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

MAR [illegible] 1979



The Honorable Paul Trible
United States House of Representatives
Washington, D. C. 20515

Dear Congressman Trible:

Thank you for sending NRC the editorial "Patient Exposure to X-Rays: "Whose Responsibility" by Suresh K. Agarwal, Ph.D., and Theodore E. Keats, M.D., that was published in the Virginia Medical Journal, February 1979.

At the Federal level, the Food and Drug Administration's Bureau of Radiological Health (BRH/FDA) has the basic responsibility for regulating x-rays. I am sending a copy of this letter and the editorial to Mr. John Villforth, Director, BRH. He can provide you with a more detailed and informative response to the editorial from BRH's perspective.

Because there are many parallels between the use of x-rays in medicine and the use of radioisotopes in medicine, which NRC does regulate, you may be interested in some recent activities of NRC in the area of patient radiation safety.

Drs. Agarwal and Keats express a valid concern about the radiation safety of patients and particularly the training of technologists. Both FDA and NRC have shared that concern and both agencies are doing something about it. In February 1979, NRC published a policy statement on the regulation of the medical uses of radioisotopes that I am enclosing for your information.

Regarding patient safety the policy statement reads:

> 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.

Recently, NRC has taken several actions in this regard:

1. In November 1978 NRC issued a final rule requiring hospitals to perform radiation surveys of patients to make sure that all radioactive sources are removed from patients following therapy.

2. In January 1979 NRC issued a final rule requiring hospitals to have qualified experts to calibrate their teletherapy units annually.

3. In the past few days NRC issued an order modifying hospital licenses to require special testing of certain radiopharmaceuticals before they are administered to patients.



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Copies of these actions are enclosed for your information.

Drs. Agarwal and Keats are concerned about the training of users and, in particular, technologists. Before issuing a license, NRC reviews the training and experience of the physician and the training and experience of the radiation safety officer. Physicians are allowed to delegate certain tasks to technologists and nurses but the physicians are responsible for those delegated tasks. Thus, under NRC licensing procedure, the physicians are responsible for evaluating the training and experience of their technologists and nurses.

On March 13, 1979, BRH/FDA published a Federal Register notice of intent to develop recommendations on voluntary standards for qualifications of medical radiation technologists. A copy of the notice is enclosed for your information. The initial recommendations will address the qualifications of medical diagnostic x-ray personnel. Subsequent recommendations will address qualifications for radiation therapy and nuclear medicine technologists. NRC plans to cooperate with BRH/FDA in their efforts to develop standards for technologists' qualifications.

Regarding the editorial's final point about the relative emphasis within the Federal sector between the regulation of nuclear power and the regulation of medical radiation, for many reasons Federal attention is focussing on the regulation of the medical uses of ionizing radiation and, in particular, on the radiation safety of the patient. On February 27, 1979, the Secretary of the Department of Health, Education and Welfare issued a draft report from an "Interagency Task Force on Ionizing Radiation" which recommends, among other things, "... improving the availability, training, and credentialing of personnel who administer radiation-related procedures...". At the Federal level the emphasis on regulating medical radiation is certain to increase in the future.

Thank you again for sending the editorial. I trust that I have been responsive to your request by conveying the essentials of NRC's concerns and actions in regulating the medical uses of radioisotopes.

Sincerely,

cc: John C. Villforth

Enclosures:
1. NRC Medical Policy Statement
2. Patient Radiation Survey Rule
3. Teletherapy Calibration Rule
4. Order to Medical Licensees
5. BRH/FDA Notice of Intent

[7590-01-M]

Title 10—Energy

CHAPTER I—NUCLEAR REGULATORY COMMISSION

PART 10—HUMAN USES OF BYPRODUCT MATERIALS

**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 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

[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.



ENCLOSURE 1

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.[2] 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.

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

The NAS-BEIR[3] 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]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.

## Title 10—Energy

## CHAPTER I—NUCLEAR REGULATORY COMMISSION

## PART 35—HUMAN USES OF BYPRODUCT MATERIAL

### Radiation Surveys of Therapy Patients

AGENCY: U.S. Nuclear Regulatory Commission (NRC).

ACTION: Final rule.

SUMMARY: Certain NRC licensees are authorized to treat patients with temporary implants incorporating radioactive material. NRC will require such licensees to confirm the removal of the implants at the end of the treatment by (1) a source count and (2) a radiation survey of the patient. Failure to account for all implants at the conclusion of patient treatment has resulted in some instances of unnecessary radiation exposure to patients and members of the general public.

