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SECY-R 621

POLICY SESSION ITEM

SUMMARY SHEET

Subject: PROPOSED AMENDMENTS TO 10 CFR PART 35: USER AND REPORTING REQUIREMENTS FOR MEDICAL USES OF BYPRODUCT MATERIALS

Purpose: To seek Commission approval of proposed amendments to 10 CFR Part 35 which would specify certain responsibilities of physicians and allow certain delegations to paramedical personnel, require appropriate training of paramedical personnel, and require reporting to the Commission and to the patient or his family of misadministrations of byproduct material.

Discussion: The proposed amendments would implement recommendations made by the General Accounting Office that AEC (1) define the activities that may be delegated by physicians and those that may not, (2) require physicians to determine that technicians have been properly trained, and (3) require medical licensees to report to AEC misadministrations of radioactive material to patients. The proposed requirement for notifying patients or their families of misadministrations was recommended by the Advisory Committee on the Medical Uses of Isotopes. It is probable that the proposed requirement for notifying the patient or his family of misadministrations which could adversely affect the patient will result in reaction and comments from members of the medical profession with respect to their feeling that it is an unnecessary and inappropriate governmental interference in a professional ethical matter.

Issue: The Commission agreed (Policy Session Item SECY-R 462,* May 18, 1972) to implement items 1 and 2 of the above GAO recommendations. The issues remaining to be resolved are whether to require reporting to the Commission and to patients or their families of misadministrations of byproduct material.

Recommendations: The Commission

(a) approve publication in the Federal Register of proposed amendments to 10 CFR Part 35 which would (1)

*SECY-R 462 - "Proposed Letter to the Honorable Elmer B. Staats, Comptroller General, Commenting on Draft GAO Report"

specify certain responsibilities of physicians authorized to use byproduct materials in humans, (2) specify certain acitivities that may be delegated by physicians to paramedical personnel, (3) require appropriate training of paramedical personnel, (4) require reporting to the Commission of misadministrations of byproduct material, and (5) require notification to the patient or his family of misadministrations that could adversely affect the patient unless in the physician's professional judgment such notification would be adverse to the best interests of the patient or a surviving relative.

(b) note:

1. the proposed amendments will be published in the Federal Register for a 45-day comment period;

2. if no significant adverse comments or significant questions are received and no substantial changes in the rule are indicated after the public comment period, the Director of Regulation will arrange for publication of the amendments in final form (Commissioner Doub will be informed of all comments received); if significant adverse comments or significant questions are received or substantial changes in the text of the rule are indicated, the revised amendment will be submitted to the Commission for approval;

3. the JCAE will be informed;

4. a public announcement will be issued;

5. an environmental statement need not be prepared.

Coordination: The Office of General Counsel (Assistant General Counsel for Licensing and Regulation) has no legal objection. The Division of Applied Technology has no objections. The Divisions of Biomedical and Environmental Research, Naval Reactors and Operational Safety concur.

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ATOMIC ENERGY COMMISSION

PROPOSED AMENDMENTS TO 10 CFR PART 35: USER AND REPORTING REQUIREMENTS FOR MEDICAL USES OF BYPRODUCT MATERIALS

Report to the Director of Regulation by the Director of Licensing

THE PROBLEM

1. To consider proposed implementation of recommendations made by the General Accounting Office and related additional requirements on regulating the medical uses of radioactive materials by amending 10 CFR Part 35, "Human Uses of Byproduct Material." The proposed amendments would (1) specify certain responsibilities of physicians authorized to use byproduct materials for human uses, (2) specify certain activities that may be delegated by physicians to technicians and other paramedical personnel, (3) require physicians to determine that technicians and other paramedical personnel are properly trained to perform such activities, (4) require reporting to the Commission of misadministrations of byproduct materials or radiation therefrom, and (5) require notification to the patient or his family of misadministrations which could adversely affect the patient.

BACKGROUND AND SUMMARY

2. As part of a review of the Commission's regulatory program, the General Accounting Office has reviewed certain matters related to the efficiency and effectiveness of AEC's inspection and enforcement programs for materials licenses. GAO furnished to the regulatory staff a draft report to the Congress on this review. The report was issued in final form on August 18, 1972.

3. On May 23, 1972, the Director of Regulation sent a letter to the Honorable Elmer B. Staats, Comptroller General, commenting on the recommendations made by GAO in their draft report. This letter had been approved by the Commission as Policy Session Item SECY-R 462* on May 18, 1972. We have

*SECY-R 462 - "Proposed Letter to the Honorable Elmer B. Staats, Comptroller General, Commenting on Draft GAO Report".

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had informal discussions with the GAO staff on the proposed approach for implementing the GAO recommendations. It is our understanding from these discussions that the amendments to 10 CFR Part 35 proposed herein will be consistent with the recommendations covered in their report.

4. In chapter 3 of the report dealing with medical uses of radioactive materials, GAO recommended that AEC:

-- Define in its medical licenses or regulations the activities that may be delegated by physicians and those that may not.

