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

OCT 21 1976

TO ALL MEDICAL LICENSEES:

This is to clarify our recent letter concerning the revised criteria for training and experience for medical users of byproduct material. Sections 35.11 and 35.12 of 10 CFR Part 35 provide that the Commission will approve a license application for medical use of byproduct material if it determines, among other things, that the physician named as the individual user is adequately trained and experienced in basic radioisotop handling techniques. The Commission establishes its criteria for acceptable training and experience with the assistance of its Advisory Committee on the Medical Uses of Isotopes.

These criteria are not requirements, but are intended to describe to license applicants the type of training that will be considered acceptable. If a physician wishes to use radiopharmaceuticals, but does not have the exact training and experience described, he may submit an application listing his specific qualifications and this will be reviewed by the Commission with the assistance of the Medical Advisory Committee.

The changes that have occurred in the nuclear medicine field in the past several years required that the Commission reconsider the amount of training in basic radioisotope handling techniques that would be acceptable. The quantities of radioactive material used in most nuclear medicine laboratories have increased by factors of one hundred to one thousand. Instead of being purchased in prepackaged, pre-calibrated form, many radiopharmaceuticals are now eluted from radioisotope generators or prepared from reagent kits in the nuclear medicine laboratory. This requires more handling of large quantities of radioactive material and thus more need for knowledge of proper radiation safety measures, instrumentation and handling procedures.

Taking these and other factors into consideration, the amount of training in basic radioisotope handling techniques that an applicant should have has been increased to 200 hours. All forms of training, e.g., lectures, laboratory sessions, discussion groups and supervised experience in a

nuclear medicine laboratory, should be included in the 200 hours. The hours listed for each subject in Section 1A are suggested values and should not be interpreted as requirements.

There has been no change in the total training time. The criteria for training in basic radioisotope handling techniques (200 hours), experience with the types and quantities of byproduct material for which application is being made (500 hours), and supervised clinical training in an institutional nuclear medicine program (500 hours) can be satisfied concurrently in a total of 500 hours if all three are included in the training program.

While many programs have provided training that meets these requirements, we recognize that documentation of the training in each subject area may be difficult to obtain. If the training in basic radioisotope handling techniques has already been received but complete documentation from the training institution is not available, the physician should state where the training was received, the total number of hours for each subject and the type of training.

The Nuclear Regulatory Commission is preparing a new licensing guide to aid physicians and hospitals in preparing applications for the medical use of radioisotopes and the training and experience criteria will be included as an appendix to that guide. The Commission will welcome any comments pertaining to the training and experience criteria or to items that should be included in the guide. Comments should be made before December 31, 1976 to:

U.S. Nuclear Regulatory Commission
Office of Nuclear Material Safety and Safeguards
Division of Fuel Cycle and Material Safety
Radioisotopes Licensing Branch
Washington, D. C. 20555

Bernard Singer, Chief
Radioisotopes Licensing Branch
Division of Fuel Cycle and
Material Safety

Enclosure:
Revised Appendix A

APPENDIX A

ACCEPTABLE TRAINING AND EXPERIENCE FOR MEDICAL USES OF BYPRODUCT MATERIAL

Section 35.11 (d) of 10 CFR 35 provides that the Commission will approve a license application by an institution for medical use of byproduct material if it determines, among other things, that the physician designated as the individual user is adequately trained and experienced in (a) basic radioisotope handling techniques and (b) the clinical use of byproduct material proposed in the application. Similar criteria are established in Section 35.12 (c) of 10 CFR 35 for approval of licenses for medical use of radiopharmaceuticals by individual physicians. Outlined below are training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes, has found acceptable for physicians who use radiopharmaceuticals. Each physician's training and experience are examined on a case-by-case basis. If a physician wishes to use radiopharmaceuticals but does not have the training and experience described, he may submit an application listing his specific qualifications and this will be reviewed by the Commission with the assistance of the Medical Advisory Committee.

I. GENERAL TRAINING

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups I, II and/or III, Section 35.100 of 10 CFR Part 35, a physician should have:

A. Training in basic radioisotope handling techniques consisting of lecture, laboratory sessions, discussion groups or supervised experience in a nuclear medicine laboratory in the following areas: (200 hours)

1. Radiation physics and instrumentation (100 hours)
2. Radiation Protection (30 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (20 hours)
4. Radiation biology (20 hours)
5. Radiopharmaceutical chemistry (30 hours)

(The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.)

B. Experience with the types and quantities of byproduct material for which the application is being made, or equivalent (500 hours).

C. Supervised clinical training in an institutional nuclear medicine program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

2. Collaboration in calibration of the dose and the actual administration of the dose to the patient, including calculation of the radiation dose, related measurements and plotting data.
3. Follow-up of patients when required.
4. Study and discussion with preceptor of case histories to establish most appropriate diagnostic procedures, limitation, contraindication, etc.

Note:

The requirements specified in Sections A, B and C may be satisfied concurrently in a three month training program IF all three areas are integrated into the program.

Note:

For each physician named in Item 4 of Form NRC-313 complete a separate Page 3 of the Form NRC-313a (Preceptor Statement) and append the statement of training in basic radioisotope handling techniques. For each subject covered in basic training, state where the training was obtained, the dates, total number of hours and type of training (e.g., lectures, laboratory sessions).