EFFECTIVE DATE: The amendment becomes effective on December 28, 1978.

FOR FURTHER INFORMATION CONTACT:

Edward Podolak, Office of Standards Development, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (Phone: 301-443-5966).

SUPPLEMENTARY INFORMATION: NRC regulations in § 35.14(b)(5)(vii) require Group VI licensees [1] to assure that patients treated with cobalt-60, cesium-137 or iridium-192 temporary implants remain hospitalized until the implants have been removed. The primary method for confirming that all sources have been removed is to count the sources implanted and count the sources removed. The source counting has not always been performed accurately, or on a timely basis.

Some patients have been discharged from the hospital with radioactive sources still implanted. (It is particularly difficult to count iridium-192 seeds, which sometimes become dislodged from their encasement in nylon ribbon). Because a backup radiation survey of the patient could have prevented these incidents, on June 28, 1978 NRC published a proposed rule in the FEDERAL REGISTER adding a requirement for source counting and patient radiation surveys to the existing § 35.14(b)(5)(vii) which prohibits Group VI licensees from discharging patients until all sources are removed. The comment period ended August 14, 1978.

Twenty-one comments were received. Eleven favored the proposal without qualification. Three commenters suggested that bulky afterloaded devices that protrude from the body be exempted from the radiation survey. One commenter suggested that an x-ray be permitted as an alternative to the radiation survey. One commenter asked what was meant by "the end of the treatment" and one commenter, while favoring the proposal, suggested that the radiation survey should be performed within one hour of source removal. Four commenters objected to the proposal because they believe that regulations that define what is already good medical practice are useless. One commenter objected to the proposal because he believes that there are some cases where it would be impossible to survey the patient before discharge.

The wording of the final rule is the same as the proposed and requires a radiation survey of the patient before discharge. The radiation survey is the most positive (active) method of verifying source removal. The x-ray is a passive method. Although good practice would suggest a radiation survey soon after source removal, the regulation has to recognize the realities of the clinical setting where other tasks may have higher priority. Placing a tight time limit on this essentially quality control function may interfere with patient care. However, it is extremely unlikely that the licensee will experience difficulty performing the survey between source removal and discharge of the patient.

The suggestion to exempt afterloaded devices is well made. The devices are bulky relative to the actual source size and it is difficult to imagine that patients would be discharged with these devices in-place. However, NRC inspectors, who are familiar with incidents of overexposure from implants remaining in patients, say that this is an area where the "impossible" happens in spite of great care and precautions. Also, NRC inspectors have investigated an incident where a patient was discharged with an afterloaded device in-place with the sources loaded. The radiation survey is simple and inexpensive and it will also detect any sources lost in the bedclothes or room where the survey is performed. Therefore, the afterloaded devices will not be exempted from the requirements for a radiation survey.

Finally, regulations that define what is generally considered good practice may seem useless or may even dismay conscientious licensees. However, this is insufficient reason to forgo these regulations when there is evidence that the good practices are not universal.

Under the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended and sections 552 and 553 of title 5 of the United States Code, notice is hereby given that the following amendment to 10 CFR Part 35 is published as a document subject to codification.

In 10 CFR Part 35, § 35.14(b)(5)(vii) is amended to read as follows:

**§ 35.14 Specific licenses for certain groups of medical uses of byproduct material.**

* * * * *

(b) Any licensee who is authorized to use byproduct material pursuant to one or more groups in §§ 35.14(a) and 35.100 is subject to the following conditions:

* * * * *

(5) For Group VI any licensee who possesses and uses sources or devices containing byproduct material shall:

* * * * *

(vii) Assure that patients treated with cobalt-60, cesium-137 or iridium-192 implants remain hospitalized until a source count and a radiation survey of the patient confirm that all implants have been removed.

* * * * *

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); Sec. 201, Pub. L. 93-438, 88 Stat. 1243 (42 U.S.C. 5841).)

Dated at Bethesda, Maryland this 14th day of November 1978.

For the Nuclear Regulatory Commission.

LEE V. GOSSICK,
*Executive Director for Operations.*

[FR Doc. 78-33229 Filed 11-27-78; 8:45 am]

[1] The most common types of NRC specific licenses for the medical use of byproduct material are the *Group* medical licenses under § 35.14 that apply to those radioactive materials listed in § 35.100. The radioactive materials listed 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. Groups I, II, and III are lists of radiopharmaceuticals for diagnostic procedures; Groups IV and V are lists of radiopharmaceuticals for therapeutic procedures; and Group VI is a list of radioactive medical devices for both diagnostic and therapeutic procedures.



