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OFFICE OF NUCLEAR REGULATORY RESEARCH

DRAFT REGULATORY GUIDE AND VALUE/IMPACT STATEMENT

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GUIDE FOR THE PREPARATION OF APPLICATIONS FOR LICENSES IN MEDICAL TELETHERAPY PROGRAMS

1. INTRODUCTION

1.1 Purpose of Guide

This guide describes the type and extent of information needed by the Nuclear Regulatory Commission (NRC) to evaluate an application for a specific license for the possession of byproduct material (reactor-produced radionuclides) in a teletherapy unit for the treatment of human beings. This type of license is provided for under § 35.13, "Specific Licenses for Human Use of Byproduct Material in Sealed Sources," of 10 CFR Part 35, "Human Uses of Byproduct Material."

The NRC will usually issue a single byproduct material license to cover an institution's teletherapy program. An institution's other medical programs will be covered in a separate license.

The applicant should carefully study this guide and the regulations (see Section 1.2 of this guide) and should submit all information requested. The NRC will request additional information when necessary to provide reasonable assurance that the applicant has established an adequate radiation safety program. Such requests will delay final action on the application.

1.2 Applicable Regulations

In addition to 10 CFR Part 35, other regulations pertaining to this type of license are found in 10 CFR Part 19, "Notices, Instructions and Reports to Workers; Inspections"; 10 CFR Part 20, "Standards for Protection Against

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This regulatory guide and the associated value/impact statement are being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. They have not received complete staff review and do not represent an official NRC staff position.

Public comments are being solicited on both drafts, the guide (including any implementation schedule) and the value/impact statement. Comments on the value/impact statement should be accompanied by supporting data. Comments on both drafts should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by JUN 15 1982

Requests for single copies of draft guides (which may be reproduced) or for placement on an automatic distribution list for single copies of future draft guides in specific divisions should be made in writing to the U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Director, Division of Technical Information and Document Control.

Radiation"; 10 CFR Part 21, "Reporting of Defects and Noncompliance"; 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material"; 10 CFR Part 40, "Domestic Licensing of Source Material"; and 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended."

1.3 As Low As Is Reasonably Achievable (ALARA)

Paragraph 20.1(c) of 10 CFR Part 20 states, "...persons engaged in activities under licenses issued by the Nuclear Regulatory Commission pursuant to the Atomic Energy Act of 1954, as amended, and the Energy Reorganization Act of 1974 should, in addition to complying with the requirements set forth in this part, make every reasonable effort to maintain radiation exposures, and releases of radioactive materials in effluents to unrestricted areas, as low as is reasonably achievable." Regulatory Guide 8.10, "Operating Philosophy for Maintaining Occupational Radiation Exposures As Low As Is Reasonably Achievable," provides the NRC staff position on this important subject. Regulatory Guide 8.18, "Information Relevant to Ensuring That Occupational Radiation Exposures at Medical Institutions Will Be As Low As Reasonably Achievable," provides ways of applying the ALARA philosophy in medical institutions. License applicants should give consideration to the ALARA philosophy, as described in Regulatory Guides 8.10 and 8.18, in the development of plans for work with radioactive materials. NUREG-0267, "Principles and Practices for Keeping Occupational Radiation Exposures at Medical Institutions As Low As Reasonably Achievable," contains information and references useful in establishing radiation safety programs to maintain exposures ALARA in medical institutions.

Applications for new licenses, renewal requests, and requests for significant license amendments (i.e., to broaden programs, to increase possession limits) should be accompanied by a description of the applicant's or licensee's ALARA program. Item 21 and Appendix I of this guide provide further information about acceptable ALARA programs.

2. LICENSE FEES

An application fee is required for most types of licenses and renewals and amendments to licenses. The applicant should refer to § 170.12, "Payment of Fees," and § 170.31, "Schedule of Fees for Materials Licenses and Other Regulatory Services," of 10 CFR Part 170 to determine the amount of the fee that must accompany the application. Review of the application will not begin until the proper fee is received by the NRC. Checks should be made payable to the U.S. Nuclear Regulatory Commission.

3. FILING AN APPLICATION

A license application for a specific license for a teletherapy program should be submitted on Form NRC-313T, "Application for Materials License -- Teletherapy," (see Exhibit A). The applicant should complete all items on the application form in sufficient detail for the NRC staff to determine that the applicant's equipment, facilities, and radiation protection program are adequate to protect health and minimize danger to life and property. Drawings, diagrams, and tables should be used when information may be presented more adequately or conveniently by such means. These illustrations should be located in the section where they are first referenced. Care should be taken to ensure that all information presented in drawings is legible, that symbols are defined, and that drawings are not reduced to the extent that they cannot be read by unaided normal eyes.

Since the space provided on Form NRC-313T is limited, the applicant should append separate sheets of paper for Items 10 through 21 listed in the form. Each separate sheet should contain the item number and the application date in the lower right corner. In addition, each sheet of text should have physical dimensions of 8½ x 11 inches; drawings and graphics should have the same dimensions, but a larger size is acceptable provided the finished copy when folded twice does not exceed 8½ x 11 inches. Paper stock and ink should be of suitable quality for handling and for reproduction.

One copy of the application, with all attachments, should be retained by the applicant because the license will require as a condition that the licensee follow the statements and representations set forth in the application and any

supplement to it. The original and one copy should be mailed to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555.

4. CONTENTS OF AN APPLICATION

The following paragraphs explain the information requested on Form NRC-313T (Exhibit A). If, after careful review of this guide, applicants have specific questions, the Material Licensing Branch may be contacted for clarification.

Item 1.a. The applicant should enter the name, mailing address, and telephone number (including area code) of the applicant. If the teletherapy unit is located on the premises of a medical institution, the license will be issued in the name of the medical institution.

Item 1.b. The applicant should specify the actual location of the teletherapy source. This location should be clearly identified by street address, building name, room number, etc. If no street address is available, the applicant should provide a description that designates the location accurately.

Item 2. The applicant should enter the name and telephone number (including area code) of the individual to be contacted about this application.

Item 3. The applicant should indicate whether this is an application for a new license, an amendment, or a renewal.

Item 4. The applicant should list the full names of all individuals who will use or supervise the use of the teletherapy unit. This list should include the physicians who will actually use the teletherapy unit or direct the use of the unit by technologists or other paramedical personnel, or who will supervise physicians-in-training in a program of training in therapeutic radiology. Nonphysicians may be authorized to use the teletherapy unit for nonhuman use (e.g., instrument calibration).

Authorized physician-users have the following responsibilities:

a. Examination of the patient and his or her medical records to determine if radiation therapy is appropriate,

b. Prescription of the radiation dose and how it is to be administered (e.g., 5000 rads to be delivered at the rate of 200 rads per day under specified conditions of field size, distance, angle, etc.),

c. Regular review of the patient's progress and modification of the originally prescribed dose as warranted by the patient's reaction to the radiation,

d. Actual use of, or direction of technologists or other paramedical personnel in the use of, the teletherapy unit, and

e. Provision of necessary followup medical care.

Items a through d may be delegated to physicians who are in training under the supervision* of an authorized physician-user.

Properly trained technologists or other paramedical personnel, as evidenced by state licensing, board registry, or completion of a training program, may administer radiation from the teletherapy source under a user's direction where permitted under applicable Federal, State, or local laws.

Item 5. The applicant should state the name and title of the person designated by, and responsible to, the applicant's management for the coordination of the applicant's radiation safety program (sometimes designated the "Radiation Safety Officer").

Items 6 and 7. In Item 6, the applicant should identify each sealed source to be used in teletherapy by element and mass number, the name of the manufacturer, the manufacturer's source model number, the maximum activity per source,

*Supervision means that the physician-user has adequately instructed the physician(s)-in-training in the specific human use and has ascertained that they are receiving training in the safe use of these materials in humans. It also means that the physician-user periodically reviews the work of those supervised and assures himself that proper medical records are made of each use. It does not mean that the physician-user is necessarily present for each teletherapy treatment.

and the number of sources. Normally, the number of sources specified will be twice the number of sources that will actually be used. In this manner, a licensee will automatically be licensed for additional sources that may be temporarily stored at the facility during source exchange.

In Item 7, the applicant should specify the manufacturer's name and model number of the teletherapy unit in which each teletherapy source will be housed. The teletherapy units should be keyed alphabetically to the sources listed in Item 6, i.e., the teletherapy unit whose source is listed in Item 6-A should be listed in Item 7-A, etc., as shown in Figure 1.

Figure 1

6. SEALED SOURCES TO BE USED IN TELETHERAPY UNITS *(Attach supplemental pages if necessary)*

	BYPRODUCT MATERIAL *(Element and Mass No.)*	NAME OF SOURCE MANUFACTURER	SOURCE MODEL NUMBER	MAXIMUM ACTIVITY PER SOURCE	NUMBER OF SOURCES
A.	Cobalt-60	ABC Corporation	567	5000 Curies	2
B.	Cesium-137	XYZ Industries	5	4500 Curies	2
C.					

7. TELETHERAPY UNITS *(Attach supplemental pages, if necessary)*

	NAME OF MANUFACTURER *(Include description, if unit is custom made)*	MODEL NUMBER
A.	ABC Corporation	89
B.	Sierra Medical Products	123456
C.		

Item 8. The applicant should specify whether the teletherapy source will be for human use only or for other additional uses. If other, specify the uses on a separate page. The uses should be keyed alphabetically to the sources listed in Item 6.

Item 9 Personnel Monitoring Equipment. The applicant should specify the type of personnel monitoring device (e.g., film badge or thermoluminescence dosimeter) that will be used and the names and addresses of the suppliers that may be used. The frequency for changing the monitoring devices should also be specified.

If pocket chambers or pocket dosimeters are also used, the manufacturer's name, model number, and the range should be identified. The applicant should further specify the frequency of reading of the dosimeters and the procedures for maintenance and calibration.

Items 10 through 21. For Items 10 through 21, the applicant should check the appropriate box(es) and submit a detailed description of all the requested information. Each item should begin on a separate page. The item number and the date of the application should be identified in the lower right corner of each page. If an appendix to this guide will be followed, it is not necessary to submit the pages of the appendix; the applicant needs only to indicate at the top of page 2 of the application form the number and date of this regulatory guide.

Item 10 Medical Isotopes Committee. In accordance with paragraph 35.11(b) of 10 CFR Part 35, an institution applying for a byproduct material license for human use is required to establish a medical isotopes committee. This committee, which should contain at least three members, evaluates all proposals for research, diagnosis, and therapeutic use of radioisotopes. The following information should be submitted:

a. The responsibility and duties of the committee,
b. The meeting frequency of the committee (at least quarterly), and
c. The name and specialty of each member of the committee.