-- Require that physicians determine whether technicians have been properly trained to perform their duties and keep records showing the bases for such determinations.

-- Establish a specific requirement that suppliers verify that transferees are authorized to receive the quantity or type of material being shipped and provide guidance as to acceptable methods of verification. (While this recommendation was made by GAO because of its medical uses connotation, its implementation will involve other categories of licensees, especially commercial suppliers. This recommendation is the subject of a separate staff paper : SECY-R-571.)*

-- Require medical licensees to report to AEC all known misadministrations of radioactive material to patients so that AEC can determine the causes and whether adequate corrective actions were taken by the licensee.

5. The GAO report stated "Under AEC's interpretation of current regulations, medical licensees are not required to report the accidental overexposures of patients to radiation during intentional exposures for medical diagnoses or therapy when such exposures are attributed exclusively to the actions of physicians or to those acting under their orders." The basis for not requiring reports of such accidental overexposures is the language of 10 CFR 20.107 which states that "Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy." Although

*SECY-R 571 - "Proposed Amendments to 10 CFR Parts 30, 40, and 70 - Transfer of Radioactive Material.

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such reports have not been required no statistics on the extent of misadministrations are available. Twelve instances of misadministrations of radiopharmaceuticals involving a total of 20 patients have been brought to AEC's attention from February 1961 through April 1972.

6. GAO noted that while the Commission's licensing practices require physicians who use isotopes to have formal training and experience in the use, handling and administration of these materials, they do not provide minimum qualification standards for technicians who assist physicians, since the Commission considers physicians responsible for ensuring that technicians assisting them are adequately trained to perform their assigned tasks. A number of the misadministrations of isotopes to patients which GAO reviewed involved technicians and other paramedical personnel making mistakes in the ordering and preparation of radiopharmaceuticals and the apparent inadequate training and supervision of these technicians.

7. The staff has developed, with the assistance of the Advisory Committee on the Medical Uses of Isotopes, a list of responsibilities which may not be delegated by authorized physician users of radioisotopes - except to other physicians who are under the supervision of authorized physicians - and a list of activities which may be delegated by physicians to paramedical assistants. The responsibilities which must be retained and activities which must be performed by physicians involve decisions on individual cases which require the exercise of medical judgement. The activities which may be delegated to paramedical assistants are those which are performed using established procedures and techniques but which do not require the making of decisions involving medical judgement on individual cases. Paragraphs (a), (b) and (c) of the proposed new § 35.32 of 10 CFR 35 would codify these non-delegable responsibilities and permissible delegations in the Commission's regulations.

8. Paragraph (d) of § 35.32 would require physicians to determine that paramedical personnel are properly trained to perform their duties and to record the bases for such determinations and paragraph (f) would require

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licensees describe in their applications their proposed program for training and for determining the qualifications of such personnel. The subjects which shall be included in such training would be listed in § 35.32(d)(1). Subsection 35.32 (d)(2) would require appropriate retraining for maintenance of proficiency and to keep abreast of developments in the field of nuclear medical technology. Section 35.32(e) would provide that certification in nuclear medical technology by either the American Registry of Radiologic Technologists or the Registry of Medical Technologists will be deemed to satisfy the training requirements.

9. The scope and complexity of activities which physicians authorize paramedical personnel to perform vary widely from licensee to licensee and, therefore, it is not practicable or reasonable to specify in regulations the minimum amount of training which should be required for such personnel. If minimum quantitative standards for training were prescribed in the regulations, they might be used to weaken the stature of the extensive technician training and certification programs which have been developed by the American Registry of Radiologic Technologists and the Registry of Medical Technologists in cooperation with the American College of Radiology, the American Society of Clinical Pathologists and the Society of Nuclear Medicine. On the other hand, while certification by these registries is acceptable evidence of adequate training, it would not be reasonable to require paramedical personnel who only assist physicians with simple manipulations or in programs of limited scope to be fully trained and certified technologists. The listing in § 35.32(d)(1) of subjects to be included in technician training would follow the precedent set in 10 CFR Part 34 for regulating the training of industrial radiographers. While this listing is not a quantitative requirement, it would provide physicians with an outline of the subject matter to be covered to qualify their assistants to perform their duties and would aid physicians in describing in their applications, their program for training technicians. Furthermore, it would provide a basis for the Directorate of Regulatory Operations to review the training and qualifications of paramedical personnel as part of inspections or incident investigations of medical licensees.

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10. With respect to requiring medical licensees to report misadministrations of radioactive materials, the May 23, 1972, letter to the Comptroller General stated that this recommendation would be reviewed with the Advisory Committee on the Medical Uses of Isotopes with regard to accepted medical ethics of the physician-patient relationship and the possible consequences of a government agency interjecting itself into this relationship. In a memorandum dated June 13, 1972 to Commissioners Ramey, Johnson and Doub, (re SECY-R 460) the Director of Regulation indicated a plan to include in the scope of the study of GAO's recommendation on the reportability of misadministrations of radioactive materials, the policy questions of whether investigation findings and conclusions should be put in the Public Document Room and whether the licensee should be required to inform the patient or the patient's family of significant misadministrations.