ENCLOSURE 2

7590-01-M]

## Title 10—Energy

## CHAPTER I—NUCLEAR REGULATORY COMMISSION

## PART 35—HUMAN USES OF BYPRODUCT MATERIAL

### Calibration of Teletherapy Units

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Final rule.

SUMMARY: The Nuclear Regulatory Commission (NRC) is amending its regulations to require medical licensees to (1) calibrate each teletherapy unit annually and (2) perform monthly spot checks on those calibrations. The annual full calibrations must be performed by a qualified expert. The monthly spot checks need not be performed by a qualified expert but the results of the spot checks must be reviewed by a qualified expert on a timely basis.

The amendments will help ensure that a patient receives the prescribed radiation dose by requiring that teletherapy units are properly calibrated.

EFFECTIVE DATE: The amendments become effective on July 9, 1979. Any full calibrations performed in accordance with the procedures in this amendment during the 365 days prior to the effective date of this amendment will count as the first full calibration.

NOTE--The Nuclear Regulatory Commission has submitted this rule to the Comptroller General for review under the Federal Reports Act, as amended, 44 U.S.C. 3512. The date on which the rule becomes effective, unless advised to the contrary, accordingly reflects inclusion of the 45-day period which that statute allows for this review (44 U.S.C. 3512(c)(2)).

FOR FURTHER INFORMATION CONTACT:

Mrs. Patricia C. Vacca, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555 (301-427-4232).

SUPPLEMENTARY INFORMATION: In May 19, 1977, the NRC published in the FEDERAL REGISTER (42 FR 26743) proposed amendments to its regulations pertaining to the human uses of byproduct materials including teletherapy units. The proposed amendments to § 35.13 would have required teletherapy licensees to:

1. Have a qualified expert perform all calibration measurements at least once each year;

2. Perform spot-check measurements on their teletherapy units at least monthly; and

3. Report to NRC if these measurements indicate that patients treated by teletherapy units received a radiation dose differing from the prescribed dose by more than 10 percent.

The public was invited to submit written comments and suggestions on the proposed amendments. The comment period, originally set to close on July 5, 1977, was extended to July 29, 1977.

### I. COMMENTS ON PROPOSED RULE

Fifty-nine comments were received. Copies of the comments and a detailed analysis of the comments may be examined in the NRC Public Document Room at 1717 H Street, NW., Washington, D.C. Approximately one-half of the commenters supported the proposed rule. Of the remainder, approximately one-half disapproved of the proposed rule and the other half were non committal. Virtually all of the commenters offered helpful suggestions, most of which were accommodated as detailed in Section II below, *"Summary of Major Changes in the Final Rule"*.

Most of the commenters who disapproved of the proposed rule questioned either the need for a rule or whether NRC was the appropriate federal agency to require calibrations of teletherapy units.

The Commission agrees with those commenters who pointed out that the Riverside Hospital incident involving 400 patients was an isolated case and that NRC's efforts to alert other licensees and check on their calibrations were successful. However, the Commission believes that the Riverside incident evidences the magnitude of the harm which could be caused by a single uncalibrated teletherapy unit. The purpose of this rule is to ensure that teletherapy units remain properly calibrated throughout their useful lives.

Those commenters who questioned whether NRC was the appropriate agency to require calibration of teletherapy units, pointed to potential conflicts with the Food and Drug Administration's (FDA) new authority under the Medical Device Amendments of 1976. Through the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974, as amended, NRC has direct regulatory control over the human use of byproduct material in teletherapy units. NRC is the only Federal Agency with *direct* regulatory control over the *use* of byproduct material and, as such, is certainly an appropriate agency to require calibration of NRC regulated teletherapy units. NRC is aware that its responsibilities and those of FDA do overlap in the area of medical devices. NRC and FDA staff members have met on several occasions to coordinate the responsibilities of the two agencies. It appears that it will be some time before the FDA has standards or guidelines in place for teletherapy calibration. As they are developed, NRC will work closely with FDA to minimize overlapping regulation by the two agencies.

One commenter suggested that licensees be required to participate in calibration check programs such as those sponsored by FDA or the National Bureau of Standards. The Commission encourages teletherapy licensees to participate in voluntary calibration check programs but will not require it.

Several commenters did not understand that a qualified expert need not actually perform the spot-check measurements. The final rule states clearly that the qualified expert need not actually perform the spot check, but the results of the measurements must be reviewed by a qualified expert within 15 days.