Alternative:

Certification by the American Board of Nuclear Medicine will be accepted as evidence that a physician has had adequate training and experience to use Groups I, II and III.

II. TRAINING REQUIREMENTS FOR SPECIFIC DIAGNOSTIC PROCEDURES

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical procedures commensurate with the procedures and quantities of byproduct material being requested. Such requests will be examined on a case-by-case basis by the Commission with the assistance of the Advisory Committee on the Medical Uses of Isotopes.

III. TRAINING REQUIREMENTS FOR THERAPY PROCEDURES INVOLVING RADIOPHARMACEUTICALS

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Groups IV and/or V, Section 35.100 of 10 CFR Part 35, a physician should have:

A. Training in basic radioisotope handling techniques (80 hours) including:

1. Radiation physics and instrumentation (25 hours)
2. Radiation protection (25 hours)
3. Mathematics pertaining to the use and measurement of radioactivity (10 hours)
4. Radiation biology (20 hours)

(These requirements are in lieu of, not in addition to, those specified in Section I.A., above.)

B. Clinical training in specific therapy procedures:

For Group IV

(i) Iodine-131 for treatment of hyperthyroidism and/or cardiac conditions:

- Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

(ii) Phosphorus-32 for treatment of polycythemia vera, leukemia and/or bone metastases:

- Treatment of three patients with any combination of these three conditions.

(iii) Colloidal phosphorus-32 for intracavitary treatment:

- Active participation in the treatment of three patients.

For Group V

(i) Iodine-131 for treatment of thyroid carcinoma:

- Clinical experience in diagnosis of thyroid function and treatment of hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma.

(ii) Colloidal gold-198 for intracavitary treatment:

- Active participation in the treatment of three patients.

IV. TRAINING REQUIREMENTS FOR THERAPY PROCEDURES INVOLVING SEALED SOURCES

To qualify as adequately trained to use or directly supervise the use of byproduct material listed in Group VI, Section 35.100 of 10 CFR Part 35, a physician should have:

A. Training in basic radioisotope handling techniques (200 hours) as described in Section I.A. of this Appendix.

B. Clinical training in specific therapy procedures:

(i) Radiation sources for interstitial, intracavitary, or surface treatment of cancer:

- Active practice in therapeutic radiology with a minimum of three years experience.

(ii) Beta ray applicators for the treatment of superficial eye disease:

- Active practice in therapeutic radiology or ophthalmology and experience in the therapeutic use of beta rays or soft X-rays.

(Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology may be submitted in lieu of the information requested in Subsections A and B, above.)

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Revised Training and Experience Criteria for Nuclear Medicine Physicians

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of revised training and experience criteria for physicians who apply for authorization to perform nuclear medicine procedures.

SUMMARY: The Nuclear Regulatory Commission is publishing revised training and experience criteria for physicians who request authorization to use reactor-produced radioactive isotopes (byproduct material) in nuclear medicine procedures. This revision increases the minimum time appropriate for a physician to obtain acceptable training and experience for authorization to perform diagnostic nuclear medicine studies.

EFFECTIVE DATE: July 1, 1984. This revision does not affect physicians who begin their nuclear medicine training prior to the effective date.

FOR FURTHER INFORMATION CONTACT: Joseph DelMedico, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards.

U.S. Nuclear Regulatory Commission, Washington, D.C., 20555, 301-427-4082.

SUPPLEMENTARY INFORMATION: NRC is revising Appendix A of Regulatory Guide 10.8. Appendix A concerns training and experience criteria for physicians who apply for authorization to use byproduct material in medical diagnosis and therapy. Regulatory Guide 10.8 describes the type and extent of information needed by the Nuclear Regulatory Commission (NRC) staff to evaluate an application for a specific license for the possession of byproduct material and its use in or on human beings. This type of license is provided for under 10 CFR Part 35, "Human Uses of Byproduct Material." The revision of Appendix A is based upon the recommendation of NRC's Advisory Committee on the Medical Uses of Isotopes (ACMUI).

Essentially, the revised criteria indicate that physicians who apply for authorization to use byproduct material for diagnostic nuclear medicine studies, including cardiovascular nuclear medicine studies, should have a minimum of six months of special education, training, and experience in these uses. The previous criteria indicated a minimum of three months.

The revison does not affect physicians who are presently authorized to perform nuclear medicine procedures, nor physicians who begin their nuclear medicine training prior to the effective date. The effective date was chosen so as to allow the various training programs sufficient time to restructure their curricula.

Background

The revised Appendix A evolved from proposals initiated by the medical community to reflect the training believed necessary for a physician to use licensed materials safely and to protect workers, patients, and the public from unnecessary radiation exposure. This topic was discussed at public meetings held on January 18, 1980, August 18, 1980, and August 31, 1981. Information concerning these meetings was published in the **Federal Register** prior to each meeting (44 FR 73170, 45 FR 42904, and 46 FR 32354). Transcripts of these meetings are available from NRC's Public Document Room at 1717 H Street, NW., Washington, D.C.

A **Federal Register** notice that the new criteria were under consideration and that public comments were invited was published on January 22, 1982 (47 FR 3228). The Commission received 232 comment letters, of which 159 supported the new criteria, 36 expressed support but suggested specific changes, and 33 expressed opposition. Most of the opposing comments either supported or actually enclosed a copy of the position taken jointly by the American College of Cardiology (ACC) and the American Heart Association (AHA). All comments were carefully considered and, wherever possible, the new criteria were changed to take them into account. Copies of the comment letters are available for inspection at NRC's Public Document Room.