Appendix A to this guide contains an example of typical responsibilities, duties, and membership specialties for a medical isotopes committee. Indicate by checking the appropriate box in Item 10 that the responsibilities, duties, and meeting frequency will be as described in Appendix A or that alternatives are being proposed. If the responsibilities, duties, or meeting frequency will be different from those described in Appendix A, the applicant should submit a complete description. The name and specialty of each member of the committee should be submitted in all cases. Medical institutions with an existing medical isotopes committee need not establish a second committee. However, the existing committee's duties and responsibilities should be amended to include teletherapy.

Item 11 Training and Experience

a. Authorized Users

If a physician has been previously authorized to perform teletherapy treatment, it is necessary to submit only the previous license number (if issued by the AEC or NRC) or a copy of the license (if issued by an Agreement State).

If a physician has not been previously authorized to perform teletherapy treatment, the applicant should state where the physician is licensed to practice medicine and submit a complete description of his or her training and experience on Supplements A and B to Form NRC-313T (see Exhibits B and C). Criteria for acceptable training and experience are contained in Appendix B.

b. Radiation Safety Officer

If the Radiation Safety Officer (RSO) is not one of the individuals named in Item 4, the applicant must submit a complete description of the individual's training and experience. Supplement A to Form NRC-313T may be used for the description of the RSO's training and experience. If the RSO is not a full-time paid employee of the applicant (e.g., a consultant or other service contractor), a description of the time this individual will devote to the applicant's program and the duties and responsibilities is also needed. In this situation an on-site person who will assume responsibilities for radiation safety when the designated RSO is not on the premises must also be appointed. The applicant must then specify the name, training and experience, and assigned responsibilities of this individual. Supplement A to NRC 313T may be used.

Item 12 Instrumentation. The applicant should describe the instrumentation that is available for the teletherapy program. Such instrumentation should include the following:

a. A portable survey meter on the licensee's premises;

b. A beam-on radiation monitor permanently mounted in the teletherapy room and equipped with backup battery power supply;

c. A dosimetry system if the facility performs its own full calibrations or spot checks as required by § 35.21 and § 35.22; and

d. An instrument of sufficient sensitivity to count wipe samples if the facility will perform its own leak tests (a low-level survey meter is usually not acceptable for this purpose).

In addition, a high-range survey meter should be available either on the premises or through a consultant.

Appendix C of this guide contains a form that may be used to describe these instruments. If this form is used, it should be referenced in the application at Item 12. If the form is not used, equivalent information should be attached.

Item 13 Instrument Calibration

a. Calibration of Portable Survey and Leak-Test Instruments

If an applicant wishes to perform in-house calibration of portable survey and leak-test instruments, the following information should be submitted:

1. The type (i.e., radionuclide, manufacturer's name, and model number) and activity of the source to be used or exposure rates at fixed distances from the source as certified by measurements involving direct comparisons with sources or dosimeters calibrated at the National Bureau of Standards;

2. The accuracy of the source;*

3. The frequency of calibration of survey and leak-test instruments;

4. The specific step-by-step procedures to be used for instrument calibration, including radiation safety procedures to be followed during use of the calibration source; and

5. The name and pertinent experience of each individual who will perform instrument calibration.

*The maximum deviation of the nominal value of the source from the true value. This information is normally provided by the manufacturer.

Specific instructions and procedures should be included in the operating procedures. A description for an acceptable procedure for calibrating survey instruments is provided in Appendix D and may be referenced in Item 13 of the application. The form in Appendix D, "Calibration of Survey Instruments," may be completed to furnish this information. Procedures for calibrating leak-test instruments should be described in detail.

If instrument calibrations will be performed by a service organization or individual, the applicant should include (1) the name, address, and NRC or Agreement State license number of the organization or individual, (2) a description of the calibration procedure, and (3) a description of the instrument calibration data that will be furnished to the applicant.

b. Calibration of Beam-On Monitor

While no calibration procedures specifically apply to beam-on monitors, the applicant should describe the procedures for ensuring that the monitor is operating properly. These procedures should be performed daily and may be incorporated in the procedures for other checks.

c. Calibration of Dosimetry Systems

For dosimetry systems used for teletherapy calibration or spot checks, § 35.23 requires that these systems be calibrated every two years by the National Bureau of Standards or by a regional calibration laboratory accredited by the American Association of Physicists in Medicine. Alternatively, systems used solely for spot checks may be calibrated by a direct intercomparison with a system calibrated by the aforementioned calibration services.

Item 14 Facilities and Equipment. The applicant must provide a detailed description of the facilities and equipment of the teletherapy installation. Such description should include the following:

a. Annotated plan and elevation drawings or sketches of the teletherapy room and its surroundings showing:

1. The scale to which the drawings are made (the applicant should use the same scale for all drawings; recommended scale is 1/4 inch = 1 foot);

2. The direction of north;

3. The location of the teletherapy unit and source within the room;

4. The type, thickness, and density of shielding materials used on all sides of the room, including floor and ceiling;

5. The location of entrance, windows, conduits, and other penetrations and voids in the shielding materials;

6. The nature of and distances to all areas adjacent to, above, and below the treatment room (plan and elevation drawings are particularly helpful in showing the relationship between the teletherapy facility and the roof and the rest of the building);

7. The type of use of all areas adjoining the treatment room, including those above and below (areas should be specified as restricted or unrestricted as defined in § 20.3); and

8. The height of earth against outside walls, if applicable.

b. Description of the systems that will be used to view and communicate continuously with the patient. If a shielded viewing window is used, the applicant should specify the thickness, density, and type of material. If electronic means are used to view or communicate with the patient (e.g., TV monitor, intercom), the applicant should specify the backup system that will be used in the event the system malfunctions or should confirm that patient treatment will be suspended until the systems are repaired and functioning again.

c. Description of area security safeguards (e.g., locks, signs, warning lights and alarms, and interlocking systems) for each teletherapy treatment room and the method of controlling occupancy of all restricted areas. Each door leading into the teletherapy room must be provided with an interlock to control the "on-off" mechanism of the teletherapy unit. The interlock must cause the source to move to the "off" condition if the door is opened when the source is exposed. The mechanism must be so wired that the source cannot be returned to the "on" condition until the door is closed and the system is reset at the control.

If other radiation-producing equipment (e.g., linear accelerator, x-ray machine) is located in the teletherapy room, the applicant should describe

the steps that will be taken to ensure that no two units can be operated simultaneously.

Item 15 Beam Stops. It may be necessary to restrict use of the teletherapy unit's primary beam because the treatment room walls, ceiling, or floor will not adequately shield adjacent areas from direct or scattered radiation. Electrical, mechanical, or other physical means (rather than administrative controls) must be used to limit movement or rotation of the unit.

The applicant should specify the mechanical or electrical beam stops that are operational and restrict beam orientation, the direction in which the teletherapy head can be moved, and the maximum angle (from vertical) of the beam orientation in each direction. The applicant should identify the angle orientation convention (e.g., 0° is vertical toward the floor; 90°, horizontal toward the east wall; 180°, vertical toward the ceiling; and 270°, horizontal toward the west wall). If the teletherapy unit has an integral beam absorber (beam catcher), the applicant should provide similar information for those orientations in which (a) the primary beam is directed toward the integral beam absorber and (b) the primary beam is directed away from the integral beam absorber. The applicant may use sketches to describe beam stops that limit the use of the primary beam.

Item 16 Shielding Evaluation. The facility must be designed so that the levels of radiation in any unrestricted area (as defined in 10 CFR Part 20) adjacent to the facility meet the requirements of paragraph 20.105(b). This paragraph requires that radiation levels in unrestricted areas be such that a person in the area will receive a radiation dose exceeding neither 2 millirems in any 1 hour nor 100 millirems in any seven consecutive days if the person were continuously present in the area.

To demonstrate compliance with this regulation, the applicant should submit calculations of the maximum radiation levels that will exist in each restricted and unrestricted area adjacent to and above and below the shielded facility. These calculations should clearly indicate all parameters used in the calculations and should consider contributions from primary, leakage, and scattered radiation. These parameters will include beam orientation, maximum field size, scatter angles, scatter ratios, distance to scatterer, distances to areas of concern, type of material and thickness of barrier, attenuation factor of the

barrier, etc. The calculations should show maximum radiation levels to be expected in any one hour and in any one week. In this regard, the applicant should give anticipated workload data (e.g., maximum number of patients treated per hour and per week, treatment time per patient, "on time" per hour and per week, average dose per patient). It should be noted that continuous occupancy must be used in making these calculations. The applicant should refer to Appendix E for a discussion of restricted and unrestricted areas, and submit information indicated in Section 2 of Appendix E for each restricted area.

If the beam absorber is not used for all treatments, radiation levels must be calculated on the basis of an unattenuated primary beam where appropriate.

Calculated radiation levels in each area adjacent to the teletherapy room, including those above and below, should be indicated on a supplementary sheet keyed to the drawings.

The applicant should be aware that Conditions 18 and 19 of the license (see Exhibit D) will require surveys and tests to be made prior to initiation of treatment and following any changes made in the use of the teletherapy unit or the treatment room that could result in increased radiation levels outside the room. The results of these surveys and tests must be reported to the Nuclear Regulatory Commission within 30 days after installation of the source or any changes. Appendix F describes the minimum information and measurements that should be included in the report to meet these license conditions.

Item 17 Operating and Emergency Procedures. The applicant should describe the operating procedures that will be followed by teletherapy personnel. Appendix G describes items and procedures that should be included.

In addition, the applicant should submit a copy of emergency procedures to be followed in the event of a malfunction of a teletherapy unit. Appendix G describes an acceptable emergency procedure and may be referenced in the application.

Item 18 Instruction to Personnel. The applicant should describe the program of instruction that will be given to all personnel who work with or in the vicinity of the teletherapy facility, including ancillary personnel (e.g., clerical, housekeeping, nursing, security personnel). Training should be provided:

a. Before a new employee assumes duties with or in the vicinity of radioactive materials;
b. During the annual refresher training for all employees; and
c. Whenever a significant change occurs in duties, regulations, or terms of the license.

Appendix H describes the elements of an acceptable training program and a schedule for conducting training. The applicant should either indicate by checking the appropriate box in Item 18 of Form NRC-313T that the training program and training schedule in Appendix H will be followed or submit a copy of an equivalent program and schedule.

