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

June 30, 1982

MEMORANDUM FOR: William Walker, Section Leader
Medical Section
Materials Licensing Branch, NMSS

FROM: Leo B. Higginbotham, Chief
Fuel Facilities and Materials Branch, IE

SUBJECT: PROPOSED REVISION TO PART 35

In a discussion a couple of weeks ago I promised to send you some comments and a marked-up copy of the draft rule change to supplement our memorandum of June 2 on this subject. After looking again at our specific and general comments we decided to take a different approach as our comments would not completely convey the thoughts we have with the proposed rule change. The enclosed material is the result.

There are two "documents" enclosed. The first is a rewrite of the first part of the rule, and the second is a proposed Appendix A. These are first drafts, not finished documents. They were put together to explain a conceptual approach. They contain some inconsistencies, parts are incomplete, and should be looked at in the context of explaining a concept. (A total of only about 13 staff hours over a period of several days went into the writing and typing.)

The rewrite of the first part of the rule would replace Subpart A, B, C of the draft. Subparts D to H would remain the same, although there are some minor improvements that could be made.

The proposed Appendix A would be the general requirements for a radiation safety program. It is written (or should be) in the form of general requirements and objectives. It is patterned after Appendix B of Part 50, QA programs. This would cover the important elements of programs for an institutional license, and there should be something similar for other types of medical licenses. We didn't deal with that but have some ideas if you're interested.

There are two other documents needed for this kind of approach. A regulatory guide for the "Standard format and content" of the application, and a guide (an "advisory standard" if you will) which would explain in more detail the requirements and objectives of Appendix A.

In developing the guide for the standard format and content the decision would be made regarding the type and extent of information needed for the licensing decision. We (NRC) need assurances from applicants but assurance can also be obtained through pre-licensing inspections if we (NRC) choose to make that a part of the process.

Note that in the concept proposed we would neither review the qualifications of individuals nor include their names in licenses. The qualifications requirements are stated in the rule and the licensee would be required to establish a system to assure those requirements are met and certify persons as RSO and authorized users. This approach places responsibility where it should be, on the licensee.

The last remark explains a major part of our trouble with making rules too specific. Detailed requirements removes responsibility from the licensee and restricts his freedom in running an operation. Also, I don't believe we can include all specific requirements in a rule. There must be other things equally important, yet we single out only a few. Labels for vials and shields for syringes are examples.

In our discussion of the proposed draft rule, I said we concurred - with reluctance. I explained by saying that licensing is your responsibility and while the proposed rule "liberalized" the licensing process somewhat, it did not go far enough. The enclosures to this memo explain what I meant by that remark (far enough).

I apologize for taking so long to provide these comments. But the long delay shouldn't be misleading, as I pointed out earlier, the total staff time of writing involved only about 13 hours or so.

I would be glad to provide more explanation of the enclosures and the concept that they represent if you are interested.

Leo B. Higginbotham, Chief
Fuel Facilities & Materials Branch, IE

Enclosures:
1. Draft Subpart A
2. Draft Appendix A

cc: R. Cunningham, NMSS
T. Dorian, ELD
D. Nussbaumer, SP
L. Cobb, IE

SUBPART A -- General Provisions

§35.1 Purpose and scope

This part prescribes requirements for issuance of specific licenses authorizing the human use of byproduct material. This part also prescribes requirements for the human use of byproduct material. The provisions and requirements of this part are in addition to, and not in substitution for, the requirements and provisions of Parts 19, 20, 21, 30, and 170 of this chapter unless specifically exempted.

§35.2 License requirements.

No person shall manufacture, produce, acquire, receive, possess, use, or transfer byproduct material for human use except in accordance with a specific license issued by the Commission or an Agreement State.

§35.3 Reporting, recording, and application requirements: OMB approval.

(a) The Nuclear Regulatory Commission has submitted the information collection requirements contained in this part to the Office of Management and Budget for approval as required by the Paperwork Reduction Act (Pub. L. 96-511). OMB approved the information collection requirements on _____.

(1) The OMB control number is _____.

(2) OMB approval expires _____.