Discussion of Public Comments

A. Comments of an Editorial Nature

All comments of an editorial nature were accommodated in the new criteria. These changes included: (a) Revision of Section VII.A to eliminate confusion concerning colloidal gold 198, which is currently not in use; (b) modification of Section IX to include all of the radiation therapy certification boards listed in Table 1; (c) mention of the accrediting authority for osteopathic training in Table 3; (d) inclusion of xenon 133 studies in the training criteria; (e) use of the term "cardiovascular nuclear medicine" in place of the less descriptive "nuclear cardiology;" (f) modifications to emphasize that the new criteria represent the minimum that NRC finds acceptable; and (g) revision of the **Federal Register** notice to stress that the new criteria will not affect physicians who are currently authorized to perform nuclear medicine studies or physicians who begin their training prior to the effective date.

B. Comments Concerning Table 1

A number of commenters questioned why certain medical specialty certification boards were or were not included in Table 1, and whether certain procedures should or should not be authorized on the basis of various board certifications. Each individual board initiates action to become accepted by providing evidence of adequate training for certain procedures. The board sends the Commission evidence of eligibility requirements, accreditation programs, and examination procedures which assure that NRC's criteria will be met. Additional boards may be included at any time provided that they approach NRC and present this information. These submissions are examined by the staff and by appropriate members of the ACMUI. A recommendation is made to the full ACMUI at an open public meeting. The boards listed in Table 1 met the requirements specified above.

C. Comments Calling for More Stringent Criteria

Over 50 commenters stated that six months of training was minimum or not enough. Some recommended that only board-certified physicians should be authorized. Many of the commenters noted that six months of specific study in nuclear medicine may not allow enough time to satisfy the radiation safety training as well as the clinical requirements of that specialty. The increasing complexity of the field, especially as related to equipment and clinical procedures, was cited by several commenters. In determining that the published criteria are justified, the staff took into account the facts that these criteria received strong support during the public meetings and that no significant new information has been presented to support a period of training longer than six months. Commenters are therefore referred to the meeting transcripts.

D. Comments Concerning Documentation of Training and Experience

Comment: A number of comments concerned the nethod for documenting training and experience. One commenter suggested that NRC issue certificate-type credentials to a qualified physicians. The commenter stated that the certificate would be convenient for physicians changing jobs. The premise was that a physician, once licensed, could thereafter show a new employer or radiation safety committee the certificate as evidence that NRC accepted his credentials.

Response: The staff feels that the current Supplements A and B of Form NRC 313M are adequate for documenting training and experience. Physicians authorized as users on NRC licenses may make copies of the license to present to a new employer as evidence of such approval.

E. Comments Concerning the Medical Competence of Physician-Users

Comment: Several commenters asked NRC to notify physican and hospital licensees that NRC authorization relates only to radiation safety and not to medical competence.

Response: In 1979, the NRC published "Regulation of the Medical Uses of Radioisotopes: Statement of General Policy" (44 FR 8242). The third and final specific area in the policy stated, "The NRC will minimize intrusion into medical judgements affecting patients and into other areas traditionally considered to be a part of the practice of medicine." The staff has and will

continue to interpret this to mean NRC approval of a physician to use byproduct materials in humans for treatment and diagnosis relates to radiation safety and to training sufficient to avoid unwarrented radiation exposure to the physician, medical workers and the public, inlcuding patients. Such authorization does not imply a standard for professional clinical achievement as would be evidenced by a medical specialty board certification. Further clarification of NRC's position is being considered in connection with a separate revision to Part 35 of Title 10, Code of Federal Regulations. This revision is under way at the present time.

F. Comments Opposing the New Criteria

The concerns of those who object to the criteria (as paraphrased by the NRC staff) and the staff response are summarized below:

Comment: The current criteria have been more than adequate in protecting the public; therefore, there is no basis for an increase.

Response: The current criteria have been adequate because they have been revised whenever necessary to keep pace with developments in nuclear medicine, a rapidly expanding, technology based clinical specialty. In 1972, the Atomic Energy Commission, NRC's predecessor agency, had physician training criteria that involved only 30 hours of training in basic radioisotope handling techniques. Since that time, the criteria have been revised and increased three separate times. Transcripts of NRC's ACMUI meetings show that each change was made in response to the increasing complexity of the field, not in response to accidents or incidents.

The transcripts of the public meetings concerning the present changes indicate that there has been an increase in the complexity of the diagnostic interpretation of nuclear medicine studies and that this has resulted in a concomitant increase in the portion of the time that is allotted to this aspect of training during the three month programs. It is apparent from the transcripts that, in order to stay within the three month limit, many programs have made proportionate decreases in the aspects of training involving basic radioisotope handling techniques and actual experience handling unsealed radioactive materials. In order to maintain the previous level of training in these last two areas, the increase to program of six months duration is justified.

The concept of concurrent training in three month programs originated because such programs were offered as part of the residency training leading to certification by the American Board of Radiology (ABR). The ABR and AOBR programs have recognized the need for a minimum of six months of training and experience and have voluntarily taken action to restructure their programs accordingly. The new programs will be in place by July 1, 1984. NRC's action will maintain its criteria equal to the minimum standards set by the profession.