Item 19 Leak Testing. The applicant should submit a description of the leak-testing program for the sealed sources:

a. If the applicant will use the services of a consultant or commercial organization that is licensed by the Commission or an Agreement State to take the necessary test samples (smears), to evaluate the samples, and to report the results to the customer, the name, address, and license number of the consultant or commercial organization should be specified.

b. If the applicant wishes to be licensed by the Commission to use a commercially available leak-test kit, the application should identify each kit to be used by designating the kit supplier and the kit model number. Only leak-test kits that are identified will be authorized. The application should also identify those individuals who will perform the leak test (using the kit).

c. If an applicant wishes to be licensed by the Commission to perform in-house leak tests, including taking and evaluating the smears, the applicant should provide the following information:

1. A description of the instrumentation to be used in evaluating the smears, including its sensitivity and accuracy (survey instruments are generally not designed for such measurements and may not be acceptable for this use);

2. A description of the calibrating and standardizing procedures with a sample calculation showing conversion of results to the required microcurie units;

3. A description of the material to be used in taking the smears and the points on the equipment that will be smeared (smears are not normally taken directly from the surface of a source, but rather from the nearest accessible surface, e.g., collimator blades);

4. A description of the radiation safety procedures to be followed during the smearing process and the method for handling and disposing of the smears; and

5. A description of the pertinent training and experience of each person who will take or evaluate the smears.

Distributors of sealed sources usually supply a certificate with each source giving the results and date of the last leak test performed on a source. If such a certificate is not received, the source may not be used until a leak test has been performed and the results of the test have been received showing that the source is not leaking or contaminated. Thereafter, the source must be tested for leakage and contamination at intervals not to exceed 6 months. License conditions require that records of the testing of each source identifying the source tested, date of the test, and the results of the test in units of microcuries be maintained for Commission inspection.

Item 20 Qualified Expert. If the individual who will perform the full calibration of the teletherapy unit does not meet the qualifications specified in § 35.24, the applicant should provide a statement of the individual's training and experience for evaluation. This statement should include all of the information requested in Footnote 2, § 35.24 of 10 CFR Part 35.

Item 21 ALARA Program. Applications for new licenses, renewal requests, and requests for significant license amendments (e.g., to broaden programs or to increase possession limits) should be accompanied by a description of the applicant or licensee's ALARA program. By checking the appropriate box in Item 21 of the application, applicants should indicate whether the model program described in Appendix I to this guide has been adopted. Alternatively, an equivalent program may be developed and submitted for NRC review.

5. AMENDMENTS TO LICENSES

Licensees are required to conduct their programs in accordance with statements, representations, and procedures contained in the license application and supporting documents. The license must therefore be amended if the licensee plans to make any changes in the facilities, equipment (including types of monitoring and survey instruments), procedures, authorized users, or radiation safety officer.

Applications for license amendments must be filed on Form NRC-313T. The application should identify the license by number and should clearly describe the exact nature of the changes, additions, or deletions. References to previously submitted information and documents should be avoided. Appendix J provides guidance for the most commonly requested license amendments.

An original and two copies of the application for amendment should be prepared. The applicant should retain one copy and should submit the original and one copy to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. A fee must accompany amendment applications as indicated in Section 2 of this guide.

6. RENEWAL OF A LICENSE

An application for renewal of a license should be filed at least 30 days prior to the expiration date. Timely submission will ensure that the license does not expire until final action on the application has been taken by the NRC as provided for in paragraph 30.37(b) of 10 CFR Part 30.

Renewal applications should be filed on Form NRC-313T appropriately supplemented, should contain complete and up-to-date information about the applicant's current program, and should meet all licensing and regulatory requirements in effect at the time of renewal. Appendix J provides guidance for license renewals.

To facilitate the review process, the application for renewal should provide the information requested in Appendix J without reference to previously submitted documents and information (except for previously approved users). If such references cannot be avoided, they are acceptable provided:

a. The reference is made in response to a particular item of required information,
b. The reference is clear and specific (e.g., title of document, date of submission, page and paragraph), and
c. The referenced document contains all information required for a particular item at the time of renewal.

Prepare an original and two copies of the application. Retain one copy of the application, with all attachments, because the license will require, as a condition, that the institution follow the statements and representations set forth in the application and any supplement to it. Mail the original and one copy to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. A fee must also accompany renewal applications as indicated in Section 2 of this guide.

LIST OF APPENDICES

LIST OF EXHIBITS

APPENDIX A

MEDICAL ISOTOPE COMMITTEE

Responsibility

The Committee is responsible for

1. Ensuring that all individuals who work with or in the vicinity of radioactive material have sufficient training and experience to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license, and

2. Ensuring that all use of radioactive material is conducted in a safe manner and in accordance with NRC regulations and the conditions of the license.

Duties

The Committee shall

1. Be familiar with all pertinent NRC regulations, the terms of the license, and information submitted in support of the request for the license and its amendments;

2. Review the training and experience of all individuals who use radioactive material (including physicians, technologists, and physicists) and determine that their qualifications are sufficient to enable them to perform their duties safely and in accordance with NRC regulations and the conditions of the license;

3. Establish a program to ensure that all radiation workers and all other individuals whose duties may require them to work in the vicinity of radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by § 19.12 of 10 CFR Part 19;

4. Review and approve all requests for use of radioactive material within the institution;

5. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with NRC regulations and the conditions of the license (the review shall include an examination of all records, reports from the radiation safety officer, results of NRC inspection, written safety procedures, and management control system);

6. Recommend remedial action to correct any deficiencies identified in the radiation safety program;

7. Maintain written records of all committee meetings, actions, recommendations, and decisions; and

8. Ensure that the radioactive material license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel (authorized user and RSO).

Meeting Frequency

The radiation safety committee shall meet as often as necessary to conduct its business but not less than once in each calendar quarter.

Membership

Membership of the committee should include

a. Physicians expert in internal medicine, hematology, therapeutic radiology, and a person experienced in assay of radioisotopes and protection against ionizing radiations;

b. A person with special competence in radiation safety; and

c. A representative of the institution's management.

APPENDIX B

ACCEPTABLE TRAINING AND EXPERIENCE FOR TELETHERAPY USES OF RADIOACTIVE MATERIAL

"Physician" means an individual 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. (See paragraph 35.3(b) of 10 CFR Part 35.)

Outlined below are the minimum training and experience criteria that the Commission, with the assistance of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), has found acceptable for physicians who will use or supervise or direct the use of radioactive materials in teletherapy units:

1. Training in basic radioisotope handling techniques (200 hours) consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas:

a.	Radiation physics and instrumentation	(110 hours)
b.	Radiation protection	(40 hours)
c.	Mathematics pertaining to the use and measurement of radioactivity	(25 hours)
d.	Radiation biology	(25 hours)

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

2. Experience with the types and quantities of radioactive material for which the application is made, or equivalent (500 hours). This experience should include the following areas:

a. Review of initial source calibration and periodic spot-check measurements of teletherapy units,

b. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes,

c. Calibration of ion chambers and survey meters,

d. Preparation of treatment plans and treatment times for teletherapy and brachytherapy, and

e. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.

3. Clinical training in teletherapy procedures:

Active practice in therapeutic radiology with a minimum of 3 years experience of which at least one year should have been spent in a formal training program accredited by the Residency Review Committee of Radiology and the Liaison Committee on Graduate Medical Education. This training must include therapeutic treatment of patients of both sexes, all ages, various organs, etc., using teletherapy or brachytherapy.

As evidence of the foregoing training and experience, the applicant should complete Supplements A and B of Form NRC 313T. Supplement B should be submitted by each preceptor physician under whom the applicant physician gained experience or training. Submission of letters of evaluation from each preceptor physician on behalf of the applicant physician should be included with the application. If a 5-year gap occurs in radiotherapy experience or between training and licensure, the applicant must demonstrate evidence of having taken refresher courses or of continuing involvement in radiation therapy.

Note: Evidence of certification by the American Board of Radiology in Radiology or Therapeutic Radiology, certification by the American Osteopathic Board of Radiology in Radiation Oncology, certification as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR), or Canadian certification from the Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology may be submitted in lieu of the

information requested in 1, 2, and 3 above. Physicians certified by the FFR or FRCR must also submit evidence of specialization in radiotherapy. Evidence of previous approval by the NRC or an Agreement State may also be submitted in lieu of the information requested in 1, 2, and 3 above. In this case, the applicant should specify the number of the NRC license or submit a copy of the Agreement State license on which the applicant physician was specifically listed as an authorized user.

APPENDIX C
INSTRUMENTATION

1. Survey meters

   a. Manufacturer's name: _____
   Manufacturer's model number: _____
   Number of instruments available: _____
   Minimum range: _____ mr/hr to _____ mr/hr
   Maximum range: _____ mr/hr to _____ mr/hr

   b. Manufacturer's name: _____
   Manufacturer's model number: _____
   Number of instruments available: _____
   Ranges: _____
   Minimum range: _____ mr/hr to _____ mr/hr
   Maximum range: _____ mr/hr to _____ mr/hr

2. Beam-on Monitor

   Manufacturer's name: _____
   Manufacturer's model number: _____
   Number of instruments available: _____
   Backup Battery Power Supply: Yes _____ No _____

3. Dosimetry System

   a. Electrometer

   Manufacturer's name: _____
   Manufacturer's model number: _____

   b. Probes

   Manufacturer's name: _____
   Manufacturer's model number: _____
   Number of probes: _____
   Ranges: _____

4. Other (use additional pages)

APPENDIX D
CALIBRATION OF INSTRUMENTS

1. Methods for Calibration of X- and Gamma-Ray Survey Meters, Including Procedures, Standards, and Frequency

a. Calibration of survey meters will be performed with radionuclide sources.

(1) The sources will be approximate point sources.

(2) The source activities or exposure rates at given distances will be traceable by documented measurements to a standard source certified within 5 percent accuracy to the U.S. National Bureau of Standards (NBS) calibrations.

(3) The frequency will be at least annually and after servicing.

(4) Each scale of the instrument will be calibrated at least at two points located at approximately 1/3 and 2/3 of full scale. For logarithmic rate-changing instruments, a calibration will be made near the mid-range of each decade and two points will be calibrated on at least one of the decades.

(5) The exposure rate measured by the instrument will differ from the true exposure rate by less than ±10 percent at the calibration points (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration). Readings within ±20 percent will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within ±10 percent for radiation protection purposes.

Note: Sources of Cs-137, Ra-226, or Co-60* are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to

*Minimum activities of typical sources are 85 mCi of Cs-137, 21 mCi of Co-60, and 34 mCi of Ra-226 (to give at least 700 mR/hr at 20 cm).

calibrate the survey meters on all ranges, or at least up to 1 R/hr on the higher-range instruments. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation.

b. A reference check source of long half-life, e.g., Cs-137 or Ra D and E, will also be read at the time of the above calibration or as soon as the instrument is received from a calibration laboratory. The readings will be taken with the check source placed in specific geometry relative to the detector. A reading of this reference check source should be taken:

(1) Before each use and also after each survey to ensure that the instrument was operational during the survey,
(2) After each maintenance or battery change, and
(3) At least quarterly.

