with misadministrations. Several commenters question NRC's authority to require such reports, stating that this is within the traditional practice of medicine and such a reporting requirement would be unique in all of medical practice. Several commenters do not object to keeping records of misadministrations for on-site examination by NRC inspectors, but these commenters feel that more harm than good would result from making such reports directly to NRC, where they would become a part of the public record.

The Advisory Committee on the Medical Uses of Isotopes does not have a consensus on the issue of misadministration reporting. The members who

commented are against requiring reports of those misadministrations having no demonstrable health effects on the patient.

One general comment occurred several times during the morning and afternoon meetings and in many of the public comments. It concerns the need for uniformity in Federal, State and private regulation of the medical uses of radioisotopes. Several commenters call for uniformity between NRC and State regulations, but most focus on the discrepancy between the regulation of byproduct material and the regulation of naturally-occurring and accelerator-produced radioactive materials and accelerator therapy. One commenter discusses this discrepancy with regard to therapy. This commenter expresses his concern that regulatory considerations have come to play an important part in decision making, particularly in matters where the decision is for a choice among near equals. Specifically, he is concerned that the competition between cobalt-60 and electron accelerator teletherapy may be influenced, not from differences in hazards, but because NRC regulates cobalt-60 teletherapy units and does not regulate electron accelerator units. He feels that physicians may choose the least regulated alternative in order to have more time available for the patient-oriented demands of their practice. He suggests that NRC should cooperate with those agencies that can regulate accelerator teletherapy, so that these competing alternatives receive more uniform regulation. He further suggests that any increase in the regulation of one alternative would be counterproductive to public health and safety.

V. Conclusion

This proposed policy statement on NRC's regulation of the medical uses of radioisotopes is published with the expectation that public comment will improve the ultimate Commission decision. To that end, it would be helpful if responses include the reasons for a particular point of view or recommendation.

Dated at Washington, D.C., this 13th day of March 1978.

For the Nuclear Regulatory Commission.

Samuel J. Chilk,
Secretary of the Commission.

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

June 25, 1980

TO ALL MEDICAL AND ACADEMIC LICENSEES

There are a number of steps licensees engaged in nuclear medicine practice and biomedical research can take under NRC rules to substantially reduce, and in some cases eliminate, the need to send radioactive waste to commercial low-level waste disposal facilities. By taking advantage of these alternatives and following good waste management practices, licensees can often reduce the risk of having their programs impacted through further curtailment of commercial waste disposal facilities. Some of the more important steps that can be taken are to:

1 Segregate radioactive waste from non-radioactive waste to reduce unnecessary volume. This simply requires a little time and discipline in the laboratory.

2. Hold waste with short-lived radionuclides in storage for decay to background levels, then dispose of it in the ordinary trash. This procedure requires a license amendment. (See Enclosure 1 for information to be submitted with the amendment request).

3. Release certain materials into the sanitary sewage system in accordance with 10 CFR Part 20.303. No license amendment is required but 10 CFR Part 20.303 should be carefully reviewed to stay within limits.

Judicious use of these three steps can substantially reduce the volume of waste shipped to burial grounds. Some nuclear medicine laboratories using only short-lived radionuclides can eliminate waste shipments.

Waste from biomedical research is generally somewhat more difficult to manage. Two of the most common problems are disposal of liquid scintillation counting waste (LSCW) and animal carcasses. The most frequently used radioisotopes in both are tritium and carbon-14. LSCW presents a particularly troublesome problem due to the flammability and toxicity of the solvents. Disposal of LSCW has been given special consideration by NRC. The staff has investigated alternatives to managing these wastes and the results have been published in NUREG-0656.

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Consideration should be given to disposal by incineration for LSCW and laboratory animals containing small amounts of tritium and carbon-14. This method requires a license amendment; 10 CFR Part 20.305 contains the provisions for incineration. Enclosure 2 identifies the information to be submitted with an amendment request for incineration.

There are other provisions in the regulations that cover waste disposal. We have mentioned only the few that are most easily and commonly used. Other regulatory provisions include:

1. Disposal by burial in soil in accordance with 10 CFR 20.304 (A proposed rule change is under consideration to delete this provision. It will likely be replaced by a provision which requires specific approval by license amendment for burial).

2. Release as effluents to unrestricted areas pursuant to 10 CFR Part 20.106. In keeping with the ALARA concept, this method should normally be used only for releases incident to the procedures involved.