Comment: Technetium 99m is the only NRC-licensed material used in cardiovascular nuclear medicine studies and its properties make it uniquely safe for handling and use; therefore, an increase in the training and experience criteria is unwarranted.

Response: The criteria in Section V of Appendix A apply to physicians who use or supervise the use of molybdenum 99/technetium 99m generators and reagent kits to prepare Tc-99m labeled radiopharmaceuticals. These materials do present serious safety hazards if they are misused or improperly supervised. Tc-99m radiopharmaceuticals are also available in prepared, unit dose form, ready for patient injection. If a physician wishes to use this form for one or two types of diagnostic studies and accepts a limited possession limit, he or she may apply under the provisions of Appendix A, Section VI.

Comment: Through their training and experience with cardiac catherization and angiocardiography, cardiologists are already familiar with the principles of radiation exposure.

Response: Any hours of training that are specifically applicable to basic handling techniques using unsealed radioisotopes may be included in the physician's application to NRC.

Comment: There are important risks if cardiovascular nuclear medicine studies are performed by physicians who lack formal training in cardiovascular hemodynamics, coronary artery disease physiology, exercise testing and exercise physiology, arrhythmia detection, and cardiopulmonary resuscitation.

Response: The implication here is that NRC should not allow physicians with little or no training in cardiovascular disease to perform cardiovascular nuclear medicine studies. Training and experience criteria set by NRC relate specifically to safe handling of the reactor-produced radioisotopes that are used during the medical procedure. NRC does not regulate the quality of medical practice. Matters of medical competence have traditionally been addressed by the State medical licensing authorities and by peer review groups and professional societies within the medical profession. As stated previously, NRC published its decision to minimize intrusion into areas traditionally considered to be a part of the practice of medicine in 1979 (44 FR 8242).

Comment: If the training and experience criteria are increased to six months, the only aspect that would be augmented for cardiologists would be in the area of interpretation of scans.

Response: NRC believes that actual experience handling unsealed radioactive materials (Item B of Table 2, Appendix A) should be augmented. Presently there is little incentive for a physician-in-training to acquire such experience. It is the physician, however, who is listed on the NRC license as the authorized user and who may be listed as the radiation safety officer. The physician is responsible for the use of the material. To fulfill this responsibility, the physician must have had adequate "hands-on" experience during the training period.

Comment: Additional requirements will serve to discourage persons well trained in cardiology from participating in cardiovascular nuclear medicine and will therefore deprive the public of the expertise that cardiologists lend to these studies.

Response: The NRC licensing process does not prohibit cardiologists or any other physicians from being present, providing patient care, and participating in the diagnosis during cardiovascular nuclear medicine procedures. The license specifies only what physician (or physicians) may use or supervise the use of the radioactive material that is needed to perform the procedure. In many hospitals, these procedures are performed as a coordinated effort between the nuclear medicine physician and the cardiologist.

The revision to Appendix A of Regulatory Guide 10.8 is printed in its entirety below:

Appendix A—Acceptable Training and Experience for Medical Uses of Byproduct Material

I. General Criteria

Paragraphs 35.11 and 35.12 of 10 CFR Part 35 provide that the Commission will approve a license application for medical use if it determines, among other things, that the physician designated as the individual user has adequate experience in the proposed use, the handling and administration of isotopes, and where applicable the

clinical management of radioactive patients. In addition, § 30.33 of 10 CFR Part 30 requires that applicants be qualified by training and experience to use licensed material for the purpose requested in the application.

This appendix outlines training and experience criteria that the Commission, with the assistance of its Advisory Committee on the Medical Uses of Isotopes (ACMUI), has found acceptable for physicians [1] who wish to use byproduct material for human use.[2] We recommend that this training and experience be obtained in a formal, accredited training program for resident physicians.

Physician training and experience can be examined on a case-by-case basis. A physician wishing to use radioactive material but not having the training and experience described, may submit an application listing specific qualifications; and these will be reviewed by the Commission with the assistance of the ACMUI.

II. Acceptance of Medical Specialty Board Certification

Certification by the medical specialty boards listed in Table 1 will be accepted as evidence that a physician has had adequate training and experience for the corresponding procedures listed in the table.

III. Documenting Training and Experience

Supplements A and B of Form NRC 313M are used to document training and experience. Physicians who wish to qualify on the basis of board certification need only complete Items 1, 2, and 3 on Supplement A. Other applicants should submit Supplements A and B with all items completed. A separate Supplement B form should be completed and signed by each preceptor who provided training or supervised experience.

IV. Time Limitation on Acceptable Training and Experience

Training and experience must have been obtained within five years of the date of the application, or else the applicant must demonstrate continuing involvement in the procedures since the time of training.

V. Training for Routine Diagnostic Procedures (Groups I–III,[3] Including Cardiovascular Nuclear Medicine)

To qualify as adequately trained to use byproduct material listed in Groups I, II, and III of § 35.100, 10 CFR Part 35, a physician should have the training and experience listed in Table 2.

VI. Training for Specific Diagnostic Procedures

A physician who wishes to be authorized for only one or two specific diagnostic procedures should have training in basic radioisotope handling techniques and clinical experience commensurate with the types, quantities and uses of byproduct material being requested. Such requests will be examined case-by-case by the Commission with advice from the ACMUI.