If any reading with the same geometry is not within ±20 percent of the reading measured immediately after calibration, the instrument should be recalibrated (see item a).

c. Records of Items a and b above must be maintained.

d. The use of the small check source that is incorporated into some survey meters is not appropriate or acceptable for calibration purposes.

e. The inverse square law and radioactive decay law may be used for calibration.

(1) A calibrated source will have a calibration certificate giving its output at a given distance or its activity measured on a specified date by the manufacturer.

(a) The inverse square law may be used with any point source to calculate the exposure rate at other distances.
(b) The radioactive decay law may be used to calculate the output at any time.

(2) Inverse Square Law

If R_a is the exposure rate at a distance D_a from a point source and R_b is the exposure rate at a distance D_b from the same point source, then

$$R_a D_a^2 = R_b D_b^2$$

Note: R_a and R_b must be in the same units of exposure rate (e.g., mR/hr, R/hr), and D_a and D_b must be in same units of distance (e.g., centimeters, meters)

If R_a, D_a, and D_b are known, R_b can be calculated from

$$R_b = \frac{D_a^2}{D_b^2} \times R_a$$

(3) Radioactive Decay Law

The exposure rate of a standard source at a time after a specified calibration date is given by

$$R_t = R_0 \times e^{-(0.693 \times \frac{t}{T_{1/2}})}$$

$$= R_0 \times (1/2)^n$$

where

R_t is the exposure rate at a time t after the source calibration date

R_0 is the exposure rate on the day the standard source was calibrated

t is the time elapsed since the calibration date

$T_{1/2}$ is the radionuclide half-life

n is the number of half-lives through which the radioactive source has decayed and is equivalent to the quantity $t/T_{1/2}$

Note: R_t and R_0 must be in the same units of exposure rate (e.g., mR/hr, R/hr) and t and $T_{\frac{1}{2}}$ must be in the same units of time (e.g., seconds, days, years).

2. Calibration of Beam-on Monitor

While no calibration procedures specifically apply to beam-on monitors, the applicant should make a daily check of the monitor to ensure that it is operating properly.

3. Calibration of Dosimetry Systems

For dosimetry systems used for teletherapy calibration or spot checks, § 35.23 requires that such systems be calibrated every two years by the National Bureau of Standards or by a regional calibration laboratory accredited by the American Association of Physicists in Medicine. Alternatively, systems used solely for spot checks may be calibrated by a direct intercomparison with a system calibrated by the above calibration services.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

_____ 1. Survey instruments will be calibrated at least annually and following repair.

_____ 2. Calibration will be performed at least at two points on each scale used for radiation protection purposes.

The two points will be located at approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within ±10% of the calculated or known values for each point checked. Readings within ±20% are considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings to within ±10% for radiation protection purposes.

3. Survey instruments will be calibrated

_____ a. By the manufacturer

_____ b. At the licensee's facility

(1) Using the calibration source described below:

Radionuclide _____

Manufacturer's name _____

Model No. _____

Activity (e.g., millicuries) or exposure rate output (e.g., R/hr at 1 meter)_____

Accuracy _____

_____ (2) Following the calibration procedures in this appendix,

or

_____ (3) Following the step-by-step procedures, including radiation safety procedures, that are attached.

_____ c. By a consultant or outside firm

(1) Name _____

(2) Location _____

(3) Procedures and sources for calibrating instruments for clients

_____ have been approved by NRC and are on file in NRC License No. _____

_____ have been approved by an Agreement State. Attached are a copy of the Agreement State license, a description of the procedures and sources used for calibration, and a copy of the consultant's report* on an instrument calibration.

_____ are described in the attached documents that also include a copy of the consultant's report* on an instrument calibration.

*A sample Certificate of Instrument Calibration is on the following page.

CERTIFICATE OF INSTRUMENT CALIBRATION

For:

Instrument:

Manufacturer _____

Type _____

Model No. _____

Serial No. _____

Calibration Data:

Scale	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)	Exposure rate (mR/hr)	Instrument reading (mR/hr)

Comments:

Nuclide	Activity or Exposure Rate at Specified Distance	Calibration Accuracy

Calibration Source:

Calibrated by _____ Date _____

APPENDIX E

UNRESTRICTED AND RESTRICTED AREAS FOR TELETHERAPY LICENSEES

Each area adjacent to a teletherapy facility must be identified and maintained as either an unrestricted or a restricted area.

1. Unrestricted Areas:

a. A standard teletherapy license condition requires that radiation levels in unrestricted areas meet the requirements of paragraphs 20.105(b)(1) and (2) of 10 CFR Part 20. This section of the regulations requires that a person continuously present in an unrestricted area will not receive a dose exceeding 2 millirems in any one hour or 100 millirems in any 7 consecutive days.

b. In showing compliance with paragraphs 20.105(b)(1) and (2), the applicant:

(1) Must use an occupancy factor of unity because the regulation assumes that a person is continuously present, and

(2) May take advantage of "on-time" (i.e., that fraction of an hour or week during which the primary beam of radiation is on regardless of the orientation of the beam).

c. In showing compliance with paragraph 20.105(b)(1), the applicant may not use a fractional use factor, i.e., that fraction of the time during which the primary beam is directed at a particular barrier.

d. If appropriate records are maintained for inspection by the Commission, the applicant may use a fractional use factor to show compliance with paragraph 20.105(b)(2).

e. If compliance with paragraphs 20.105(b)(1) and (2) cannot be demonstrated, the applicant has several options:

(1) Beam operation may be restricted (e.g., using electrical or mechanical stops) to limit the anticipated radiation level,

(2) Additional shielding may be added to the barrier in question,

(3) The applicant may designate and maintain the area as restricted, or

(4) The applicant may request an exemption and demonstrate that the requirements of paragraph 20.105(a) are met. In this case, the applicant must include information on average radiation levels and anticipated occupancy times for each unrestricted area. The applicant must also maintain records to support the assumptions used in justifying the request for an exemption.

2. Restricted Areas:

For each restricted area, the applicant must describe:

a. The physical and administrative controls used to restrict access to the restricted area,

b. The number, wording, size, and location of warning signs to be placed in the vicinity of the restricted area,

c. The program for ensuring that personnel entering the restricted area receive proper instruction in accordance with § 19.12 of 10 CFR Part 19,

d. The program for ensuring that personnel entering the restricted area are monitored in accordance with § 20.202 of 10 CFR Part 20, and

e. The surveys that will be performed in accordance with § 20.201 of 10 CFR Part 20.

APPENDIX F

TELETHERAPY SURVEY REPORTS

Conditions 18 and 19 of a standard teletherapy license require the licensee to perform a radiation survey and to submit a survey report each time the teletherapy source is replaced or whenever any changes are made in the shielding, location, or use of the teletherapy installation that could affect radiation levels in surrounding areas.

The radiation survey should be conducted by a person who is qualified by training and experience to measure ionizing radiation, to evaluate safety techniques, and to advise regarding protection needs and who has good knowledge and understanding of the operating characteristics, including the limitations, of the radiation detection instrumentation and measuring devices that are used in the survey.

1. Contents of Survey Report

To fulfill the requirement for reporting the results of the radiation survey to the Commission, the survey report should:

a. Provide the name, address, and license number of the person or organization that possesses the teletherapy unit and source.

b. Provide the names and addresses of persons conducting the survey.

c. Describe the reason for the survey (e.g., installation of a new source, relocation of unit).

d. Provide the date on which the work described in Item c was completed.

e. Provide the dates on which the survey was conducted.

f. Provide for each radiation detection instrument used for the survey measurements:

(1) The manufacturer's name and model number,

(2) The date of the last calibration prior to use in making these measurements, and

(3) The standards (i.e., radionuclide, activity, and accuracy) and procedures used in the calibration.

g. Provide the manufacturer's name and model number of the teletherapy unit.

h. Provide the manufacturer's name and model number of the teletherapy source.

i. Specify the activity of the source (in curies) on the date of installation or the date of the survey.

j. Specify the intensity of the primary beam of radiation at a specified distance (e.g., RHM or RMM) as measured after the source has been installed in the head of the licensee's teletherapy unit and the date that this intensity was certified. The applicant or licensee should note that Sections 35.21 to 35.25 of 10 CFR Part 35 provide for full calibration measurements to be made by a qualified expert using a properly calibrated dosimetry system, as well as monthly spot checks. Records demonstrating compliance with these sections of NRC's regulations must be maintained by the licensee. These records need not be submitted with the required survey report.

k. Provide the maximum and average radiation levels measured at one meter from the source in the "off" position. The average radiation level may be obtained by averaging measurements taken at 14 points on the surface of a sphere one meter in radius centered on the source; the diagram in Figure F-1 shows the location of the 14 primary points. Up to 26 points may be measured in accordance with NCRP Report No. 33. Describe the locations of the 14 to 26 points and the radiation levels measured at each of the 14 to 26 points.

l. Describe the limits of beam orientation permitted by electrical or mechanical stops installed on the teletherapy unit. Specify each direction in which the teletherapy head can be moved and the maximum angle (from vertical) of the beam orientation in each direction. Also specify the angle orientation (e.g., 0° is vertical toward the floor; 90° is horizontal toward the east wall; 180° is vertical toward the ceiling; and 270° is horizontal toward the west wall). The applicant may use sketches to describe the beam stops that limit the use of the primary beam.

For units with an integral beam absorber, provide this information for orientations with the primary beam directed (a) toward the integral beam absorber and (b) away from the integral beam absorber.

m. For measurements of radiation levels in adjacent areas, which should be made during irradiation of a phantom at the normal treatment distance using maximum field size, describe:

(1) The phantom used, including the material of which it is made and its size;

(2) The source-to-phantom distance; and

(3) The field size (field size should be the maximum permitted by the collimators unless physical means are used to restrict field size).

n. Submit plan and elevation drawings or sketches of the teletherapy facility; a scale of 1/4 inch = 1 foot is recommended.

(1) Indicate the direction of north,

(2) Show the location of the teletherapy unit and source within the room,

(3) Identify each area adjacent to the teletherapy facility (including above and below), and

(4) Identify the locations at which radiation levels were measured (see Items o and p below).

o. Rotational Units:

(1) For the primary beam directed <u>toward</u> the integral beam absorber, determine the rotational position of the teletherapy unit that causes the maximum radiation level in each area adjacent to the teletherapy facility (including above and below the facility). Report the maximum levels measured with a phantom in the primary beam and specify the corresponding rotational position (i.e., angulation toward each area). In general, the maximum levels will be encountered with the beam oriented 30° from the perpendicular toward the barrier in question.