11. A special meeting of the Advisory Committee on the Medical Uses of Isotopes was held on June 25, 1972, to study this GAO recommendation and the related considerations of misadministrations. The consensus of the Committee was:

a. Regulations should require licensees to report to the Commission all misadministrations of radiopharmaceuticals or radiation from teletherapy and brachytherapy sources. Misadministration would be defined to include administration of (1) a radiopharmaceutical, or radiation from a source, other than the one intended, (2) a radiopharmaceutical or radiation to the wrong patient, or (3) a dose of a radiopharmaceutical or exposure to a radiation source outside of the intended dose range prescribed by the physician or by a route of administration other than intended by the physician.

b. A physician has an ethical responsibility to inform the patient or his family about a misadministration which could adversely affect the patient, unless in the physician's professional judgment it would be contrary to the best interests of the patient to do so. It would not be appropriate for the Commission to inform the patient or his

family of such misadministrations since this would interfere with th normal physician-patient relationship, but it would be appropr for the Commission to assure that the physician carries out s responsibility described above by making it a regulatory requirement.

c. The physician-patient privilege is solely for the protection of the patient. If the patient's identity and other details necessary to protect the patient from unwarranted invasion of privacy are deleted, the Committee foresaw no reason why reports of misadministrations and related correspondence with licensees should not be available to the public.

12. The new § 35.33 would add a requirement for licensees to report to the Commission any misadministration of byproduct materials or radiation therefrom and to notify the patient or a responsible relative of the patient of any misadministration which could cause a demonstrable adverse effect on the patient unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient. These proposed requirements were not included in the GAO recommendations. Rather they are based on the response of the Advisory Committee on Medical Uses of Isotopes to the question raised by the Director of Regulation (see paragraphs 10 and 11b. above).

13. The new § 35.33 would also require that if the misadministration could cause a demonstrable adverse effect on the patient, the licensee's report to the Commission shall either confirm that notification has been made to the patient or to a responsible relative of the patient or shall state that such notification was not given because in the physician's judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient. If the patient or relative is not notified, the physician shall confirm that this decision was reviewed by a local Ethics Committee or an equivalent group of peers and shall state whether or not the committee or group concurred with the decision. The decision not to notify the patient or family would be part of the public record on the reported misadministration.

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14. Although the proposed requirement for notifying patients or responsible relatives of misadministrations was recommended by the Advisory Committee on Medical Uses of Isotopes (composed primarily of physicians, including the then president and several trustees of the Society of Nuclear Medicine), if this proposed requirement is published in the Federal Register for comment, it is probable that members of the medical profession will submit considerable comments and reactions with respect to their feelings that this is an unnecessary and inappropriate governmental interference in a professional matter.

STAFF JUDGMENTS

15. The Directorates of Regulatory Standards and Regulatory Operations and the Divisions of Biomedical and Environmental Research, Naval Reactors and Operational Safety concur in the recommendations of this paper. The Office of the General Counsel has no legal objection and the Division of Applied Technology has no objection. The Office of Information Services prepared the draft public announcement. The Office of Congressional Relations concurs in the draft letter to the Joint Committee on Atomic Energy.

RECOMMENDATIONS

16. The Director of Regulation recommends that the Atomic Energy Commission:

a. Approve publication in the Federal Register of proposed amendments to 10 CFR Part 35 which would: (1) specify certain responsibilities of physicians authorized to use byproduct materials for human uses, (2) specify certain activities that may be delegated by physicians to technicians and other paramedical personnel, (3) require physicians to determine that technicians and other paramedical personnel are properly trained to perform such activities, (4) require reporting to the Commission of misadministrations of byproduct materials or radiation therefrom, and (5) require notification to the patient or a responsible relative of the patient of misadministrations which could adversely affect the patient unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or a surviving relative.

b. Note that the notice of proposed rule making in Appendix "A" will be published in the Federal Register, allowing 45 days for public comment;

c. Note that, if after expiration of the comment period no significant adverse comments or significant questions have been received and no substantial changes in the text of the rule are indicated, the Director of Regulation will arrange for publication of the amendment in final form. If significant adverse comments or significant questions have been received or substantial changes in the text of the rule are indicated, the revised amendment will be submitted to the Commission for approval;

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d. Note that the Joint Committee on Atomic Energy will be informed of these actions by a letter such as Appendix "B";

e. Note that a public announcement such as Appendix "C" will be issued on filing of the notice of proposed rule making with the Office of the Federal Register,

f. Note that an environmental impact statement need not be prepared in connection with this rule making action since the proposed amendments of 10 CFR Part 35 will not significantly affect the quality of the human environment.