VII. Training for Therapy Procedures Involving Radiopharmaceuticals (Groups IV and V)

A. Physicians who meet the criteria for Groups I–III may qualify to perform specific therapy procedures with the following clinical experience:

1. I–131 for treatment of hyperthyroidism and/or cardiac conditions:

Clinical experience in the diagnosis of thyroid function and active participation in the treatment of ten patients.

2. Soluble P–32 for treatment of polycythemia vera, leukemia, and/or bone metastases:

Active participation in the treatment of three patients with any combination of these three conditions.

3. Colloidal P–32 for intracavitary treatment:

Active participation in the intracavitary treatment of three patients using colloidal forms of either P–32 or Au–198.

4. I–131 for treatment of thyroid carcinoma:

Clinical experience in the [illegible] of thyroid function, per[illegible]tion in the treatment of te[illegible] hyperthyroidism and/or cardiac dysfunction, and active participation in the treatment of three patients with thyroid carcinoma.

5. Colloidal Au–198 for intracavitary treatment:

Active participation in the intracavitary treatment of three patients using colloidal forms of either Au–198 or P–32.

B. To perform *only* Group IV and V therapy procedures, physicians who do *not* meet the criteria for Groups I–III need to obtain the specific clinical experience listed in VII. A. above and, as a minimum:

	Hours
Training in basic radioisotope handling techniques specifically applicable to the use of unsealed sources for therapy procedures, including:	80
1. Radiation physics and instrumentation	25
2. Radiation protection	25
3. Mathematics pertaining to the use and measurement of radioactivity	10
4. Radiation biology	20

VIII. Training for Therapy Procedures Involving Sealed Sources (Group VI)

To qualify as adequately trained to use byproduct material listed in Group VI of § 35.100, 10 CFR Part 35, a physician should have the training and experience listed in Table 3.

When a physician is not board certified in one of the radiation therapy specialties listed in Table 1, his or her training will be reviewed with the assistance of the ACMUI. In addition to Supplements A and B as described in Section III. above, the applicant should submit letters of evaluation from each physician who served as preceptor. These letters of evaluation should describe the scope and extent of the applicant's training and experience and should state whether, in the opinion of the preceptor, the applicant is fully qualified to independently perform Group VI therapy procedures.

IX. Training for Physicians Wishing To Use SR–90 Eye Applicators Only

To qualify as adequately trained to use a Sr–90 eye applicator only, a physician should submit evidence of certification by one of the radiation therapy specialty boards listed in Table 1 or, as a minimum, evidence of:

A. Active practice in therapeutic radiology or opthalmology.

	Hours
B. Training in basic radioisotope handling techniques, including	24
a. Radiation physics and instrumentation	6
b. Radiation protection	6
c. Mathematics pertaining to the use and measurement of radioactivity	4
d. Radiation biology	8

This information should be submitted on Supplement A of Form NRC–313M. The hours listed next to each of the four subjects are suggested minimum values and should not be interpreted as specific requirements.

C. Active participation in the treatment of five patients (to be submitted on Preceptor Statement, Form NRC 313M, Supplement B).

"Active participation" should include supervised examination of patients, collaboration and calculations concerning the dose to be administered, administration of the dose to the patient, followup and study of patient case histories.

[1] As defined in 10 CFR 35.3

[2] Physicians authorized for Group II or III may also use Xenon-133.

TABLE I.—ACCEPTANCE OF MEDICAL SPECIALTY BOARD CERTIFICATION

Board	Specialty	Procedures
American Board of Nuclear Medicine	Nuclear Medicine	Groups I–V.
American Board of Radiology	Diagnostic Radiology with Special Competence in Nuclear Radiology	Groups I–III
	Radiology	Group VI.
	Therapeutic Radiology	Group VI.
American Osteopathic Board of Radiology.	Diagnostic Radiology [1]	Groups I–III.
	Radiology [1]	Groups I–III.
	Radiation Oncology	Groups V & VI.
British Faculty of Radiology [1]	Radiology	Group VI.
British Royal College of Radiology [1]	Radiology	Group VI.
Canadian Royal College of Physicians and Surgeons.	Therapeutic Radiology	Group VI.

[1] Board examination must have been passed within five years prior to the date of the application, or else the physician must demonstrate continuing involvement in the procedures since the time of the board certification.
[2] Applicants must also submit evidence of specialization in radiotherapy.

Table 2.—Minimum Acceptable Training for Routine Diagnostic Procedures (Groups I–III)

Concurrent Training in Six month Programs. The criteria specified below may be satisfied concurrently in a formal intergrated six-month training program. Note, however, that all of the requirements in Sections A., B. and C. must be fully intergrated into the program. Physicians who do not recieve their training in such a program should obtain the specified number of hours in each area:

	Hours
A. Training in basic radioisotope handling techniques *specifically applicable to the use of unsealed sources.* This training should consist of lectures, laboratory sessions, discussion groups, and supervised experience in a nuclear medicine laboratory in the following areas:	200
1. Radiation physics and instrumentation	100
2. Radiation protection	30
3. Mathematics pertaining to the use and measurement of radioactivity	20
4. Radiation biology	20
5. Radiopharmaceutical chemistry	30

The hours listed next to each of the five subjects above are suggested values and should not be interpreted as specific requirements.

B. Experience handling unsealed radioactive materials under the supervision of a qualified instructor (500 hours). This experience should cover the types and quantities of byproduct material requested in the application and should include:

1. Ordering, recieving and unpackaging radioactive materials safely, including performance of the related radiation surveys.