(2) For the primary beam directed <u>away from</u> the integral beam absorber, report the maximum radiation levels that are measured in each area adjacent to the teletherapy facility (including above and below) and specify

the orientation (i.e., angulation toward each area) that produces these maximum levels. Radiation measurements should be made with a phantom in the primary beam and the beam in its most adverse orientation with respect to each barrier. In general, measurements should be made at the maximum limits permitted by the beam stops as described in Item 1.

p. For vertical units, report the maximum radiation levels that are measured in each area adjacent to the teletherapy facility (including above and below) and specify the orientations (i.e., angulation toward each area) that produces the maximum radiation levels. Radiation measurements should be made with a phantom in the primary beam and with the beam in its most adverse orientation with respect to each barrier. In general, measurements should be made at the maximum limits permitted by the beam stops described in Item 1.

q. For each measured radiation level reported in Items o or p that exceeds 2 milliroentgens per hour, explain how the licensee is complying with NRC's regulations and the terms of the license. See Appendix E for further guidance.

r. Describe (1) the tests that were conducted and (2) the results of these tests that ensure proper operation of the safety systems described below. <u>All tests should use a radiation detection instrument to confirm the "on-off" status of the source</u>.

(1) Teletherapy treatment room door interlock. The test should be sufficient to ensure that the door interlock operates in the manner described in Condition 17 of the license.

(2) Teletherapy "on-off" indicators, both mechanical and electrical (e.g., lights on head of teletherapy unit, over door to room, at console).

(3) Electrical or mechanical stops installed to limit use of the primary beam of radiation. The test should be sufficient to ensure that beam stops operate in the manner described in Item 1.

(4) Teletherapy treatment timing device. The tests should be sufficient to ensure that the timer is accurate, that the source returns to the "off" position at the end of the preset time, and that the source does not return to the "on" position until the timer is reset.

s. If a teletherapy unit or source was removed, provide:

(1) The date of removal, and
(2) The name, address, and license number of the person or firm who took possession of the unit or source.

t. If the surveyor recommends any changes to improve the safety of the operation of the teletherapy facility, describe the recommendations and the licensee's response to those recommendations.

2. Instructions for Filing Survey Report

a. A report of the results of the required survey should be sent to:

(1) The Material Licensing Branch, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and
(2) The appropriate NRC Regional Office (see Appendix D of 10 CFR Part 20).

These reports should be sent no later than thirty days following the installation of a new source or completion of the changes requiring the survey.

b. The licensee should keep a copy of the survey report in his or her files.

Figure F-1
TELETHERAPY HEAD SURVEY

(Source in "OFF" position. Measurements taken one meter from source)

Position No.		Radiation Level (mr/hr)
View A	1	
	2	
	3	
	4	
View B	5	
	6	
	7	
	8	
View C	9	
	10	
View D	11	
	12	
	13	
	14	
Average value		
Maximum value		

Date of survey _____

Instrument used _____

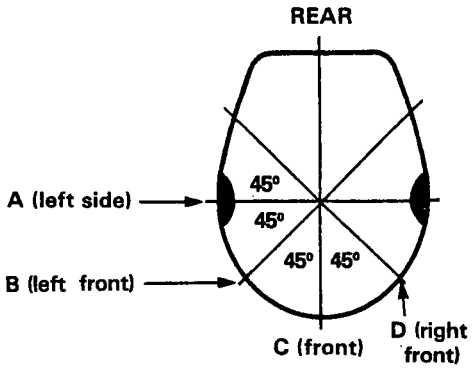
Manufacturer's name & model number of teletherapy source _____

Date of installation _____

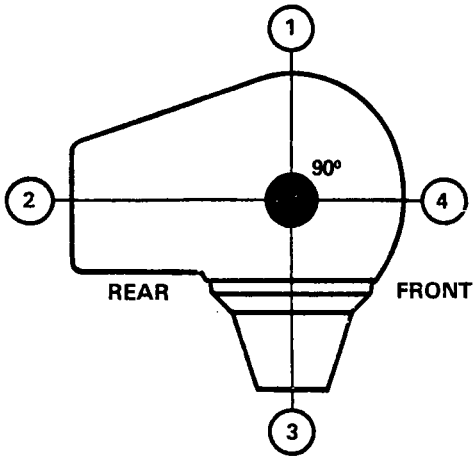
OUTPUT _____ ☐ RHM ☐ RMM

Date of output measurement _____

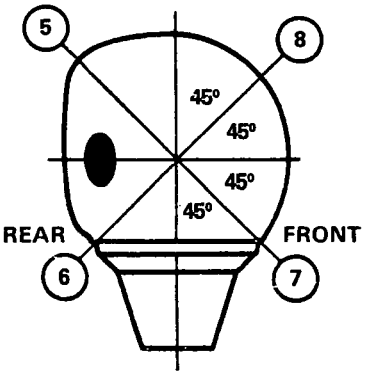
Top View-Showing orientation of Views A through D



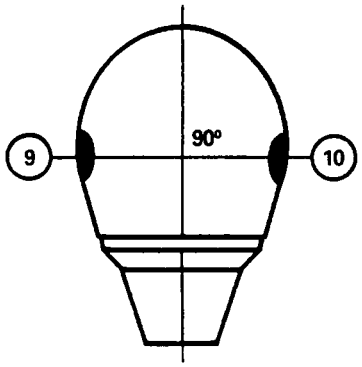
View A-Vertical from left side



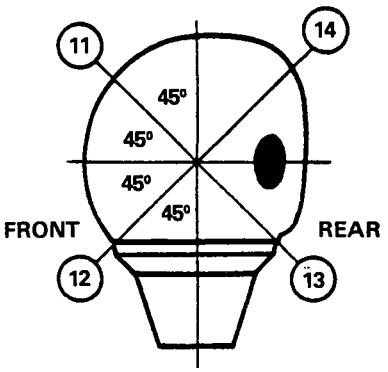
View B-Vertical from left front



View C-Vertical from front



View D-Vertical from right front



APPENDIX G

OPERATING AND EMERGENCY PROCEDURES

1. Operating Procedures

Good health physics practice dictates that a licensee provide facility personnel with operating procedures to give them clear and specific directions in their duties and responsibilities. These duties may include safety device checks, instrument calibration, monthly spot checks, and leak testing. Operating procedures should not contain information that does not apply specifically to persons to whom they are directed. For example, housekeeping personnel would not follow the same procedures as therapy technicians.

The operating procedures should be designed to fit the program proposed in the application. Procedures should be complete and self-contained. Pertinent information contained in equipment manuals and other publications should be extracted and inserted into the operating procedures.

Topics that should be contained in the operating procedures include the following:

a. Safety Device Checks. Safety devices should be checked periodically to ensure that they are operating properly. Such devices include timers, mechanical and electrical interlocks, warning lights and alarms, safety switches, beam collimators, and other devices that actively warn of, limit, or prevent radiation exposure to either patients or personnel. The recommended frequency for safety device checks is at least once a week. A record of the results of the checks should be made. The operating procedures should include instructions for making the checks, the frequency with which they will be made, recording of the results, and prompt correction of any malfunctions or defects noted. A simple checklist may be used to complete the task quickly and efficiently. When checks of safety devices indicate defects or malfunctions, there may be some delay before the defects or malfunctions can be corrected. The applicant should describe the procedures that personnel will follow should a delay occur. For example, use of the teletherapy unit might be forbidden until the problem is corrected, or alternative equivalent procedures such as requiring personnel to enter the room with an operable survey meter might be implemented.

b. Personnel Dosimetry. Operating procedures should require teletherapy personnel to wear personnel monitoring devices (film or TLD badges), and should contain instructions about the manner in which they should be worn. If pocket dosimeters will also be used, frequent reading should be required. The operating procedures should contain directions to be followed in the event that a person receives or suspects that he or she has received a high exposure. In this case, it may be necessary for the film badge of the affected person to be processed immediately. Procedures for storing the monitoring devices when not being worn should be in the operating procedures.

c. Procedures for Securing Teletherapy Unit. The operating procedures should specify the actions to be taken to ensure that the teletherapy unit is secure when unattended. Such actions should include locking the treatment room and the control panel but may also include restricting access to the entire treatment area.

d. Instrument Calibration. If facility personnel will perform survey instrument calibration, the operating procedures should provide the procedures and frequency for calibration. If instruments will be calibrated by an outside service organization, the procedures should specify the actions that facility personnel should follow to prepare the instruments for shipment or transfer to the service organizations. For beam-on monitors, daily functional checks are normally sufficient. Dosimetry systems require special calibrations as specified in § 35.23. The operating instructions should include instructions for preparing the dosimetry system for shipment and shipping it to the calibration facility.

e. Full Calibration of Teletherapy Units. If facility personnel will perform the annual teletherapy source calibration, the operating procedures that will be followed should be provided. Section 35.21 of 10 CFR Part 35 specifies the procedures for full calibration of teletherapy units.

f. Monthly Spot-Check Measurements of Teletherapy Units. If facility personnel will perform the monthly spot checks of teletherapy units, the operating procedures that will be followed should be provided. Section 35.22 of 10 CFR Part 35 specifies the procedures for monthly spot-check measurements of teletherapy units.

g. Leak Testing. If facility personnel will perform leak tests of sealed sources, specific instructions for performing the leak tests should be in the operating procedures. If the applicant will use commercially available leak-test kits, the instructions and procedures provided by the kit suppliers should be incorporated into the applicant's program.

h. Recordkeeping. Operating procedures should specify those records that must be maintained by personnel during the course of their work. Records for which management or supervisory personnel have responsibility should not be included in the operating procedures directed toward facility support personnel.

i. Emergency Procedures. Operating procedures should include instructions to be followed in the event of an emergency or other unusual occurrence. The procedures should be clear and specific and should emphasize special features of the equipment or facility that may determine emergency action (e.g., using the main power disconnect to retract the source with possible cutting of power to room lights, gantry, or table controls). Thus, limitations on action that may be taken by personnel should be specified. Normal procedures should limit action taken by teletherapy personnel to quickly removing the patient from the room, securing or locking the room, and notifying proper persons. Emergency procedures should be posted at the control console of the teletherapy unit. Practice runs of these procedures should be performed after significant changes in personnel and periodically (e.g., semiannually) thereafter. Section 2 of this appendix contains an acceptable procedure.

j. Procedures for Notifying Proper Persons in the Event of an Accident or Unusual Occurrence. The operating procedures should specify the actions to be taken by facility personnel to notify appropriate persons in the event of an accident or unusual occurrence. The names and telephone numbers (both on and off duty) of at least two persons to be notified should be clearly indicated in the procedures. In addition, others, such as the hospital administrator, teletherapy manufacturer service representative and, in the case of a misadministration, the NRC, may require notification and should be indicated in the procedures.