(3) The approved information collection requirements include the application, recording, and reporting requirements contained in §§35.16, 35.17, 35.18, 35.30(d), 35.31(a), 35.32(f) and (h), 35.34(c), 35.35(b), 35.37(a)-(d), 35.50(d), 35.51(e), 35.53(c), 35.59(c), 35.5(d), 35.70(c), 35.80(e), 35.92(b), 35.204, 35.304(b), 35.404, 35.405, 35.604, 35.606

35.610, 35.621(d), 35.630(c), 35.632(g), 35.633(e) and (j), 35.641(c), 35.642(c), 35.644, and 35.645(c).

§35.4 Definitions.

As used in this part:

"Agreement State" means a State with which the Commission or the Atomic Energy Commission has entered into an effective agreement under subsection 274b of the Atomic Energy Act of 1954, as amended.

"ALARA" means as low as reasonably achievable.

"Authorized user" means a physician duly authorized under the provisions and requirements of this part to use radioactive material for human use.

"Medical facility" means the room or rooms in which byproduct material is used or stored.

"Human use" means the intentional internal or external administration of byproduct material, or the radiation therefrom, to human beings.

"Institution" means an organization in which several medical disciplines are practiced.

"Management" means the chief administrative officer of an institution.

"Misadministration" means the administration of:

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

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

(3) A radiopharmaceutical or radiation by a route of administration other than that intended by the prescribing physician;

(4) A diagnostic dose of a radiopharmaceutical differing from the prescribed dose by more than 50 percent;

(5) A therapeutic dose of radiopharmaceutical differing from the prescribed dose by more than 10 percent; or

(6) A therapeutic radiation dose from a sealed source such that errors in the source calibration, time of exposure, and treatment geometry result in a calculated total treatment dose differing from the final prescribed total treatment dose by more than 10 percent.

"Mobile service" means the transportation and removal of byproduct material for human use and its use for checks and tests of equipment used in conjunction with human use by the licensee.

"Physician" means a medical doctor or doctor of osteopathy licensed by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico to prescribe drugs in the practice of medicine.

"Radiation Safety Officer" means a individual trained and experienced in radiation protection and duly authorized and assigned responsibility under the provisions and requirements of this part to carry out a radiological protection program.

"Sealed source" means any byproduct material that is encased in a capsule designed to prevent leakage or escape of the byproduct material.

"Visting Physician" means who qualifies as an authorized user and serves as an interim or temporary member of a licensee's staff.

SUBPART B - Application for Specific License

§35.10 Application form for specific licenses.

Application for specific licenses for human use under §§35.11 and 35.12 of this part shall be filed on form NRC-313MH, "Application for Materials License -- Human Use", with the Director of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Applications may be filed in person at the Commission's offices at 1717 H Street NW, Washington, D.C.; or at _____ Eastern Ave., Silver Spring, Maryland. To assure expeditious processing applicants should be filed by mail to the following addresses:

(a) If the applicant is a Federal agency, if the applicant is located in the District of Columbia or a non-Agreement State not mentioned in paragraph (b) or (c) of this section, or if the application is for a teletherapy unit, the applicant should mail the completed application form to the Director of Nuclear Material, Safety, and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

(b) If the applicant is not a federal agency and is located in Connecticut, Delaware, Maine, Massachusetts, New Jersey, Pennsylvania, or Vermont, and the application is not for a teletherapy unit, the applicant should mail the completed application form to U. S. Nuclear Regulatory Commission, Region I, Material Licensing Section, 631 Park Avenue, King of Prussia, Pennsylvania 19406.

(c) If the applicant is not a federal agency and is located in Illinois, Indiana, Iowa, Michigan, Minnesota, Missouri, Ohio, or Wisconsin, and the application is not for a teletherapy unit, the applicant should mail the

completed application form to U.S. Nuclear Regulatory Commission, Region III, Radioisotopes Licensing Section, 799 Roosevelt Road, Glenn Ellyn, Illinois 60137.

§35.11 Types of licenses.

Specific licenses for human use of byproduct material are of two types: Broad and limited. Application may be made for a broad license for medical use or uses of unspecified quantities or multiple types of byproduct material, or application may be made for a limited license for medical use or uses of byproduct material in specified quantities and specified types of use or in one or more of Groups I to VIII, inclusive, of Subparts D to H of this part.

§35.12 Specific licenses for human use of byproduct material in institutions.