2. Calibration of dose calibrators and diagnostic instrumentation, and performance of operational checks on survey meters.

3. Calculation, preparation and calibration of patient doses, including radiation safety considerations.

4. Administration of doses to patients, including proper use of syringe shields.

5. Appropriate internal control procedures to prevent the misadministration of materials to patients.

6. Emergency procedures to handle and contain spilled materials safely, including related decontamination procedures.

7. Elution of Tc–99m from generator systems, assay and testing of the eluate for Mo–99 and alumina contamination, and processing the eluate with reagent kits to prepare Tc–99m labeled radiopharmaceuticals. (Required when physicians apply for Group III authorization.)

C. Supervised clinical training in an institutional nuclear medicine (or cardiovascular nuclear medicine) program (500 hours). The clinical training should cover all appropriate types of diagnostic procedures and should include:

1. Supervised examination of patients to determine the suitability for radioisotope diagnosis and recommendation on dosage to be prescribed.

2. Selection of the proper radiopharmaceutical and dosage, calculation of the related radiation dose and collaboration in the interpretation of the radioisotope test results.

3. Follow-up of patients when required.

4. Study and discussion of case histories with preceptor to establish the most appropriate diagnostic procedures, limitations, contraindications, etc.

Table 3.—Minimum Acceptable Training for Therapy Procedures Involving Sealed Sources (Group VI)

To qualify as adequately trained to use byproduct material listed in Group VI of § 35.100, 10 CFR Part 35, a physician should have:

	Hours
A. Training in basic radioisotope handling techniques *specifically applicable to the use of sealed sources for therapy procedures*, consisting of lectures, laboratory sessions, discussion groups, and supervised experience in the following areas.	200
1. Radiation physics and instrumentation	110
2. Radiation protection	40
3. Mathematics pertaining to the use and measurement of radioactivity	25
4. Radiation biology	25

The hours listed next to each of the four subjects above are suggested values and should not be interpreted as specific requirements.

B. Experience handling sealed radionuclide therapy sources under the supervision of a qualified instructor (500 hours). This experience should cover the types and quantities of byproduct material requested in the application and should include:

1. Ordering, receiving, and unpackaging sealed sources safely, including performance of the related radiation surveys.

2. Performance of operational checks on ion chambers and survey meters.

3. Safe handling of sealed sources during preparation, insertion and removal.

4. Quality control and emergency procedures.

C. Clinical training in Group VI procedures: Active practice in therapeutic radiology with a minimum of 3 years experience of which at least 1 year should have been in a formal training program approved by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association.

Dated at Silver Spring, Md this 27th day of September 1982.

For the Nuclear Regulatory Commission.

Richard E. Cunningham,

Director, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards.

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

JUN 16 1980

TO ALL NRC MEDICAL LICENSEES

Dear Licensee:

On September 28, 1979 we sent you a letter about an ALARA program to be implemented by December 4, 1979. We subsequently informed you that the implementation date was being delayed until March 4, 1980 in order to revise the model ALARA program to take into account many comments we received. Enclosed is a revised program which should be implemented by August 15, 1980. Additional time is being allowed so that licensees can make appropriate adjustments in their programs. During the past two months we have sought and considered the opinions and comments of many professionals in all areas involving the use of radiation in medicine. These discussions have led us to modify several program elements and to clarify others. The revised program reduces the administrative burden on the licensee while still meeting the original goal; to provide management a tool for maintaining occupational exposures ALARA and to provide NRC with a basis for inspecting ALARA programs.

The original program provided for establishment of an Action Level which was misinterpreted as a lowering of the maximum permissible dose limits. This was not, and is not, the intention of the program. The revised program applies the concept of "Investigational Levels" as defined in ICRP Report No. 26 "Recommendations of the Commission on Radiological Protection," January 17, 1977. The Investigational Levels in the revised program are not new dose limits but, as noted in the ICRP report, serve as check points above which the results are considered sufficiently important to justify further investigations. Investigational Levels are tools to be used by those in your institution responsible for the management of radiation safety programs. In determining compliance with regulations, NRC will be concerned with whether a review and/or investigation has been carried out rather than whether the Investigational Level has been exceeded.

There was concern on the part of some licensees that improved measurements would be required to comply with the program. Current methods of recording personnel exposures for purposes of compliance with 10 CFR 20, §20.101 are also adequate for use in determining the need for a review or investigation in accordance with the ALARA program.

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The new program has been revised to considerably reduce the paperwork burden. Actions to be taken under the revised ALARA program will be included in, or covered by, documentation already required to be maintained by licensees. Results of personnel monitoring are already recorded at least quarterly on Form NRC-5 or an equivalent form as required by 10 CFR 20, §20.401. Results of investigations you make when an Investigational Level is exceeded should be made part of the Radiation Safety Committee minutes, thus eliminating the need for a separate record. A private practice nuclear medicine licensee would need to maintain review or investigation records but since the majority of these licensees employ few staff requiring personnel monitoring this obligation should create no undue burden.