2. Emergency Procedures in Case Beam Control Fails or Malfunctions

If the light signals or beam-on monitor indicate that the beam control mechanism has failed to terminate the exposure at the end of the preset time (e.g., if the red light stays on and the green light is off, or if both the red and the green lights stay on for more than a few seconds), the source may still be in the on position. The following steps are to be carried out promptly and in a calm manner.

For the Radiation Therapy Technologist

a. Open the door to the treatment room.

b. If the patient is ambulatory, direct him to get off the table and leave the room.

c. If the patient is not ambulatory:

Enter the treatment room but avoid exposure to the direct beam.
Pull the treatment table as far away from the direct beam as possible.
Transfer the patient to a stretcher and remove the patient from the room.

d. Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.

e. Turn off the main switch at the control panel.

f. Notify the radiation therapist and radiation safety officer at once.

g. Conspicuously post a sign in the area to warn others of the problem.

Radiation Therapist _____

Phone No.: On Duty _____ Off Duty _____

Radiation Safety Officer _____

Phone No.: On Duty _____ Off Duty _____

APPENDIX H
INSTRUCTION OF PERSONNEL

1. Content of Training Program

The training program for personnel who work with or in the vicinity of the teletherapy unit should be of sufficient scope to ensure that all personnel, including technical, clerical, housekeeping, and security personnel, receive proper instruction in the items specified in § 19.12 of 10 CFR Part 19, including:

a. Areas where radioactive material is used;

b. Potential hazards associated with radioactive material;

c. Radiological safety procedures appropriate to their respective duties;

d. Pertinent NRC regulations, including those that pertain to employee rights as specified in 10 CFR Part 19;

e. Pertinent rules and regulations of the licensee;

f. Pertinent conditions of the license, including specific conditions of operation and the application itself that is incorporated as part of the license;

g. Their obligation to report unsafe conditions and the individual to whom unsafe conditions should be reported;

h. Appropriate response to emergencies or unsafe conditions, including practice drills in the emergency procedures;

i. Their right to be informed of their radiation exposure; and

j. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by 10 CFR Part 19.

In addition, each employee will receive that portion of a facility's operating procedures that are specific for that employee's duties and responsibilities.

2. Schedule for Training

Training will be provided:

a. Before a new employee assumes duties with or in the vicinity of radioactive materials,

b. During the annual refresher training for all employees, and

c. Whenever a significant change in duties, regulations, or the terms of the license occurs.

APPENDIX I
MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

1. 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 will include reviews of operating procedures and past exposure records, inspections, and consultations with the radiation protection staff or outside consultants.

   c. Modifications to operating and maintenance procedures and to equipment and facilities will be made if they will reduce exposures unless the cost, in our judgment, 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. 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.

2. 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 ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

[1]Private practice physician licenses do not include an RSC.
[2]The RSO identified on private practice physician licenses will assume the responsibilities of the RSC in Section 2.

(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 should have incorporated the use of special equipment such as syringe shields and rubber gloves in his proposed use.

(3) The RSC will ensure that the user justifies his procedures and that doses 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 in which it is necessary for the RSO to assert authority. When 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 to 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 in which Investigational Levels in Table 1 are exceeded. The principal 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 6).[3]

(3) The RSC will evaluate the 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.

3. 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.

[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 checkpoints above which the results are considered sufficiently important to justify further investigations.

(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 4 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 ensure 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 will 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.

4. Authorized Users

a. New Procedures Involving Potential Radiation Exposures

(1) The authorized user will consult with and receive the approval of the RSO or RSC or both 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 Supervised

(1) The authorized user will explain the ALARA concept and the commitment to maintain exposures ALARA to all of those supervised.

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

5. Persons Who Receive Occupational Radiation Exposure

a. Workers will be instructed in the ALARA concept and its relationship to their working procedures and work conditions.

b. Workers will know what recourses are available if they feel that ALARA is not being promoted on the job.

6. 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 that, when exceeded, will initiate review or investigation by the Radiation Safety Committee or the Radiation Safety Officer or both. The Investigational Levels apply to the exposure of individual workers.

TABLE 1

	Investigational Levels - (mrems per calendar quarter)	
	LEVEL I	LEVEL II
Whole body, head and trunk, active blood-forming organs, lens of eyes, or gonads	125	375
Hands and forearms, feet and ankles	1875	5625
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) the results of personnel monitoring at least once in any calendar quarter. The exposures will be compared with the Investigational Levels in Table 1 and the following actions will be taken:

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

Except when deemed appropriate by the RSO, no further action will be taken in those cases in which an individual's exposure is less than Table 1 values for Investigational Level I.

b. Personnel exposure 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 exposure equals or exceeds Investigational Level I and will report the results of such 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 causes 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 the 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. Establishment of an individual occupational worker's Investigational Level II above that listed in Table 1.

If worker or a group of workers needs 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 Level 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.

APPENDIX J

GUIDANCE ON REQUESTS FOR LICENSE AMENDMENTS, RENEWALS, AND TERMINATIONS

Requests for license amendments, renewals, and terminations should be prepared in triplicate, one copy to be retained by the applicant and two to be submitted to the NRC. These requests should be submitted on Form NRC-313T, which must be signed by an authorized representative of management (e.g., the hospital administrator) and dated. The appropriate fee (see 10 CFR Part 170, "Fees for Facilities and Materials Licenses and Other Regulatory Services Under the Atomic Energy Act of 1954, as Amended") must also be enclosed with amendment and renewal requests. Terminations do not require a fee. Review of an amendment or renewal request will not begin until the appropriate fee has been paid.

1. License Amendment Requests

a. To change or add new users, the applicant should complete Items 1-4, 11a, and 22 of Form NRC 313T for each change or addition. The applicant should refer to Appendix B of this guide for acceptable training and experience.

b. To change the Radiation Safety Officer (RSO), the applicant should complete Items 1-3, 5, 11b, and 22 of Form NRC 313T for the RSO.

c. To change sources in existing teletherapy units, the applicant should complete Items 1-8 and 22 of Form NRC 313T. If the activity of the new source to be installed will exceed that authorized by Subitem 8 of the license, Items 15, 16, and 21* of Form NRC 313T must also be completed. If the license already authorizes by manufacturer's name and model number the source to be installed and if the activity of the new source is less than the maximum activity authorized by Subitem 8 of the license, the applicant does not need a license amendment.

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* An ALARA program need not be submitted if the licensee's ALARA program has already been approved by the NRC.

d. To change or add teletherapy units and sources, the applicant should complete Items 1-8, 14-16, 21,* and 22 of Form NRC 313T. The applicant should also submit information, as appropriate, for any program changes in Items 9-13 and 17-20 of Form NRC 313T.

e. To move the teletherapy unit and source to a new location, the applicant should complete Items 1-8, 14-16, 21,* and 22 of Form NRC 313T. The applicant should also submit information, as appropriate, for any program changes in Items 9-13 and 17-20 and 22 of Form NRC 313T.

2. License Renewal Requests

To renew a license, the applicant should complete Items 1-9, 10,** 11-12, 17-19, 21, and 22 of Form NRC 313T. If the applicant wishes authorization to use a teletherapy unit and source different from that listed in Items 6 and 7 of the license or requests a possession limit different from that listed in Item 8 of the license, Items 6-8 of Form NRC 313T must also be completed as appropriate. To add another physician as an authorized user, Item 11a must also be completed.

3. License Termination Requests

To terminate a teletherapy license, the applicant should specify to whom and when the teletherapy unit and source were transferred and the recipient's NRC or Agreement State License Number.

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* An ALARA program need not be submitted if the licensee's ALARA program has already been approved by the NRC.

** Item 10 on the application applies only to institutional licensees.

EXHIBIT A

NRC Form 313T
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

Approved by OMB
3150-0081
Expires 1-31-85

APPLICATION FOR MATERIALS LICENSE — TELETHERAPY

INSTRUCTIONS — Complete Items 1 through 22 if this is an initial application or an application for renewal of a license. Use supplemental sheets where necessary. Item 22 must be completed on all applications and signed. Retain one copy. Submit original and one copy of entire application to: Director, Office of Nuclear Materials Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555. Upon approval of this application, the applicant will receive a Materials License. An NRC Materials License is issued in accordance with the general requirements contained in Title 10, Code of Federal Regulations, Part 30, and the Licensee is subject to Title 10, Code of Federal Regulations, Parts 19, 20, 21, and 35 and the license fee provision of Title 10, Code of Federal Regulations, Part 170. The license fee category should be stated in Item 22 and the appropriate fee enclosed.

1.a. NAME AND MAILING ADDRESS OF APPLICANT *(Institution, firm, clinic, physician, etc.)* INCLUDE ZIP CODE	1.b. STREET ADDRESS(ES) AT WHICH RADIOACTIVE MATERIAL WILL BE USED *(If different from 1.a.)* INCLUDE ZIP CODE
TELEPHONE — AREA CODE ( ) NUMBER	
2. PERSON TO CONTACT REGARDING THIS APPLICATION	3. THIS IS AN APPLICATION FOR: *(Check appropriate item)* ☐ a. NEW LICENSE ☐ b. AMENDMENT TO LICENSE NO. _____ ☐ c. RENEWAL OF LICENSE NO. _____
TELEPHONE — AREA CODE ( ) NUMBER	
4. INDIVIDUAL USERS *(Name individuals who will use or directly supervise use of radioactive material. Complete Supplements A and B for each individual.)*	5. RADIATION SAFETY OFFICER (RSO) *(Name of person designated as radiation safety officer. If other than individual user, complete resume of training and experience as in Supplement A.)*

6. SEALED SOURCES TO BE USED IN TELETHERAPY UNITS *(Attach supplemental pages if necessary)*

	BYPRODUCT MATERIAL *(Element and Mass No.)*	NAME OF SOURCE MANUFACTURER	SOURCE MODEL NUMBER	MAXIMUM ACTIVITY PER SOURCE	NUMBER OF SOURCES
A.					
B.					
C.					

7. TELETHERAPY UNITS *(Attach supplemental pages, if necessary)*

	NAME OF MANUFACTURER *(Include description, if unit is custom made)*	MODEL NUMBER
A.		
B.		
C.		

