COMMISSION NOTICES
POLICY STATEMENTS

MEDICAL USES

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. 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 requirements that are justified by the risk to patients and where voluntary standards, or compliance with these standards, is 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 by a license issued by the State, and their applicable training and experience were evaluated in consultation with the Atomic Energy 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 1978, 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. In consultation with the States, AEC included production of the radioisotope, manufacture of the radioactive drug or device, distribution, use and disposal of the products. In 1978, the FDA renewed its 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 safety of the workers and the public.

The 1978 Medical Device Amendments to the Food, Drug, and Cosmetic Act extended FDA's authority over medical devices (including devices containing radioisotopes) 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 licenses to applicants seeking to use byproduct material for medical therapy. Section 81 directs NRC...
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FDA's activities are in harmony with regulation by the Department of Transportation, Social Security Administration, or the Commission on Accreditation of Hospitals and associated organizations. Some states have Occupational Safety and Health Administration regulation of the workplace 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 use of materials that the Joint Commission or any state laws, or local regulations of the Commission or any state. The Commission has the authority to regulate the radiation safety of medical procedures.

The NAS-BEIR report discusses the limitations of the population to medical applications of ionizing radiation. The report states that the use of radiopharmaceuticals for 1 mrem/year and an average dose rate from diagnostic radiology is to 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 be in the use of medical procedures. This is particularly essential to reduce exposures since this can be accomplished without loss of benefit and with relatively low cost. The idea 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 improvement in medical benefits accompanied by a minimum radiation exposure.

NRC will act to ensure that radiation exposure is as low as is reasonably achievable, consistent with competent medical care and with minimal impact into medical judgments. NRC will not exercise regulatory control in the areas where, upon careful consideration, it determines that there are adequate regulations by other Federal or State agencies or well administered professional standards. Moreover, 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 believes that decisions concerning the diagnosis and treatment of disease are a part of the practice of medicine. The 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 strive to find a balance between adequate controls and avoidance of undue interference in medical judgment. The cooperation 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 lightest regulation of physicians' decisions by Federal, State, and professional groups will not be able to prevent mistakes, and the consequences may be serious. The regulations are not as severe as those in the medical use of radiotopes.

The Commission recognizes that FDA regulates the diagnostic use of radioactive materials and the interstate distribution of drugs. Including those that are radioactive, FDA also regulates the standards for research use of drugs as well as the specific guidance on doses and procedures found in the product label. However, FDA does not have the authority to restrict the routine use of drugs to procedures described in the product label. The 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 hazards to the public.

The Commission believes that the diagnostic use of radioactive drugs is, in many cases, clearly a necessary element of a medical practice. 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 radiopharmaceuticals. For all diagnostic uses of radioactive drugs, and in certain diagnostic uses—such as the eye—the use of potassium-32 for visualization 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 use of therapeutic and certain diagnostic radioactive drugs to the indicated procedures that have been approved by FDA. The NRC will not control the physician's practices on patient selection and instrument selection for therapy procedures, because these procedures are specialized and patient specific.

Congress recently gave FDA authority to regulate medical use of NRC's authority to regulate drugs, but with additional authority to restrict the routine use of medical de-
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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.

III. DISCUSSION OF PUBLIC COMMENTS

A. COMMENTS ON THE POLICY STATEMENT

One commenter opposed the use of the general word "radiosotope" in the first part of the policy statement. This commenter was concerned that, in 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. That term is properly footnoted in the policy statement to include the more cumbersome but specific terms: (1) byproduct, source, and special nuclear material and to exclude naturally occurring and accelerator-produced radioisotopes.

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. This commenter further reasoned that NRC should not be involved in protecting the health and safety of the public.

This commenter believed that patient dosimetry is a responsibility of the individual institution and not NRC. This commenter also stated that NRC should not regulate a radiopharmacy, and that such a regulation would be 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 that they should be offered a definition of radiological physicist.

One commenter opposed 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 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 states: Indeed, radiation 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 the case where because NRC regulates, among other things, receipt, possession, 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 misadministra-
tion of radioactive material. Three commenters opposed any misadministra-
tion reporting and three commenters offered suggestions on how they should be reported. All of the comments will be considered in drafting NRC's new proposed misadminis-
tration reporting requirement that was published in the FEDERAL REGISTER for public comment on July 7, 1978 (43 FR 29371).

There were six comments on the specific issue of radiopharmaceuticals. 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.

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

September 29, 1995