In the original program, reference was made to guidance provided by U.S. Nuclear Regulatory Guides 8.10 and 8.18. Some interpreted this as a commitment for strict adherence to all aspects of these guides. The guidance given in these documents should be reviewed to determine if the benefits, in terms of additional dose reductions, are justified by the cost of those reductions. Both guides are now used by the NRC licensing staff as part of the basis for evaluating license applications and radiation safety programs. NRC will continue to consider equivalent alternative methods of complying with the principles contained in the guides and with specified portions of the Commission's regulations. You should be aware that these are only two of many sources of information available to guide you in maintaining occupational radiation exposures at medical institutions ALARA. Another good reference source available from NRC is NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures At Medical Institutions As Low As Reasonably Achievable." The model program applies only to the radiation exposure of personnel arising in whole or in part from NRC licensed byproduct materials. Expanding the program to cover other radiation workers in your institution is an option available to you.

The revised model of an ALARA program is provided as an enclosure to this letter. Your institution should adopt this program or develop an equivalent alternative program for review by NRC. After August 15, 1980 you will submit your program when you submit your next renewal or significant amendment application. If necessary for clarification or emphasis, you are encouraged to add explanatory text to the model program. If accepted, your program will be incorporated as a condition of your NRC license. There is no need to submit your ALARA program to NRC *until* such time as you amend or renew your license. However, you should implement the program within your institution as soon as possible, if you have not already done so. Those licensees who have already submitted programs in accordance with the original model or an equivalent alternative program may either resubmit a revised program or maintain the program as proposed unless notified otherwise by NRC.

I would like to emphasize that the ALARA concept is not new and that most of the commitments in the enclosed formal program are already adhered to by those who maintain good radiation safety programs.

Sincerely,

William J. Dircks, Director
Office of Nuclear Material Safety
and Safeguards

Approved by GAO
B-1d0225 (R0658)
Expires 83-05-31

Model Program for Maintaining Occupational
Radiation Exposures at Medical Institutions ALARA

_____
(Licensee's Name)

_____
(Date)

I. Management Commitment

a. We, the management of this (medical facility, hospital, etc.) are committed to the program described in this paper for keeping exposures (individual and collective) as low as reasonably achievable (ALARA). In accord with this commitment, we hereby describe an administrative organization for radiation safety and will develop the necessary written policy, procedures and instructions to foster the ALARA concept within our institution. The organization will include a Radiation Safety Committee (RSC)[1] and a Radiation Safety Officer (RSO).

b. We will perform a formal annual review of the radiation safety program including ALARA considerations. This shall include reviews of operating procedures and past exposure records, inspections, etc., and consultations with the radiation protection staff or outside consultants.

c. Modification to operating and maintenance procedures and to equipment and facilities will be made where they will reduce exposures unless the cost, in our judgement, is considered to be unjustified. We will be able to demonstrate, if necessary, that improvements have been sought, that modifications have been considered, and that they have been implemented where reasonable. Where modifications have been recommended but not implemented, we will be prepared to describe the reasons for not implementing them.

d. In addition to maintaining doses to individuals as far below the limits as is reasonably achievable, the sum of the doses received by all exposed individuals will also be maintained at the lowest practicable level. It would not be desirable, for example, to hold the highest doses to individuals to some fraction of the applicable limit if this involved exposing additional people and significantly increasing the sum of radiation doses received by all involved individuals.

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[1] Private practice physician licenses do not include a RSC.

II. Radiation Safety Committee (RSC)[2]

a. Review of Proposed Users and Uses

1. The RSC will thoroughly review the qualifications of each applicant with respect to the types and quantities of materials and uses for which he has applied to assure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

2. When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA, and shall have incorporated the use of special equipment such as syringe shields, rubber gloves, etc., in his proposed use.

3. The RSC will ensure that the user justifies his procedures and that dose will be ALARA (individual and collective).

b. Delegation of Authority

(The judicious delegation of RSC authority is essential to the enforcement of an ALARA program.)

1. The RSC will delegate authority to the RSO for enforcement of the ALARA concept.

2. The RSC will support the RSO in those instances where it is necessary for the RSO to assert his authority. Where the RSO has been overruled, the Committee will record the basis for its action in the minutes of the Committee's quarterly meeting.

c. Review of ALARA Program

1. The RSC will encourage all users to review current procedures and develop new procedures as appropriate to implement the ALARA concept.

2. The RSC will perform a quarterly review of occupational radiation exposure with particular attention to instances where Investigational Levels in Table I below are exceeded. The principle purpose of this review is to assess trends in occupational exposure as an index of the ALARA program quality and to decide if action is warranted when Investigational Levels are exceeded (see paragraph VI).[3]

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[2]The RSO on private practice physician licenses will assume the responsibilities of the RSC under Section II

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[3]The NRC has emphasized that the Investigational Levels in this program are not new dose limits but, as noted in ICRP Report 26, "Recommendations of the International Commission on Radiological Protection", serve as check points above which the results are considered sufficiently important to justify further investigations.

3. The RSC will evaluate our institution's overall efforts for maintaining exposures ALARA on an annual basis. This review will include the efforts of the RSO, authorized users, and workers as well as those of management.

III. Radiation Safety Officer (RSO)

a. Annual and Quarterly Review

1. Annual review of the Radiation Safety Program. The RSO will perform an annual review of the Radiation Safety Program for adherence to ALARA concepts. Reviews of specific procedures may be conducted on a more frequent basis.

2. Quarterly review of Occupational Exposures. The RSO will review at least quarterly the external radiation exposures of authorized users and workers to determine that their exposures are ALARA in accordance with the provisions of paragraph VI of this program.