8. USE *(Attach supplementary pages, if necessary)*

A	B	C	
☐	☐	☐	HUMAN USE ONLY
☐	☐	☐	HUMAN AND OTHER USE *(Specify on separate sheet)*

9. PERSONNEL MONITORING DEVICES

	TYPE (Check and/or complete as appropriate)	SUPPLIER (Service Company)	EXCHANGE FREQUENCY
☐	(1) FILM BADGE — WHOLE BODY		
☐	(2) THERMOLUMINESCENSE DOSIMETER (TLD) — WHOLE BODY		
☐	(3) OTHER *(Specify)*:		

EXHIBIT A (Continued)

INFORMATION REQUIRED FOR ITEMS 10 THROUGH 21

For Items 10 through 21, check the appropriate box(es) and submit a detailed description of all the requested information. Begin each item on a separate sheet. Identify the item number and the date of the application in the lower right corner of each page. If you indicate that an appendix to the teletherapy licensing guide will be followed, do not submit the pages, but specifiy the revision number and date of the referenced guide: Regulatory Guide 10. Rev. _____ Date: _____

10. MEDICAL ISOTOPE COMMITTEE	15. BEAM STOPS
☐ *Names and specialties attached; and (check one)*	☐ *Description of stops used to restrict beam orientation attached.*
☐ a. Duties as in Appendix A, or	16. SHIELDING EVALUATION
☐ b. Equivalent duties attached.	☐ Evaluation of proposed shielding attached.
11. TRAINING AND EXPERIENCE	17. OPERATING AND EMERGENCY PROCEDURES
☐ a. Supplements A & B attached for each individual user; and	☐ a. Description of operating procedures attached; and
☐ b. Supplement A attached for RSO	☐ b. Copy of emergency procedures attached.
12. INSTRUMENTATION *(check one)*	18. INSTRUCTION OF PERSONNEL *(check one)*
☐ a. Appendix C form attached, or	☐ a. Training program and schedule in Appendix H followed, or
☐ b. List manufacturer's name and model number	☐ b. Description of instruction program for employees attached
13. CALIBRATION OF INSTRUMENTS *(check one)*	19. LEAK TESTS OF SEALED SOURCES
☐ a. Appendix D, Part 2 procedures followed for instrumentation calibration, or	☐ Description of leak-test procedures attached.
☐ **b. Description of sources, calibration frequency and equivalent procedures attached.**	20. QUALIFIED EXPERT *(Use only if the individual fails to meet 10 CFR 35.24 requirements.)*
14. FACILITIES AND EQUIPMENT	☐ Statement of qualifications of the expert who will perform teletherapy calibrations attached.
☐ a. Description and drawing of facilities attached; and	21. ALARA PROGRAM *(check one)*
☐ b. Description of patient viewing and communicating systems attached; and	☐ ALARA Program as in Appendix I, or
☐ c. Description of area safeguards attached.	☐ Equivalent ALARA program attached

22. CERTIFICATE
(This item must be completed by the applicant)

The applicant and any official executing this certificate on behalf of the applicant named in Item 1a certifies that this application is prepared in conformity with Title 10, Code of Federal Regulations, Parts 30 and 35, and that all information contained herein, including supplements attached hereto, is true and correct to the best of our knowledge and belief.

a. LICENSE FEE REQUIRED *(See section 170.31, 10 CFR 170)*	b. APPLICANT OR CERTIFYING OFFICIAL *(Signature)*
	(1) NAME *(Type or print)*
(1) LICENSE FEE CATEGORY	(2) TITLE
(2) LICENSE FEE ENCLOSED $	c. DATE

WARNING: 18 U.S.C. Section 1001; Act of June 25, 1948; 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

EXHIBIT B

NRC Form 313T Supplement A
(9-81)
10 CFR 35

U.S. NUCLEAR REGULATORY COMMISSION

TRAINING AND EXPERIENCE
PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER

1. NAME OF PROPOSED AUTHORIZED USER OR RADIATION SAFETY OFFICER	2. STATE OR TERRITORY IN WHICH LICENSED TO PRACTICE MEDICINE *(If physician)*

3. CERTIFICATION

SPECIALTY BOARD	CATEGORY	MONTH AND YEAR CERTIFIED

4. TRAINING RECEIVED IN BASIC RADIOISOTOPE HANDLING TECHNIQUES *(To be completed by institution providing training)*

FIELD OF TRAINING	LOCATION AND DATE(S) OF TRAINING	TYPE AND LENGTH OF TRAINING	
		LECTURE/LABORATORY COURSE *(Hours)*	FORMAL SUPERVISED OJT/LABORATORY EXPERIENCE *(Hours)*
RADIATION PHYSICS AND INSTRUMENTATION			
RADIATION PROTECTION			
MATHEMATICS PERTAINING TO THE USE, MEASUREMENT, AND SHIELDING OF RADIOACTIVE SOURCES			
RADIATION BIOLOGY			

5. EXPERIENCE WITH RADIOACTIVE MATERIALS* *(Actual use of radioisotopes or equivalent experience)*

ISOTOPE	MAXIMUM AMOUNT FOR ANY SINGLE APPLICATION	WHERE EXPERIENCE WAS GAINED	DURATION OF EXPERIENCE	TYPE OF USE

*Experience with sealed radioactive sources under the supervision of qualified instructors should include:

1. Review of initial source calibration and periodic spot-check measurements of teletherapy units.
2. Initial source calibration of sealed sources other than teletherapy sources that are used for treatment purposes.
3. Calibration of ion chambers and survey meters
4. Preparation of treatment plans and treatment times for teletherapy and brachytherapy.
5. Knowledge of appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.

6. I CERTIFY THAT THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF *(Signature of program supervisor)*

TYPED OR PRINTED NAME | DATE

NAME OF INSTITUTION

MAILING ADDRESS

CITY | STATE | ZIP CODE | RADIOACTIVE MATERIALS LICENSE NUMBER

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement or representation to any department or agency of the United States as to any matter within its jurisdiction.

EXHIBIT C

NRC Form 313T Supplement 8
(9-81)

U.S. NUCLEAR REGULATORY COMMISSION

PRECEPTOR STATEMENT

Supplement B must be completed by the applicant physician's preceptor. If more than one preceptor is necessary to document experience, obtain a separate statement from each.

1. APPLICANT PHYSICIAN'S NAME AND ADDRESS

FULL NAME

STREET ADDRESS

CITY | STATE | ZIP CODE

KEY TO COLUMN C
PERSONAL PARTICIPATION SHOULD CONSIST OF:

1. Supervised examination of patients to determine the suitability for radioisotope therapy and recommendations on dosage to be prescribed.
2. Collaboration in calculation of radiation dose, related measurement, and modification of the originally, prescribed dose as warranted by patient reaction to the radiation.
3. Followup of patients when required.
4. Study and discussion with preceptor of case histories to establish the most appropriate therapy procedures, limitations, contraindications, etc.

2. CLINICAL TRAINING AND EXPERIENCE OF PHYSICIAN CITED ABOVE IN USING SOURCES OR DEVICES FOR THERAPY

ISOTOPE A	TYPES OF TREATMENT B	NUMBER OF CASES INVOLVING PERSONAL PARTICIPATION C	COMMENTS *(Append additional information, if necessary)* D
Co-60	*COURSES OF TELETHERAPY*		
OR	INTERSTITIAL		
Cs-137	INTRACAVITARY		
I-125 Ir-192 OR Au-198 SEEDS	INTERSTITIAL		
Ra-226	INTRACAVITARY		
X-RAY AND ACCELERATOR THERAPY	COURSES OF THERAPY TREATMENT		
Sr-90	SUPERFICIAL EYE CONDITIONS		
OTHER			

DATES AND TOTAL NUMBER OF HOURS IN CLINICAL TRAINING USING SEALED SOURCES FOR THERAPY

3. PRECEPTOR'S CERTIFICATION

NAME OF SUPERVISOR | NAME OF INSTITUTION | RADIOACTIVE MATERIALS LICENSE NUMBER

MAILING ADDRESS | CITY | STATE | ZIP CODE

I CERTIFY THAT (a) THE INFORMATION PRESENTED ABOVE IS TRUE AND CORRECT TO THE BEST OF MY KNOWLEDGE AND BELIEF, AND (b) I WAS AUTHORIZED BY THE REFERENCED RADIOACTIVE MATERIALS LICENSE(S) TO PERFORM THE PROCEDURES SPECIFIED ABOVE. I FURTHER BELIEVE THAT THE APPLICANT PHYSICIAN IS COMPETENT TO PERFORM THESE PROCEDURES INDEPENDENTLY. *(Signature)* | DATE

WARNING: 18 U.S.C. Section 1001, Act of June 25, 1948, 62 Stat. 749, makes it a criminal offense to make a willfully false statement of representation to any department or agency of the United States as to any matter within its jurisdiction.

PRIVACY ACT STATEMENT

Pursuant to 5 U.S.C. 552a(e)(3), enacted into law by section 3 of the Privacy Act of 1974 (Public Law 93-579), the following statement is furnished to individuals who supply information to the Nuclear Regulatory Commission on NRC Form 313T. This information is maintained in a system of records designated as NRC-3 and described at 40 Federal Register 45334 (October 1, 1975).

1. **AUTHORITY** Sections 81 and 161(b) of the Atomic Energy Act of 1954, as amended (42 U.S.C. 2111 and 2201(b)).

2. **PRINCIPAL PURPOSE(S)** The information is evaluated by the NRC staff pursuant to the criteria set forth in 10 CFR Parts 30-35 to determine whether the application meets the requirements of the Atomic Energy Act of 1954, as amended, and the Commission's regulations, for the issuance of a radioactive material license or amendment thereof.

3. **ROUTINE USES** The information may be used: (a) to provide records to State health departments for their information and use; and (b) to provide information to Federal, State, and local health officials and other persons in the event of incident or exposure, for their information, investigation, and protection of the public health and safety. The information may also be disclosed to appropriate Federal, State, and local agencies in the event that the information indicates a violation or potential violation of law and in the course of an administrative or judicial proceeding. In addition, this information may be transferred to an appropriate Federal, State, or local agency to the extent relevant and necessary for an NRC decision or to an appropriate Federal agency to the extent relevant and necessary for that agency's decision about you. A copy of the license issued will routinely be placed in the NRC's Public Document Room, 1717 H Street, N.W., Washington, D.C.

4. **WHETHER DISCLOSURE IS MANDATORY OR VOLUNTARY AND EFFECT ON INDIVIDUAL OF NOT PROVIDING INFORMATION** Disclosure of the requested information is voluntary. If the requested information is not furnished, however, the application for radioactive material license, or amendment thereof, will not be processed.

5. **SYSTEM MANAGER(S) AND ADDRESS** Director, Division of Fuel Cycle and Material Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555

NRC Form 313T
(2-82)

EXHIBIT D

NRC Form 374T
(12-81)

U.S. NUCLEAR REGULATORY COMMISSION

Page 1 of 5 Pages

MATERIALS LICENSE – TELETHERAPY

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93–438), and Title 10, Code of Federal Regulations, Chapter 1, Parts 30, 31, 32, 33, 34, 35, 36, 40 and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s); and to import such byproduct and source material. This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee	
1. XYZ Hospital 1234 A Street 2. Washington, D. C. 20000	3. License number XX-XXXXX-XX 4. Expiration date April 30, 1987 5. Docket or Reference No.