We suggest that you review and consider alternatives to commerical land burial for the management of your low-level radioactive waste. Implementation of some of these alternatives may require an amendment to your license. Amendment requests should be submitted to the Material Licensing Branch through the use of normal channels. Specific licensing questions concerning NUREG-0656 should be directed to the Material Licensing Branch (301) 427-4232. Copies of the NUREG-0656 may be obtained from the Division of Technical Information and Document Control, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

Sincerely,

Wandy L. Miller

Wandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosures:

1. Information to be submitted When Requesting Amendment to Dispose of Radioactive Waste by Decay-In-Storage.

2. Information Required for Commission Approval of Treatment or Disposal by Incineration.

Enclosure 1

Information to be Submitted When Requesting Amendment to Dispose of Radioactive Waste by Decay-In-Storage Method

This is in reference to your request for information concerning authorization to dispose of radioactive waste via decay-in-storage. In order to approve such an amendment request, we need the following information:

1. Please submit a diagram of the area where the waste will be decayed-in-storage. Show the type, location, and thickness of shielding that you will have available in this area on your diagram. Your storage area should be large enough to handle an accumulation of used Tc-99m generators as well as other solid waste.

   Identify adjacent unrestricted areas located across the walls from the storage area and show that adequate steps have been taken to assure that radiation levels do not exceed the limits specified in 10 CFR 20.105 (enclosed).

2. Describe your security measures for the decay-in-storage area.

3. Confirm that radiation levels in this area will be surveyed and recorded at least weekly.

4. Describe your procedures for monitoring the waste to assure that it has decayed to background levels prior to disposal. As a minimum, your description should include these points:

   a. Monitor the waste in a low background area.

   b. Monitor with a low level GM type survey meter as appropriate for contamination surveys. Use the most sensitive scale.

   c. Remove all shielding prior to monitoring.

   d. Maintain records of these surveys as required under 10 CFR 20.

5. Note that decay-in-storage may not be a practical method of disposal for Tc-99m generators. These generators may contain long-lived radioisotopic contaminants. If you intend to dispose of generators by this method, you should include procedures for segregating the generator columns so that they may be monitored separately.

Be certain to submit your amendment request in duplicate. Unless your institution is fee exempt, your request should be accompanied by the appropriate amendment fee. Refer to 10 CFR 170.

Enclosure 2

INFORMATION REQUIRED FOR COMMISSION APPROVAL OF TREATMENT OR DISPOSAL BY INCINERATION

Revised October 3, 1979

1. State specifically the isotopes you wish to incinerate. For each isotope listed, you should submit calculations demonstrating that air concentrations of the effluents at the stack are in accordance with the requirements of Section 20.106 of 10 CFR Part 20.

2. Submit the characteristics of the incinerator such as height of the stack, height of and distance to buildings in the surrounding areas, rated airflow of the incinerator in cubic feet per hour or similar units and its proximity to any air intake ducts.

3. The gaseous effluent from the incinerator stack should not exceed the limits specified for air in Appendix B, Table II, 10 CFR Part 20, when averaged over a twenty-four (24) hour period.

4. In order to be in compliance with the ALARA philosophy stated in Section 20.1(c) of 10 CFR Part 20, the gaseous effluent from the incinerator stack should be a fraction (approximately 10%) of the limits specified for air in Appendix B, Table II, 10 CFR Part 20, when averaged over a one year period.

5. Describe the method of measurement or estimation of the concentration of radioactive material appearing in ash residue.

6. Describe the procedures for handling and disposing of ash from the incinerator.

7. Describe procedures to be followed to prevent overexposure of personnel during all phases of the operation, including instruction given to personnel handling the combustibles and the ash.

8. Submit evidence that all State and local regulations concerning incineration of radioactive material have been met by your institution.

9. State the maximum number of burns to be performed in any one week and the maximum number of burns per year.

UNITED STATES
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JUN 04 1981

TO ALL MEDICAL LICENSEES:

On June 23, 1980 all medical and academic licensees were sent a letter describing steps that they could take to substantially reduce or eliminate radioactive waste sent to commercial low-level waste disposal facilities. One of these steps was to hold radioactive waste in storage for decay to background levels before disposal in ordinary trash. For those licensees who do not have decay-in-storage as a method for disposal of radioactive waste in their NRC license, this requires a license amendment.

In order to ease the burden of applying for an amendment to your license for decay-in-storage of radioactive waste, we have decided that we will place a condition on all medical and academic licenses which states:

"The licensee is authorized to hold radioactive material with a physical half-life of less than 65 days for decay-in-storage before disposal in ordinary trash provided:

a. Effected radioactive waste shall be held for decay a minimum of ten (10) half-lives.

b. Prior to disposal as normal waste, radioactive waste shall be monitored to determine that its radioactivity cannot be distinguished from background with typical low-level laboratory survey instruments. All radiation labels will be removed or obliterated.

c. Generator columns shall be segregated so that they may be monitored separately to ensure decay to background levels prior to disposal."

There are two ways that the above condition can be incorporated into your license:

1. Without your prior request, we will automatically place this condition on all medical byproduct material licenses as they are issued in response to new or renewal applications and amendment requests; or

2. If you desire to have this condition placed on your present license right away, you should submit a request for amendment referencing this document. This type of amendment request will be fee exempt.

You are reminded of the requirements contained in 10 CFR 20.105 and 10 CFR 20.207, which address established limits for radiation levels in unrestricted areas and storing or securing radioative material respectively.