There were numerous comments on the section of the proposed rule that would have required reporting to NRC, and to the patient's referring physician, certain misadministrations involving teletherapy units. The misadministration reporting requirement in the proposed teletherapy calibration rule has been deleted from the final rule. All comments received on this subject will be considered as comments on the more comprehensive proposed misadministration reporting requirement that was published in the FEDERAL REGISTER on July 7, 1978 (43 FR 29297), for public comment.

### II. SUMMARY OF MAJOR CHANGES IN THE FINAL RULE

NRC has decided to issue the final rule by adding §§ 35.21-35.25, inclusive, to 10 CFR Part 35, rather than amending § 35.13 as proposed. This change will make the final rule easier to read and understand. It will also be clear that the rule pertains only to teletherapy units and not to other sealed sources.

As discussed in Section I above, the misadministration reporting requirement of the proposed rule has been deleted.

Section 35.21 on full calibration has been expanded to require full calibration following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly and prior to treating humans. In § 35.21 the term "significant change," which related to the spot-check measurement and will trigger a recalibration, now reads "output differs by more than 5 percent." Section 35.21 now includes a performance standard of "to an accuracy within ± 3 percent" for the calibration of teletherapy output. Finally, § 35.21 now



ENCLOSURE 3

includes a requirement to correct the calibration of teletherapy output for physical decay at intervals not to exceed one month.

Under the effective rule, the licensee generally will not have to submit the training and experience of the qualified expert to NRC for evaluation. Rather, § 35.24 requires the licensee to determine, pursuant to the provisions of that section, if a person is an expert qualified by training and experience to calibrate teletherapy units. The licensee will then keep records of that evaluation of the expert's training and experience for inspection by NRC.

A new requirement has been added to ensure that dosimetry systems used to calibrate the teletherapy units are also properly calibrated. Section 35.23 requires that the dosimetry system used for full calibrations has itself been calibrated by the National Bureau of Standards (NBS) or by one of three Regional Calibration Laboratories (RCL), who in their turn are directly "traceable" to NBS. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system calibrated by NBS or one of the RCLs.

## III. Final Rule

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974, as amended, and Sections 552 and 553 of Title 5 of the United States Code, the following amendments to Title 10, Chapter I, Code of Federal Regulations, Part 35, are published as a document subject to codification.

10 CFR Part 35 is amended by adding a new center heading and new §§ 35.21-35.25, as follows:

### Special Requirements for Teletherapy Licensees

**§ 35.21 Requirement to perform full calibration measurements of teletherapy units.**

(a) Any licensee authorized under § 35.13 to use teletherapy units for treating humans shall cause full calibration measurements to be performed on each teletherapy unit:

(1) Prior to the first use of the unit for treating humans;

(2) Prior to treating humans:

(i) Whenever spot-check measurements indicate that the output value differs by more than 5 percent from the value obtained at the last full calibration corrected mathematically for physical decay;

(ii) Following replacement of the radiation source or following reinstallation of the teletherapy unit in a new location;

(iii) Following any repair of the teletherapy unit that includes removal of the source or major repair of the components associated with the source exposure assembly; and

(3) At intervals not exceeding one year.

(b) Full calibration measurements required by paragraph (a) of this section shall include determination of:

(1) The exposure rate or dose rate to an accuracy within ±3 percent for the range of field sizes and for the range of distances (or for the axis distance) used in radiation therapy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

(3) The uniformity of the radiation field and its dependence upon the orientation of the useful beam;

(4) Timer accuracy; and

(5) The accuracy of all distance measuring devices used for treating humans.

(c) Full calibration measurements shall be made in accordance with the procedures recommended by the Scientific Committee on Radiation Dosimetry of the American Association of Physicists in Medicine (*Physics in Medicine and Biology*, Vol. 16, No. 3, 1971, pp. 379-396).[1]

(d) The exposure rate or dose rate values determined in paragraph (b)(1) of this section shall be corrected mathematically for physical decay for intervals not exceeding one month.

(e) Full calibration measurements required by paragraph (a) of this section and physical decay corrections required by paragraph (d) of this section shall be performed by an expert qualified by training and experience in accordance with § 35.24.

**§ 35.22 Requirement to perform periodic spot-check measurements of teletherapy units.**

(a) Any licensee authorized under § 35.13 to use teletherapy units for treating humans shall cause spot-check measurements to be performed on each teletherapy unit at intervals not exceeding one month.