3. Quarterly review of records of Radiation Level Surveys. The RSO will review radiation levels in unrestricted and restricted areas to determine that they were at ALARA levels during the previous quarter.

b. Education Responsibilities for an ALARA Program

1. The RSO will schedule briefings and educational sessions to inform workers of ALARA program efforts.

2. The RSO will assure that authorized users, workers and ancillary personnel who may be exposed to radiation will be instructed in the ALARA philosophy and informed that management, the RSC and the RSO are committed to implementing the ALARA concept.

c. Cooperative Efforts for Development of ALARA Procedures

Radiation workers will be given opportunities to participate in formulation of the procedures that they will be required to follow.

1. The RSO will be in close contact with all users and workers in order to develop ALARA procedures for working with radioactive materials.

2. The RSO will establish procedures for receiving and evaluating the suggestions of individual workers for improving health physics practices and encourage the use of those procedures.

d. Reviewing Instances of Deviation from Good ALARA Practices

The RSO will investigate all known instances of deviation from good ALARA practices; and, if possible, determine the causes. When the cause is known, the RSO will require changes in the program to maintain exposures ALARA.

IV. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

1. The authorized user will consult with, and receive the approval of, the RSO and/or RSC during the planning stage before using radioactive materials for a new procedure.

2. The authorized user will evaluate all procedures before using radioactive materials to ensure that exposures will be kept ALARA. This may be enhanced through the application of trial runs.

b. Responsibility of the Authorized User to Those He Supervises

1. The authorized user will explain the ALARA concept and his commitment to maintain exposures ALARA to all of those he supervises.

2. The authorized user will ensure that those under his supervision who are subject to occupational radiation exposure are trained and educated in good health physics practices and in maintaining exposures ALARA.

V. Persons Who Receive Occupational Radiation Exposure

a. The worker will be instructed in the ALARA concept and its relationship to his working procedures and work conditions.

b. The worker will know what recourses are available if he feels that ALARA is not being promoted on the job.

VI. Establishment of Investigational Levels In Order to Monitor Individual Occupational External Radiation Exposures

This institution (or private practice) hereby establishes Investigational Levels for occupational external radiation exposure which, when exceeded, will initiate review or investigation by the Radiation Safety Committee and/or the Radiation Safety Officer. The Investigational Levels that we have adopted are listed in Table I below. These levels apply to the exposure of individual workers.

Table 1

		Investigational Levels - (mrems per calendar quarter)	
		LEVEL I	LEVEL II
1.	Whole body; head and trunk; active blood-forming organs; lens of eyes; or gonads	125	375
2.	Hands and forearms; feet and ankles	1875	5625
3.	Skin of whole body*	750	2250

* Not normally applicable to nuclear medicine operations except those using significant quantities of beta emitting isotopes.

The Radiation Safety Officer will review and record on Form NRC-5, Current Occupational External Radiation Exposures, or an equivalent form (e.g. dosimeter processor's report), results of personnel monitoring, not less than once in any calendar quarter, as is required by 10 CFR 20, §20.401. The following actions will be taken at the Investigational Levels as stated in Table 1:

a. Quarterly exposure of individuals to less than Investigational Level I.

Except when deemed appropriate by the RSO, no further action will be taken in those cases where an individual's exposure is less than Table I values for the Investigational Level I.

b. Personnel exposures equal to or greater than Investigational Level I, but less than Investigational Level II.

The RSO will review the exposure of each individual whose quarterly exposures equal or exceed Investigational Level I. He will report the results of his reviews at the first RSC meeting following the quarter when the exposure was recorded. If the exposure does not equal or exceed Investigational Level II, no action related specifically to the exposure is required unless deemed appropriate by the Committee. The Committee will, however, consider each such exposure in comparison with those of others performing similar tasks as an index of ALARA program quality and will record the review in the Committee minutes.

c. Exposure equal to or greater than Investigational Level II.

The RSO will investigate in a timely manner the cause(s) of all personnel exposures equaling or exceeding Investigational Level II and, if warranted, take action. A report of the investigation, actions taken, if any, and a copy of the individual's Form NRC-5 or its equivalent will be presented to the RSC at the first RSC meeting following completion of the investigation. The details of these reports will be recorded in the Committee minutes. Committee minutes will be sent to the management of this institution for review. The minutes, containing details of the investigation, will be made available to NRC inspectors for review at the time of the next inspection.

d. Re-establishment of an individual occupational worker's Investigational Level II Above That Listed In Table I.

In cases where a worker's or a group of worker's exposures need to exceed Investigational Level II, a new, higher Investigational Level II may be established on the basis that it is consistent with good ALARA practices for that individual or group. Justification for a new Investigational Level II will be documented.

The Radiation Safety Committee will review the justification for, and will approve, all revisions of Investigational Levels II. In such cases, when the exposure equals or exceeds the newly established Investigational Level II, those actions listed in paragraph c above will be followed.

VII. Signature of Certifying Official[4]

I hereby certify that this institution (or private practice), has implemented the ALARA Program set forth above.

_____
Signature

_____
Name (print or type)

_____
Title

Institution (or Private Practice) Name and Address:

_____

[4] The individual who is authorized to make commitments for the administration of the institution (e.g., hospital administrator, etc.) or, in the case of a private practice, the licensed physician.