LIST OF ENCLOSURES

APPENDIX "A"

ATOMIC ENERGY COMMISSION

[10 CFR PART 35]

HUMAN USES OF BYPRODUCT MATERIAL

User and Reporting Requirements

The Atomic Energy Commission has under consideration amendments to its regulations in 10 CFR Part 35, "Human Uses of Byproduct Material," to 1) specify certain responsibilities of physicians authorized to use byproduct materials for human uses, 2) specify certain activities that may be delegated by physicians to technicians and other paramedical personnel, 3) require physicians to determine that technicians and other paramedical personnel are properly trained to perform such activities, 4) require reporting to the Commission of misadministrations of byproduct materials or radiation therefrom, and 5) require notification to the patient or a responsible relative of the patient of the misadministration of byproduct materials or radiation therefrom which could adversely affect the patient.

In its licensing of the medical uses of byproduct materials (radioisotopes) pursuant to 10 CFR Part 35, the Commission requires that the responsible user be a physician licensed by a State or territory of the United States, the District of Columbia or the Commonwealth of Puerto Rico to dispense drugs in the practice of medicine. Physicians are authorized to use radioisotopes by a

condition of specific or general licenses issued by the Commission. One of the following three standard conditions is included in each specific license issued for human use of radioisotopes:

1. "Byproduct material shall be used by (a named physician)." This condition is used in licenses to physicians in private practice.

2. "Byproduct material shall be used by, or under the supervision of, (one or more named physicians)." This condition is used in licenses issued to medical institutions which have medical isotopes committees to review all proposals for uses of isotopes within the institution. The named physicians are those designated on the application for license as having appropriate nuclear medicine training and experience with isotopes. The phrase "or under the supervision of" provides a means whereby nonapproved physicians under the supervision of a physician named on the license may obtain basic and clinical radioisotope training and experience to enable them to qualify as authorized users.

3. "A. Byproduct material shall be used by, or under the supervision of, individuals designated by the (name of institution's isotopes committee).

"B. The use of byproduct material in or on h shall be by a physician." This condition is used in ' es issued to medical institutions - usually medical schoo' - whose isotopes committees have set up appropriate administrative procedures, and training and experience criteria, for the committee to approve individual users. This condition also allows other physicians to obtain training and experience under the supervision of a physician designated by the committee as an authorized user.

It is recognized by the Commission that physicians utilize technicians and other paramedical personnel to perform some of the activities and manipulations involved in the medical uses of radioisotopes. In such instances, the physician is still considered to be the user of the byproduct material. The Commission has developed with the assistance of its Advisory Committee on the Medical Uses of Isotopes a list of responsibilities which shall not be delegated by authorized physician users of radioisotopes - except to other physicians who are under the supervision of authorized physicians - and a list of activities that may be delegated by physicians to technicians and other paramedical personnel. The proposed new §35.32 would codify these non-delegable responsibilities and permissible delegations in the Commission's regulations. Section 35.32 would also require physicians to determine that technicians and other paramedical

personnel are properly ...ned to perform the activities which are delegated to th... certification in nuclear medical technology by either ...e American Registry of Radiologic Technologists or the Registry of Medical Technologists would be deemed to satisfy the requirement for such proper training; however, the Commission does not consider it necessary to require paramedical personnel who only assist physicians with simple manipulations or in programs of limited scope to be fully trained and certified technologists.

Section 20.403 of 10 CFR Part 20 of the Commission's regulations requires licensees to notify the Commission of incidents involving the exposure of individuals to more than certain stated amounts of radiation. Paragraph 20.405(c) requires that any exposure of an individual to radiation which is required to be reported to the Commission shall also be reported to the individual. However, since §20.107 of 10 CFR Part 20 provides that nothing in the regulations in that part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy, notifications have not been required of incidents involving the exposure of patients to radiation if the patient were receiving any intentional medical exposure. Although incidents involving medical exposures have not been required to

be reported, twelve instances of misadministrations of radioactive materials involving twenty patients have been brought to the Commission's attention. Since these incidents have generally involved accidental or erroneous exposures of patients to radiation in amounts or forms other than intended, it does not appear appropriate to continue the past practice of not requiring reports of such misadministrations of radioactive materials to medical patients. The proposed new paragraphs (a) and (c) of §35.33 would require licensees to report misadministrations of radiopharmaceuticals or radiation from byproduct material sources to the Commission. Paragraph (b) of § 35.33 would also require a notification to the patient or to a responsible relative of the patient of a misadministration which could cause a demonstrable adverse effect on the patient unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient. (In accordance with the Freedom of Information Act and 10 CFR Part 9 of the Commission's Rules and Regulations, copies of reports filed under these proposed rules, except for any details which would identify the patient, will be available for public inspection.)

Pursuant to the Atomic Energy Act of 1954, as amended, and section 553 of title 5 of the United States Code, notice is hereby given that adoption of the following amendments to 10 CFR Part 35 is contemplated. All interested persons who desire to submit

written comments or suggestions for consideration in connection with the proposed amendments should send them to the Secretary of the Commission, U. S. Atomic Energy Commission, Washington, D. C., 20545, Attention: Chief, Public Proceedings Staff, within 45 days after publication of this notice in the FEDERAL REGISTER. Copies of comments on the proposed amendments may be examined at the Commission's Public Document Room at 1717 H Street, N. W., Washington, D. C.