An application by an institution for a specific license for human use of byproduct material will be approved if:

(a) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(b) The applicant has established administrative controls and provisions relating to organization and management, procedures, record keeping, material control and accounting, and management review that are necessary to achieve the requirements and objectives set forth in Appendix A and to assure safe

use of byproduct material for medical diagnostic and therapeutic purposes within the institution, including:

(1) The establishment of a radiation safety committee composed of such persons as a representative of licensee management, a radiation safety officer, and a physician expert in each type of use authorized by the licensee;

(2) The appointment of a radiation safety officer who is qualified by training and experience in radiation protection, and who is available for advice and assistance on radiological safety matters; and

(c) The applicant possess adequate facilities for the clinical care of patients;

(d) The physician(s) who will use byproduct material for human use has experience in the handling and administration of radioisotopes; the clinical management of radioactive patients, where applicable; and otherwise meets the training and experience requirements specified in Subpart J of this part for the proposed use(s).

§35.13 Specific licenses for human use of byproduct material by individual physicians.

(a) An application by an individual physician or groups of physicians for a specific license for human use of byproduct material in the applicant's practice in an office(s) outside a medical institution will be approved if:

(1) The applicant satisfies the general requirements specified in §30.33 of this chapter;

(2) The applicant has access to a hospital possessing adequate facilities to hospitalize and monitor the applicant's radioactive patients whenever it is advisable; and

(3) The applicant has experience in the proposed use; the handling and administration of radioisotopes and, where applicable, the clinical management of radioactive patients.

(b) An application by an individual physician or groups of physicians for a specific license to receive, possess or use byproduct material on the premises of a medical institution will be approved if:

(1) The medical institution does not hold a byproduct material license under §35.12;

(2) The applicant satisfies the requirements of §35.13(a)(1), (2), and (3) of this part;

(3) The use of byproduct material is limited to:

(i) The administration of radiopharmaceuticals for diagnostic or therapeutic purposes;

(ii) The performance of diagnostic studies on patients to whom a radiopharmaceuticals has been administered;

(iii) The performance of in vitro diagnostic studies; or

(iv) The calibration and quality control checks of radioactive instrumentation, and diagnostic instrumentation; and

(4) The applicant's use of byproduct material provides that the using physician brings the byproduct material with him or her to the institution and removes the material from the institution when he or she departs.

RADIATION SAFETY PROGRAMS

The applicant[1] shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a radiation safety program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout the effective duration of the NRC license in accordance with these policies.

The applicant shall be responsible for the establishment and execution of the radiation safety program. The applicant may delegate to others such as consultants, the work of establishing the program or any part thereof, but shall retain the ultimate responsibility for establishing and executing the program.

The program shall include identification of radiation safety activities covered thereunder and the institutional departments, organizations, and persons participating in the program together with the designated functions and responsibilities of these departments, organization, and persons. The program shall provide control over activities to an extent consistent with their importance to radiation safety.

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[1] While the term "applicant" is used in these criteria, the requirements are, of course, applicable after such a person has received a license to receive, possess, and use byproduct material. These criteria will also be used in evaluating the adequacy of radiation safety programs established by current holders of licenses.

Activities affecting radiation safety shall be accomplished under suitably controlled conditions, which include the use of appropriate instrumentation, suitable environmental conditions for accomplishing the activity, such as adequate area ventilation and cleanness; and assurance that all prerequisites for the given activity have been satisfied.

The program shall take into account the need for special controls of radioactive materials, their handling and use, test instrumentation, and skills to attain the required degree of quality of radiation safety, and the need for verification of safe operations by inspection and test.

The program shall provide for indoctrination and training of personnel performing radiation safety activities as necessary to assure that suitable proficiency is achieved and maintained and to satisfy the objectives of §19.12 of this chapter.

The applicant shall regularly review the status and adequacy of the radiation safety program. The applicant may delegate this function to others, such as consultants or the Radiation Safety Committee, but shall retain the ultimate responsibility for the adequacy and effectiveness of the radiation safety program.

I. ORGANIZATION

Criterion 1: The Radiatic . Safety Committee and position of Radiation Safety officer shall be established by formal action of the institution's governing

body and shall be responsible to the institutional authorities and shall have official status, rather than function as an informal, unofficial group of administrative, technical and medical staff.

Criterion 2: The authorities, duties, responsibilities, and radiation safety activities of the Radiation Safety Committee and Radiation Safety Officer shall be clearly established and delineated in writing. The radiation safety activities shall include the functions of: (1) assuring that an appropriate radiation safety program is established and effectively executed and (2) verifying, by means such as checking, auditing, and inspection, that radiation safety activities have been correctly performed.