Sandy L. Miller, Chief
Material Licensing Branch
Division of Fuel Cycle and
Material Safety, NMSS

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MEDICAL APPLICATIONS CHECK LIST

- Name - (note any changes)
- Address - (compare to previous)
- Proper signature - (Hospital Administrator or Management representative)
- User

  a) Items 8 and 9
     No. 8 - training experience (200 hrs)
     No. 9 - actual use of isotopes (500 hrs)

  b) Preceptor statement or certification

     i) All procedures
     ii) 500 hours - institutional training
     iii) Signature

  c) License to practice medicine

- Private User (Physician)

  a) Hospital and address for patients
  b) Agreement letter from hospital
  c) Procedures and equipment for management of patients

- Radiation Protection Officer - (If other than named user)

  a) Training
  b) Duties
  c) Availability - (In house vs. consultant)

- Instruments - Listing

  a) High level survey meter - to 1 R/hr
  b) Low level survey meter - Down to .1 mR/hr
  c) Dose calibrator
  d) Diagnostic instruments

- Calibration Procedures - (Check file if private consultant)

  a) Survey meters - (Check for backup if needed)

     i) Frequency (annually)
     ii) Adequate standards (energy and activity NBS)
     - Check for accuracy and manufacturer
     iii) Two points on <u>each</u> scale
     - ± 10%
     - ± 20% with chart or graph

b) Dose calibrator

i) Daily checks - Constancy ± 5%
ii) Proper standards
(1) H, M, L if needed
(2) Activity
(3) NBS
iii) Linearity check - quarterly ± 5%
- 1st elution - highest activity
iv) Accuracy - yearly ± 5%

8. Facilities and Equipment (Diagram Needed)

a) Fume hoods
b) Shielding around generator
c) Storage areas
- waste shielding
d) Preparation areas
e) Long-term storage

9. Medical Isotopes Committee

a) Membership
b) Responsibilities and authority - Check to ensure Regulation Guideline.
c) Meeting frequency (quarterly)

10. Personnel Dosimetry

a) Whole body
b) Extremeties - finger badge
c) Dosimeters - Procedures and frequency of calibration

11. Bioassays

- Iodine
- Tritium

12. Receipt and notification

a) Working hours
b) Receipt procedures for off duty hours
c) Storage location for off duty hours
d) Instructions for personnel receiving during off duty hours
- Phone No. for RSO

13. Opening procedures

    a) Monitor outside
       - 200 mR/hr at surface
       - 10 mR/hr at 1 meter
    b) Wear gloves while opening — Appendix F
    c) Check packing material after opening
    d) Report leakage
    e) Incorrect exemption of packages

14. Training

    a) Technicians - initially and yearly. — Must cover 10 CFR 19.12 including pertinent NRC regulations, etc.

    b) Others - initially and yearly.

15. Laboratory Instructions

    a) Lab coats
    b) Gloves
    c) Use of fume hoods or glove boxes
    d) Monitor hands and clothing — Appendix G
    e) Syringe shields
    f) Eating, drinking, smoking
    g) Mouth pipetting
    h) Assay of individual doses
    i) Disposal
    j) Instruction for use of personnel monitors

16. Emergency Instructions - Contact RSO immediately

    a) Immediate steps
    b) Notification — Appendix H
    c) Clean-up

17. Animal Use - must specifically request

    a) Housing facilities
    b) Handling and clean-up procedures
    c) Waste disposal

18. Area Surveys

    a) Daily - elution and preparation areas
    b) Weekly - All areas — Appendix I
    c) Wipe Testing
    d) Removed areas

19. Therapy (unsealed)

a) Instructions to nurses
b) Room assignment
c) Disposable items — Appendix K
   - Patient trash saved and monitored
d) Linens
e) Dismissal survey
f) Volatile iodine handling
   (fume hood and bioassays)

20. Brachytherapy

a) Storage
   - Precautions for handling sources — Refer to Item 20, Reg Guide 10.8
b) Transportation
c) Inventory procedures — Appendix L
   - Source Accountability
   - Quarterly required
   - Before patient discharge
d) Measurement of extremity dose
   - Wrist or ring badge
e) Instructions to nurses
   - Save linen in marked hamper
     until marked
f) Room assignment
g) Room surveys
   i) ASAP after implant
   ii) After patient leaves

21. Waste Disposal

a) Liquid — Must include copy of Appendix J in application
b) Solid
c) Generator
d) Surveys
e) Survey long-term storage area — Appendix J

22. Xenon

a) Storage location
b) Ventilation in use area
   - Recirculation
   - Periodic checks of ventilation system
   - Negative pressure assured
   - Diagram of intake and outflow vents
c) Procedures
d) Emergency procedures

e) Disposal
   i) Fume hood
   ii) Gas trap
      - Manufacturer and Model No.
   iii) Other
      - Monitoring saturated filters
      - How filters disposed
f) 20.103 (1×10^{-5} µCi (ML.) (Restricted)
g) 20.106 (3×10^{-7} µCi/ML.) (unrestricted)
h) Calculations
i) Xenon checklist