1. A new §35.32 is added to 10 CFR Part 35 to read as follows:

§35.32 Conditions of licenses for human uses of byproduct material.

(a) The user of byproduct materials in or applied to humans for diagnostic, therapeutic or investigational purposes shall be a physician authorized by a condition of a general license or a specific license, including a specific license of broad scope, issued by the Commission (authorized physician).

(b) No authorized physician may delegate to persons who are not physicians under the supervision of the authorized physician, the following:

(1) The approval of procedures involving the administration to patients of radiopharmaceuticals or the application to patients of radiation from byproduct material sources,

(2) The prescription of the radiopharmaceutical or

source of radiation and the dose or exposure to be administered,

(3) The determination of the route of administration,

(4) The interpretation of the results of diagnostic procedures in which radiopharmaceuticals are administered.

(c) Subject to the provisions of paragraphs (b), (d), (e), (f) and (g) of this section, an authorized physician may permit technicians and other paramedical personnel to perform the following activities:

(1) Preparation and quality control testing of radiopharmaceuticals and sources of radiation,

(2) Measurement of radiopharmaceutical doses prior to administration,

(3) Use of appropriate instrumentation for the collection of data to be used by the physician,

(4) Administration of radiopharmaceuticals and radiation from byproduct material sources to patients, within limits otherwise permitted under applicable federal, state or local laws.

(d) Authorized physicians who permit activities to be performed by technicians and other paramedical personnel pursuant to paragraph (c) of this section shall:

(1) Prior to such permission, determine that such technicians and other paramedical personnel have been properly trained

to perform their duties. Th[illegible]ining shall include training in the following subj[illegible] as applicable to the duties assigned:

(i) G[illegible]ral characteristics of radiation and radioactive materials.

(ii) Physical, chemical and pharmaceutical characteristics of each radiopharmaceutical to be used.

(iii) Mathematics and calculations basic to the use and measurement of radioactivity, including units of quantity of radioactivity (curies, millicuries, microcuries) and units of radiation dose and radiation exposure.

(iv) Use of radiation instrumentation for measurements and monitoring including operating procedures, calibration of instruments and limitations of instruments.

(v) Principles and practices of radiation protection.

(vi) Additional training in the above subjects, as appropriate, when new duties are added.

(2) Assure that such technicians and other paramedical personnel receive appropriate retraining in the subjects listed in subparagraph (1) of this paragraph to maintain proficiency and to keep abreast of developments in the field of nuclear medical technology.

(3) Keep records showing the bases for such determinations of proper training, and

retain responsibility as licensee or authorized user for the satisfactory performance of such activities.

(e) Certification in nuclear medicine technology by the American Registry of Radiologic Technologists or in nuclear medical technology by the Registry of Medical Technologists of the American Society of Clinical Pathologists will be deemed to satisfy the training requirements of subparagraphs (1) and (2) of paragraph (d) of this section.

(f) An applicant for a license or for amendment or renewal of a license shall state whether he desires to permit technicians or other paramedical personnel to perform activities pursuant to paragraph (c) of this section and, if so, shall include in his application for license, license amendment or license renewal a statement of the activities to be so performed and a description of an adequate program for training (including retraining as required to keep abreast of developments in technology) such personnel or for otherwise determining that such personnel are properly trained to perform their duties. With respect to licenses in effect on (effective date of rule), a licensee who is permitting or who desires to permit technicians or other paramedical personnel to perform activities pursuant to paragraph (c) of this section shall file the information required by this paragraph with the Director of Licensing, U. S. Atomic Energy Commission, Washington D. C. 20545, with his next application for amendment or renewal

of the license or within one year of _____,
whichever occurs first.

(g) Whenever a technician or other paramedical person administers a radiopharmaceutical to a patient by injection, a physician (not necessarily a physician authorized by the Commission to be a user of byproduct materials) shall be immediately accessible.

2. A new §35.33 is added to 10 CFR Part 35 to read as follows:

§35.33 Notifications and reports of misadministrations

(a) Each licensee shall notify the Director of the appropriate Atomic Energy Commission Regulatory Operations Regional Office listed in Appendix D of 10 CFR Part 20 of the Commission's regulations by telephone and telegraph of any misadministration of radiopharmaceuticals or any misadministration of radiation from teletherapy and brachytherapy sources. This notification shall be made within 24 hours after such misadministration is known. For the purpose of the requirements of this section, misadministration is defined to include the administration of:

(1) A radiopharmaceutical, or radiation from a source, other than the one intended,

(2) A radiopharmaceutical or radiation to the wrong patient, or

(3) A dose of a radiopharmaceutical, or exposure from a radiation source, outside of the intended dose range prescribed by the physician or by a route of administration other than that intended by the physician.