Criterion 3: The Radiation Safety Committee, of which the Radiation Safety Officer shall be a member, shall have sufficient authority and organizational freedom to identify radiation safety problems; to initiate, recommend or provide solutions; and to verify implementation of solutions. The Radiation Safety Committee and Radiation Safety officer shall report to an institutional management level such that this required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to radiation safety considerations, are provided.

II. PROCEDURES AND INSTRUCTIONS

Criterion 4: Activities affecting radiation safety shall be prescribed by documented instructions and procedures of a type appropriate to the circumstances of radioactive material use and shall be accomplished in accordance with these procedures and instructions.

Criterion 5: Procedures and instructions shall include appropriate quantitative and qualitative acceptance criteria for determining that important radiation safety controls and activities have been satisfactorily accomplished.

III. CONTROL OF PROCEDURE AND INSTRUCTIONS

Criterion 6: Measures shall be established to control the issuance of procedures and instructions, including changes thereto, which prescribe all activities affecting radiation safety. These measures shall assure that procedures and instructions, including changes, are reviewed for adequacy and approved for release by authorized personnel and are distributed to and used at the location where the prescribed activity is performed. Changes to procedures and instructions shall be reviewed and approved by the same organizations that performed the original review and approval unless the applicant designates another responsible organization.

IV. CONTROL OF HUMAN USE OF BYPRODUCT MATERIAL

Criterion 7: Measures shall be established to control the use of byproduct material to assure that its use for diagnostic and therapeutic purposes by administration to humans is performed only by qualified persons using qualified procedures in accordance with applicable codes, standards, specifications, criteria, and other special requirements. These measures shall include verification of the training and experience of personnel specified in Subpart J of this part and controls to verify compliance with conditions of use for specific byproduct materials specified in Subparts D tc , of this part. Certification of training and experience requirements and authorizations of persons to carry out functions of the Radiation Safety Officer and "authorized user(s)" shall be in writing and records of certification and authorization shall be maintained by the applicant.

V. PROCUREMENT AND RECEIPT OF BYPRODUCT MATERIAL

Criterion 8: Measures shall be included in procedures and instructions to assure that byproduct material for human use is procured only from approved sources and that such material is specifically approved for human use by competent authority. The only materials that shall be procured and used for human use are byproduct material manufactured by licensee authorized to distribute such material by a license pursuant to 10 CFR §§30.32, 32.70 32.72, 32.73, or 32.74 or equivalent Agreement State regulations; reagent kits which have been approved by the Commission or an Agreement State for the preparation of radiopharmaceuticals for human use; and radiopharmaceuticals authorized by the licensee's Radioactive Drug Research Committee which has been approved by the Food and Drug Administration.

Criterion 9: Measures shall be provided by a combination of checks, inspections, examination of procurement documents, and examination of received material, that byproduct material received from suppliers is of the specific types, form, and quantity that was ordered for human use.

Criterion 10: The program shall include procedures and instructions for picking up, receiving, and opening packages pursuant to requirements established in §20.205 of this chapter.

VI. CONTROL OF RADIATION EXPOSURES

Criterion 11: Controls shall be established and included in procedures and instructions to assure that occupational radiation doses are kept within

limits established in Part 20 of this chapter and are maintained as low as reasonably achievable (ALARA). The controls shall include the provision to workers of personal dosimetry monitoring for whole body and extremity radiation exposure; controls and monitoring for intake of radioactive material into the body; quality control measures for personnel dosimetry; monitoring of the work environment for direct radiation, airborne radioactivity, and surface radioactive contamination; administrative controls and limits; and inspections, tests, audits, and evaluations of facilities, equipment, procedures, and work practices.

Criterion 12: Measures shall be provided, through a combination of means such as tests, measurements, inspections, audits, and procedures and instructions, to control the administration of byproduct materials to humans for diagnostic and therapeutic purposes and prevent misadministrations.