(b) Spot-check measurements required by paragraph (a) of this section shall include determination of:

(1) Timer accuracy;

(2) The congruence between the radiation field and the field indicated by the light beam localizing device;

(3) The accuracy of all distance measuring devices used for treating humans;

(4) The exposure rate, dose rate, or a quantity related in a known manner to these rates for one typical set of operating conditions; and

(5) The difference between the measurement made in paragraph (b)(4) of this section and the anticipated output, expressed as a percentage of the anticipated output (i.e., the value obtained at last full calibration corrected mathematically for physical decay).

(c) Spot-check measurements required by paragraph (a) of this section shall be performed in accordance with procedures established by an expert qualified by training and experience in accordance with § 35.24. (A qualified expert need not actually perform the spot-check measurements.) If a qualified expert does not perform the spot-check measurements, the results of the spot-check measurements shall be reviewed by a qualified expert within 15 days.

**§ 35.23 Requirement to calibrate instruments used for full calibration and spot-check measurements.**

(a) Full calibration measurements required by § 35.21 shall be performed using a dosimetry system that has been calibrated by the National Bureau of Standards or by a Regional Calibration Laboratory accredited by the American Association of Physicists in Medicine. The dosimetry system shall have been calibrated within the previous two years and after any servicing that may have affected system calibration.

(b) Spot-check measurements required by § 35.22 shall be performed using a dosimetry system that has been calibrated in accordance with paragraph (a) of this section. Alternatively, a dosimetry system used solely for spot-check measurements may be calibrated by direct intercomparison with a system that has been calibrated in accordance with paragraph (a) of this section. This alternative calibration method shall have been performed within the previous one year and after each servicing that may have affected system calibration. Dosimetry systems calibrated by this alternative method shall not be used for full calibration measurements.

**§ 35.24 Qualified expert.**

The licensee shall determine if a person is an expert qualified by training and experience to calibrate a teletherapy unit and establish procedures for (and review the results of) spot-check measurements. The licensee shall determine that the qualified expert:

(a) Is certified by the American Board of Radiology in Therapeutic Radiological Physics, Radiological

[1] This incorporation by reference provision was approved by the Acting Director of the Federal Register on August 6, 1976. Copies are available for inspection or may be obtained from U.S. Nuclear Regulatory Commission, Public Document Room, 1717 H Street, NW., Washington, D.C. 20555.

Physics, Roentgen-Ray and Gamma-Ray Physics, or X-ray and Radium Physics; or

(b) Has the following[1] minimum training and experience:

(1) A Master's or Doctor's degree in physics, biophysics, radiological physics or health physics;

(2) One year of full-time training in therapeutic radiological physics; and

(3) One year of full-time experience in a radiotherapy facility including personal calibration and spot check of at least one teletherapy unit.

§ 35.25 Records.

The licensee shall maintain, for inspection by the Commission, records of the measurements, tests, corrective actions, and instrument calibrations made under §§ 35.21-35.23 and records of the licensee's evaluation of the qualified expert's training and experience made under § 35.24.

(a) Records of (1) full calibration measurements under § 35.21 and (2) calibration of the instruments used to make these measurements under § 35.23, shall be preserved for five years after completion of the full calibration.

(b) Records of (1) spot-check measurements and corrective actions under § 35.22 and (2) calibration of instruments used to make spot-check measurements under § 35.23, shall be preserved for two years after completion of the spot-check measurements and corrective actions.

(c) Records of the licensee's evaluation of the qualified expert's training and experience under § 35.24 shall be preserved for five years after the qualified expert's last performance of a full calibration on the licensee's teletherapy unit.

(Sec. 161, Pub. L. 83-703, 68 Stat. 948 (42 U.S.C. 2201); sec. 201, Pub. L. 93-438, 88 Stat. 1243 (42 U.S.C. 5841))

Dated at Washington, D.C., this 29th day of December, 1978.

For the Nuclear Regulatory Commission.

SAMUEL J. CHILK,
*Secretary of the Commission.*

[FR Doc. 79-532 Filed 1-5-79; 8:45 am]

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[1] Licensees that have their teletherapy units calibrated by persons who do not meet these criteria for minimum training and experience may request a license amendment excepting them from the requirements of § 35.24. The request, accompanied by the appropriate amendment fee (§ 170.31 of 10 CFR Part 170), should include the name of the proposed qualified expert, a description of his training and experience including information similar to that specified in § 35.24(b), reports of at least one calibration and spot-check program based on measurements personally made by the proposed expert within the last 10 years, and written endorsement of the technical qualifications of the proposed expert from personal knowledge by a physicist certified by the American Board of Radiology in one of the specialities listed in § 35.24(a). The individual's qualifications will be evaluated by NRC's consultants in medical physics. The amendment request should be addressed to: License Management Branch, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.