(b) Whenever a misadministration of a radiopharmaceutical or radiation from a teletherapy or brachytherapy source could adversely affect the patient to whom it was administered, the licensee or the authorized physician shall promptly notify the patient or a responsible relative of the patient of the misadministration unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient.

(c) In addition to the notification required by paragraph (a) of this section, each licensee shall make a report in writing within 30 days to the Director of Regulatory Operations, U.S. Atomic Energy Commission, Washington, D. C., 20545, with a copy to the Director of the appropriate Regulatory Operations Regional Office specified in Appendix D of 10 CFR Part 20, of each misadministration. The report required under this paragraph need not include the name of the patient but shall describe the nature, extent, and cause of the misadministration and the corrective steps taken or planned to assure against a recurrence. If the misadministration could cause a demonstrable adverse effect on the patient, the report shall either confirm that a notification has

been made to the patient or to a responsible relative of the patient or shall state that notification was not given because in the physician's judgment such notification would be contrary to the best interests of the patient or a surviving relative of the patient. If the patient or relative is not notified, the physician shall confirm that this decision was reviewed by a local Ethics Committee or an equivalent group of peers and shall state whether or not the committee or group concurred with the decision.

(d) Any notification or report filed with the Commission pursuant to paragraphs (a) and (c) of this section shall be prepared so that any details which would identify the patient will be stated in a separate part of the notification or report.

(Secs. 81, 161, 68 Stat. 935, 948 as amended; 42 U.S.C. 2111, 2201).

Dated at Washington, D. C., this ___day of _____ 1972.

FOR THE ATOMIC ENERGY COMMISSION

_____
Paul C. Bender
Secretary of the Commission

APPENDIX "B"

DRAFT LETTER FOR THE JOINT COMMITTEE ON ATOMIC ENERGY

1. Enclosed for the information of the Joint Committee on Atomic Energy is a notice of proposed rule making to amend the Commission's regulation 10 CFR Part 35, "Human Uses of Byproduct Material." This rule will implement several recommendations made by the General Accounting Office in a recent study on "Problems in the Use and Distribution of Radioactive Material in the Practice of Medicine" and add several related requirements.

2. The proposed amendments will (a) specify certain responsibilities of physicians authorized to use byproduct materials for human uses, (b) specify certain activities that may be delegated by physicians to technicians and other paramedical personnel, (c) require physicians to determine that technicians and other paramedical personnel are properly trained to perform such activities, (d) require reporting to the Commission of misadministrations of byproduct materials or radiation therefrom, and (e) require notification to the patient or his family of misadministrations which could adversely affect the patient unless in the physician's professional judgment such notification would be contrary to the best interests of the patient or his family.

3. The notice of proposed rulemaking will be filed with the Office of the Federal Register in the next few days and will allow a period of forty-five (45) days for public comment after publication in the Federal Register.

4. Enclosed also is a copy of a public announcement we plan to issue on this matter in the next few days.

APPENDIX "C"

AEC CONSIDERS RULE CHANGES CONCERNING RESPONSIBILITIES
OF PHYSICIANS IN USE OF RADIOACTIVE MATERIALS

The Atomic Energy Commission is considering amendments to its regulations which would specify certain responsibilities for physicians who are authorized to use radioactive materials in the diagnosis and treatment of patients and would outline activities which may be delegated by physicians to technicians who assist them.

The proposed rule includes a requirement that medical licensees must report to the Commission all misadministrations of radioactive materials and must notify the patient or his family of any misadministration which could cause a demonstrable adverse effect on the patient unless in the physician's judgment such notice would be contrary to the best interests of the patient or the family. All reports will be available for public inspection.

Misadministration would be defined to include administration of (1) a radiopharmaceutical, or radiation from a source, other than the one intended, (2) a radiopharmaceutical or radiation to the wrong patient, or (3) a dose of radiopharmaceutical or exposure to a radiation source outside of the intended dose range prescribed by the physician or by a method of administration other than intended by the physician.

Under the proposed amendments, certain responsibilities must be carried out personally by the authorized physician and may not be delegated except to other physicians under his supervision. These include:

· Prescribing the radiopharmaceutical or source of radiation and the quantity or exposure to be administered

· Approving all patient procedures involving the administration of radiopharmaceuticals or the application of radiation

· Determining the method of administration

· Interpreting the results of diagnostic procedures in which radiopharmaceuticals are administered.

However, physicians would be permitted to delegate to technicians and other paramedical personnel the performance of certain activities including preparation of radiopharmaceuticals and measurement of dosages prior to administration, and the use of appropriate instrumentation for the collection of data to be used by the physician. The proposed rules would require physicians to determine that technicians have been properly trained to perform their duties, to describe their training program for technicians in the license application, and to maintain records showing the basis for determination of technician qualifications.