Criterion 13: Measures shall be established to control radiation exposure in accordance with work and inspection procedures to preclude unnecessary exposure of occupational workers and the public. These measures shall include control of patients administered a radiopharmaceutical or permanent or temporary implant, including isolation of the patient when appropriate and control of persons both caring for and visiting such patients; the release from confinement for medical care of any patient administered a radiopharmaceutical or permanent implant only after the radiation exposure rate from the patient is less than 5 milliroentgens per hour at a distance of one meter; control of contamination and waste resulting from preparing, dispensing, and administering byproduct materials to patients and from

the patients administered such material; and the control and accounting at all times of radioactive material and radiation sources including radioactive implants.

VII. TEST AND MEASUREMENTS

Criterion 14: The program shall provide for tests and measurements required to assure safe use of byproduct material and radiation safety of patients, workers, and the general public. Tests and measurements will be identified and performed in accordance with written procedures and instructions which incorporate the requirements and acceptance limits contained in applicable codes, standards, specifications, criteria, and other conditions specified in this chapter.

Criterion 15: Procedures for tests and measurements shall include provisions for assuring that all prerequisites for the given test have been met, that adequate test and measurement instrumentation is available and used, and that the test or measurement is performed under suitable environmental conditions.

Criterion 16: The results of test and measurements shall be documented, inspected and evaluated to assure that test and measurements requirements have been satisfied.

VIII. CONTROL OF TEST AND MEASURING EQUIPMENT

Criterion 17: The program should include measures to assure that testing and measuring instruments and devices used in activities affecting radiation safety

are properly controlled, calibrated, checked and adjusted at specified periods to maintain accuracy within necessary limits.

Criterion 18: The results of calibration and checks of testing and measuring instruments and devices shall be documented, inspected, and evaluated to assure that standards of accuracy are satisfied.

IX. INSPECTION

Criterion 19: A program for inspection of activities affecting radiation safety shall be established and executed by or for each department and organization performing the activity to verify conformance with the documented procedures and instructions for accomplishing the activity. Such inspections shall be performed by individuals other than those who actually performed the activity being inspected.

Criterion 20: Inspections, examinations, measurements, or tests shall be performed for each work operation where necessary to assure safety of patients, workers, and the general public. If direct inspection of work operation is impossible or disadvantageous, indirect control by monitoring work process methods, instrumentation, and personnel actions shall be provided. Both direct inspection and indirect monitoring control shall be provided when control in inadequate without both.

X. HANDLING AND STORAGE OF BYPRODUCT MATERIAL

Criterion 21: Measures shall be established to control the handling and storage of byproduct material in accordance with work and inspection instructions to

prevent unnecessary radiation exposures and to preserve the quality and identity of byproduct material used for human use. Measures shall include the use of radiation shields for containers of radioactive material, isolation of areas of use from normal traffic patterns, posting and labeling of areas and rooms, and labeling of containers and storage shields for radiation warning purposes and to assure preservation of the identity of specific byproduct materials.

XI. SHIPPING OF BYPRODUCT MATERIAL

XII. HANDLING, STORAGE, & SHIPPING OF WASTE BYPRODUCT MATERIAL

XIII. INSPECTIONS, TEST, & OPERATING SITES

XIV. CORRECTIVE ACTION

Criterion : Measures shall be established to asure that conditions adverse to radiation safety, such as deficient procedures, deviations from specified instructions and work practices, nonconforming material, and malfunctioning and deviating instrumentation are promptly identified and corrected. In cases of significant conditions adverse to radiation safety, the measures shall assure the cause of the condition is determined and corrective action taken to preclude repetition. The identification of the significant condition adverse to radiation safety, the cause of the condition, and the corrective action shall be documented and reported to appropriate levels of management.

XV. RADIATION PROGRAM RECORDS

Criterion : Sufficient records shall be maintained to furnish evidence of activities affecting radiation safety. The records shall include at least the following: logs and the results of reviews, inspections, tests, audits, and monitoring of work performance; and records of procurement, control, and accounting of radioactive materials. The records shall also include closely-related information such as qualifications of personnel, procedures, and equipment. Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiences noted. Records shall be identifiable and retrievable. Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning records retention, such as duration, location, and assigned responsibility.

XVI. AUDITS OF THE PROGRAM

Criterion : The applicant shall establish and carry out a comprehensive system of planned and periodic audits to verify compliance with all aspects of the radiation safety program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or check lists by appropriately trained personnel not having direct responsibilities in the area being audited. Audit results shall be documented and reviewed by management having responsibility in the areas audited. Followup action, including reaudit of deficient areas, shall be taken where indicated.