All interested persons are invited to submit comments and suggestions concerning the proposed amendments to the Secretary of the Commission, U. S. Atomic Energy Commission, Washington, D.C. 20545, Attention: Chief, Public Proceedings Staff. Comments and suggestions should be received not later than 45 days following publication of the proposed amendments in the FEDERAL REGISTER on _____. Comments received will be available for review at the Commission's Public Document Room 1717 H Street, N.W., Washington, D.C.

JAN 1 1973
Date

SECY-R 621

POLICY SESSION ITEM

SUMMARY SHEET

Subject: PROPOSED AMENDMENTS TO 10 CFR PART 35: USER AND REPORTING REQUIREMENTS FOR MEDICAL USES OF BYPRODUCT MATERIALS

Purpose: To seek Commission approval of proposed amendments to 10 CFR Part 35 which would specify certain responsibilities of physicians and allow certain delegations to paramedical personnel, require appropriate training of paramedical personnel, and require reporting to the Commission and to the patient or his family of misadministrations of byproduct material.

Discussion: The proposed amendments would implement recommendations made by the General Accounting Office that AEC (1) define the activities that may be delegated by physicians and those that may not, (2) require physicians to determine that technicians have been properly trained, and (3) require medical licensees to report to AEC misadministrations of radioactive material to patients. The proposed requirement for notifying patients or their families of misadministrations was recommended by the Advisory Committee on the Medical Uses of Isotopes. It is probable that the proposed requirement for notifying the patient or his family of misadministrations which could adversely affect the patient will result in reaction and comments from members of the medical profession with respect to their feeling that it is an unnecessary and inappropriate governmental interference in a professional ethical matter.

Issue: The Commission agreed (Policy Session Item SECY-R 462,* May 18, 1972) to implement items 1 and 2 of the above GAO recommendations. The issues remaining to be resolved are whether to require reporting to the Commission and to patients or their families of misadministrations of byproduct material.

Recommendations: The Commission

(a) approve publication in the Federal Register of proposed amendments to 10 CFR Part 35 which would (1)

*SECY-R 462 - "Proposed Letter to the Honorable Elmer B. Staats, Comptroller General, Commenting on Draft GAO Report"

.cify certain responsibilities of physicians authorized to use byproduct materials in humans, (2) specify certain acitivities that may be delegated by physicians to paramedical personnel, (3) require appropriate training of paramedical personnel, (4) require reporting to the Commission of misadministrations of byproduct material, and (5) require notification to the patient or his family of misadministrations that could adversely affect the patient unless in the physician's professional judgment such notification would be adverse to the best interests of the patient or a surviving relative.

(b) note:

1. the proposed amendments will be published in the Federal Register for a 45-day comment period;

2. if no significant adverse comments or significant questions are received and no substantial changes in the rule are indicated after the public comment period, the Director of Regulation will arrange for publication of the amendments in final form (Commissioner Doub will be informed of all comments received); if significant adverse comments or significant questions are received or substantial changes in the text of the rule are indicated, the revised amendment will be submitted to the Commission for approval;

3. the JCAE will be informed;

4. a public announcement will be issued;

5. an environmental statement need not be prepared.

Coordination: The Office of General Counsel (Assistant General Counsel for Licensing and Regulation) has no legal objection. The Division of Applied Technology has no objections. The Divisions of Biomedical and Environmental Research, Naval Reactors and Operational Safety concur.

Scheduling: At an early Policy Session.

L. Manning Muntzing
Director of Regulation

Contact: James R. Mason, X-7463

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ATOMIC ENERGY COMMISSION

PROPOSED AMENDMENTS TO 10 CFR PART 35: USER AND REPORTING REQUIREMENTS FOR MEDICAL USES OF BYPRODUCT MATERIALS

Report to the Director of Regulation by the Director of Licensing

THE PROBLEM

1. To consider proposed implementation of recommendations made by the General Accounting Office and related additional requirements on regulating the medical uses of radioactive materials by amending 10 CFR Part 35, "Human Uses of Byproduct Material." The proposed amendments would (1) specify certain responsibilities of physicians authorized to use byproduct materials for human uses, (2) specify certain activities that may be delegated by physicians to technicians and other paramedical personnel, (3) require physicians to determine that technicians and other paramedical personnel are properly trained to perform such activities, (4) require reporting to the Commission of misadministrations of byproduct materials or radiation therefrom, and (5) require notification to the patient or his family of misadministrations which could adversely affect the patient.

BACKGROUND AND SUMMARY

2. As part of a review of the Commission's regulatory program, the General Accounting Office has reviewed certain matters related to the efficiency and effectiveness of AEC's inspection and enforcement programs for materials licenses. GAO furnished to the regulatory staff a draft report to the Congress on this review. The report was issued in final form on August 18, 1972.

3. On May 23, 1972, the Director of Regulation sent a letter to the Honorable Elmer B. Staats, Comptroller General, commenting on the recommendations made by GAO in their draft report. This letter had been approved by the Commission as Policy Session Item SECY-R 462* on May 18, 1972. We have

*SECY-R 462 - "Proposed Letter to the Honorable Elmer B. Staats, Comptroller General, Commenting on Draft GAO Report".

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had informal discussions with the GAO staff on the proposed approaches for implementing the GAO recommendations. It is our understanding from these discussions that the amendments to 10 CFR Part 35 proposed herein will be consistent with the recommendations covered in their report.

4. In chapter 3 of the report dealing with medical uses of radioactive materials, GAO recommended that AEC:

-- Define in its medical licenses or regulations the activities that may be delegated by physicians and those that may not.

-- Require that physicians determine whether technicians have been properly trained to perform their duties and keep records showing the bases for such determinations.

-- Establish a specific requirement that suppliers verify that transferees are authorized to receive the quantity or type of material being shipped and provide guidance as to acceptable methods of verification. (While this recommendation was made by GAO because of its medical uses connotation, its implementation will involve other categories of licensees, especially commercial suppliers. This recommendation is the subject of a separate staff paper : SECY-R-571.)*

-- Require medical licensees to report to AEC all known misadministrations of radioactive material to patients so that AEC can determine the causes and whether adequate corrective actions were taken by the licensee.

5. The GAO report stated "Under AEC's interpretation of current regulations, medical licensees are not required to report the accidental overexposures of patients to radiation during intentional exposures for medical diagnoses or therapy when such exposures are attributed exclusively to the actions of physicians or to those acting under their orders." The basis for not requiring reports of such accidental overexposures is the language of 10 CFR 20.107 which states that "Nothing in the regulations in this part shall be interpreted as limiting the intentional exposure of patients to radiation for the purpose of medical diagnosis or medical therapy." Although

*SECY-R 571 - "Proposed Amendments to 10 CFR Parts 30, 40, and 70 - Transfer of Radioactive Material.

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such reports have not been required and no statistics on the extent of misadministration are available, twelve instances of misadministrations of radiopharmaceuticals involving a total of 20 patients have been brought to AEC's attention from February 1961 through April 1972.

6. GAO noted that while the Commission's licensing practices require physicians who use isotopes to have formal training and experience in the use, handling and administration of these materials, they do not provide minimum qualification standards for technicians who assist physicians, since the Commission considers physicians responsible for ensuring that technicians assisting them are adequately trained to perform their assigned tasks. A number of the misadministrations of isotopes to patients which GAO reviewed involved technicians and other paramedical personnel making mistakes in the ordering and preparation of radiopharmaceuticals and the apparent inadequate training and supervision of these technicians.

7. The staff has developed, with the assistance of the Advisory Committee on the Medical Uses of Isotopes, a list of responsibilities which may not be delegated by authorized physician users of radioisotopes - except to other physicians who are under the supervision of authorized physicians - and a list of activities which may be delegated by physicians to paramedical assistants. The responsibilities which must be retained and activities which must be performed by physicians involve decisions on individual cases which require the exercise of medical judgement. The activities which may be delegated to paramedical assistants are those which are performed using established procedures and techniques but which do not require the making of decisions involving medical judgement on individual cases. Paragraphs (a), (b) and (c) of the proposed new § 35.32 of 10 CFR 35 would codify these non-delegable responsibilities and permissible delegations in the Commission's regulations.

8. Paragraph (d) of § 35.32 would require physicians to determine that paramedical personnel are properly trained to perform their duties and to record the bases for such determinations and paragraph (f) would require

licensees to describe in their applications their proposed program for training and/or determining the qualifications of such personnel. The subjects which shall be included in such training would be listed in § 35.32(d)(1). Subsection 35.32 (d)(2) would require appropriate retraining for maintenance of proficiency and to keep abreast of developments in the field of nuclear medical technology. Section 35.32(e) would provide that certification in nuclear medical technology by either the American Registry of Radiologic Technologists or the Registry of Medical Technologists will be deemed to satisfy the training requirements.

9. The scope and complexity of activities which physicians authorize paramedical personnel to perform vary widely from licensee to licensee and, therefore, it is not practicable or reasonable to specify in regulations the minimum amount of training which should be required for such personnel. If minimum quantitative standards for training were prescribed in the regulations, they might be used to weaken the stature of the extensive technician training and certification programs which have been developed by the American Registry of Radiologic Technologists and the Registry of Medical Technologists in cooperation with the American College of Radiology, the American Society of Clinical Pathologists and the Society of Nuclear Medicine. On the other hand, while certification by these registries is acceptable evidence of adequate training, it would not be reasonable to require paramedical personnel who only assist physicians with simple manipulations or in programs of limited scope to be fully trained and certified technologists. The listing in § 35.32(d)(1) of subjects to be included in technician training would follow the precedent set in 10 CFR Part 34 for regulating the training of industrial radiographers. While this listing is not a quantitative requirement, it would provide physicians with an outline of the subject matter to be covered to qualify their assistants to perform their duties and would aid physicians in describing in their applications, their program for training technicians. Furthermore, it would provide a basis for the Directorate of Regulatory Operations to review the training and qualifications of paramedical personnel as part of inspections or incident investigations of medical licensees.