6. Byproduct, source, and/or special nuclear material	7. Chemical and/or physical form	8. Maximum amount that licensee may possess at any one time under this license
A. Cobalt 60	A. Teletherapy sealed sources (ABC Corporation Model 567)	A. 10,000 curies (2 sources of not more than 5,000 curies each)

9. Authorized use

A. One source to be used in an ABC Corporation Model 89 teletherapy unit for the treatment of humans. One source in its shipping container to be in possession of the licensee as necessary to the replacement of the source in the teletherapy unit only.

CONDITIONS

10. Licensed material shall be used only at Room 103, XYZ Hospital, 1234 A Street, Washington, D. C.

11. The licensee shall comply with the provisions of Title 10, Chapter 1, Code of Federal Regulations, Part 19, "Notices, Instructions and Reports to Workers; Inspections" and Part 20, "Standards for Protection Against Radiation."

12. Licensed material shall be used by, or under the supervision of, John Jones, M.D. or Mary Smith, M.D.

13. The teletherapy facility shall be provided with a system permitting continuous observation of the patient from outside the treatment room, during patient irradiation.

NRC Form 374TA (12-81) U.S. NUCLEAR REGULATORY COMMISSION

Page 2 of 5 Pages

MATERIALS LICENSE – TELETHERAPY (Continued)

License number XX-XXXXX-XX

14. A. Teletherapy sources shall be tested for leakage at intervals not to exceed six months. Records of test results shall be kept in units of microcuries and maintained for inspection by the Commission. In the absence of a certificate from a transferor indicating that a test has been made within six months prior to the transfer, the source shall not be used until tested for leakage.

    B. The test shall be sufficiently sensitive to detect 0.05 microcurie of contamination on the test sample.

    C. The test sample shall be taken from selected accessible surfaces of the teletherapy head. The selected accessible surfaces should be those surfaces on which one might expect contamination (if there were to be leakage) to accumulate and shall include the inner surface of the most frequently used treatment cones or beam collimating device. The test sample shall be taken with the source in the "off" position.

    D. If the test reveals the presence of 0.05 microcurie or more of removable contamination, the licensee shall promptly take action to prevent spread of contamination and shall file a report within five days of the test with the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, describing the test results and the corrective action taken. A copy of such report shall also be sent to the Director of the appropriate Nuclear Regulatory Commission Regional Office of Inspection and Enforcement listed in Appendix D of 10 CFR 20.

15. Prior to initiation of a treatment program, each teletherapy unit shall be equipped with electrical or mechanical stops limiting use of the primary beam of radiation so as to assure compliance with § 20.105(b) of 10 CFR 20, "Standards for Protection Against Radiation," as evidenced by a radiation survey. Necessary use restrictions shall be fully described in radiation survey reports submitted in accordance with Condition No. 18.

16. A set of written emergency instructions shall be posted at the teletherapy machine control. These instructions shall inform the machine operator of the procedure to be followed should he be unable to turn the machine's primary beam of radiation "off" with the controls outside the treatment room.

17. A. Access to the teletherapy room shall be controlled by a door at each entrance. Such doors shall be normally closed.

    B. Each entrance to the teletherapy room shall be equipped with an electrical interlock system that will turn the teletherapy machine's primary beam of radiation off immediately upon opening of any entrance door. The interlock system shall be connected in such a manner that the teletherapy machine's primary beam of radiation cannot be turned on until all treatment room entrance doors are closed and the beam "on-off" control is reset at the control panel.

    C. Electrical interlocks on entrance doors to the teletherapy room shall be tested for proper operation at least once every six months. Records of test results shall be maintained for inspection by the Commission.

    D. In the event of malfunction of any door interlock, the teletherapy machine control shall be locked in the "off" condition and not used, except as may be necessary to the repair or replacement of the interlock system, until the interlock system is shown to be functioning properly.

18. Prior to initiation of a treatment program, and subsequent to each installation of a teletherapy source, radiation surveys and tests shall be performed in accordance with the following:

    A. A radiation survey shall be made of:

        (i) The teletherapy source housing, with the teletherapy source in the "off" position. The maximum and average radiation levels at one meter from the teletherapy source in the "off" position shall not exceed 10 milliroentgens per hour and 2 milliroentgens per hour, respectively.

        (ii) All areas adjacent to the treatment room, with the teletherapy source in the "on" position. The survey, except Item (c), shall be performed with a phantom in the primary beam of radiation, and shall clearly establish:

            (a) The radiation levels in restricted areas are not likely to cause personnel exposure in excess of the limits specified in Section 20.101, Title 10, Part 20, Code of Federal Regulations, Chapter 1, "Standards for Protection Against Radiation" (10 CFR 20).

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MATERIALS LICENSE – TELETHERAPY
(Continued)

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18. (Continued)

(b) That quantities of radiation in unrestricted areas do not exceed the limits specified in § 20.105(b), 10 CFR 20.

(c) The intensity of the primary beam of radiation at a specified distance from the teletherapy source.

B. Tests shall be made to determine proper operation of:

(i) Electrical interlocks on entrance doors to the teletherapy treatment room.

(ii) The teletherapy source "on–off" indicators, both at the source housing and on the teletherapy machine control panel.

(iii) Electrical or mechanical stops installed for the purpose of limiting use of the primary beam of radiation (restriction of source housing angulation or elevation, carriage or stand travel and operation of the beam "on–off" mechanism.)

(iv) The teletherapy treatment timing device.

C. A report of the results of the above surveys and tests shall be sent to the Material Licensing Branch, Division of Fuel Cycle and Material Safety, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, not later than thirty (30) days following each installation of a teletherapy source. A copy of such report shall be sent to the Director of the appropriate Nuclear Regulatory Commission Regional Office of Inspection and Enforcement listed in Appendix D of 10 CFR 20.

19. A. Any changes made in the treatment room shielding, location of the unit within the treatment room, or use of the teletherapy unit that could result in increased radiation levels in areas outside the teletherapy treatment room shall be evaluated by a radiation survey made in accordance with Condition 18, and reported to the Commission within thirty (30) days following completion of the changes(s).

B. Relocation of the teletherapy unit to a new facility is not permitted without prior approval of the plans and details by the Commission. Following such approval and relocation, a radiation survey shall be made in accordance with Condition 18, and reported to the Commission within thirty (30) days after completion of the move.

20. Each teletherapy machine shall be fully inspected and serviced during source replacement or at intervals not to exceed five (5) years, whichever comes first, to assure proper functioning of the source exposure mechanism. This inspection and servicing must be performed by persons specifically authorized to do so by the U.S. Nuclear Regulatory Commission* *

21. The following shall be performed only by persons specifically authorized by the Commission or an Agreement State to perform such services.

A. Installation, relocation, or removal of teletherapy units containing sources.

B. Source exchange.

C. Any maintenance or repair operations on a teletherapy unit involving work on the source drawer, the shutter, or other mechanism that could expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

* or an Agreement State and a report of the inspection and servicing must be kept on file for review by the Commission's Office of Inspection and Enforcement.

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MATERIALS LICENSE
SUPPLEMENTARY SHEET

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CONDITIONS

22. Pursuant to Title 10, Chapter 1, Code of Federal Regulations, Part 40, "Domestic Licensing of Source Material," the licensee is authorized to possess, use, transfer, and import the uranium contained as shielding material in the teletherapy units authorized by this license.

23. For a period not to exceed sixty (60) days in any calendar year, a visiting physician is authorized to use licensed material for human use under the terms of this license, provided the visiting physician:

(a) Has the prior written permission of the hospital's Administrator and its Medical Isotopes Committee, and

(b) Is specifically named as a user on a Nuclear Regulatory Commission license authorizing human use, and

(c) Performs only those procedures for which he is specifically authorized by a Nuclear Regulatory Commission license.

The licensee shall maintain for inspection by the Commission, copies of the written permission specified in subitem (a) above and of the license(s) specified in subitems (b) and (c) above. These records shall be maintained for five (5) years from the time the licensee grants its permission under subitem (a) above.

24. A. Each teletherapy room shall be equipped with a radiation monitoring device which continuously monitors the teletherapy beam condition and is equipped with a back-up battery power supply for emergency operation. This device shall energize a visible signal to make the operator continuously aware of teletherapy beam condition in order that appropriate emergency procedures may be instituted to prevent unnecessary radiation exposure. Operating procedures shall require daily operational testing of the installed radiation monitor.

B. Whenever the continuous radiation monitoring device is not operational, any person entering the teletherapy room following an irradiation shall enter with an operable, calibrated radiation survey meter and shall determine the beam condition.

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MATERIALS LICENSE
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CONDITIONS

25. Except as specifically provided otherwise by this license, the licensee shall possess and use licensed material described in Items 6, 7, and 8 of this license in accordance with statements, representations, and procedures contained in application dated January 2, 1982; and letter with enclosures dated March 2, 1982, both signed by Fred Green, Administrator. The Nuclear Regulatory Commission's regulations shall govern the licensee's statements in applications or letters, unless the statements are more restrictive than the regulations.

For the U.S. Nuclear Regulatory Commission

VOID

Date April 2, 1982

By Material Licensing Branch
Division of Fuel Cycle and
Material Safety
Washington, D.C. 20555

DRAFT VALUE/IMPACT STATEMENT

1. BACKGROUND

The Division of Fuel Cycle and Material Safety (FCMS) has requested that the Office of Nuclear Regulatory Research develop a regulatory guide for the preparation of license applications for the use of sealed sources in teletherapy. Historically, the "AEC Licensing Guide, Teletherapy Programs," dated November 1965 and now obsolete, and NUREG-0339, "Draft Licensing Guide for Teletherapy Programs," which is presently used by the Material Licensing Branch of FCMS, have been used to assist teletherapy applicants in submitting proper documentation for licensing. This regulatory guide will supersede NUREG-0339.

2. PROPOSED ACTION

2.1 Description

The applicant for a license to use radioactive materials in teletherapy programs is required to develop a program that complies with Commission regulations and to describe this program in the application for a license. The regulatory guide will detail teletherapy program requirements and provide guidance for submitting a complete description of the teletherapy program and establishing a comprehensive radiation safety program.

2.2 Need

Each year material licensing personnel review approximately 160 applications for new licenses, for renewal of existing licenses, and for amendments to existing licenses. Of these applications, approximately 90 are deficient in certain areas and each requires a letter of deficiency to the applicant. Because the number of new and renewal applications continues to increase, the availability of a comprehensive license application guide should result in applications that are more complete and thus eliminate the need for many of

the deficiency letters. In addition, license application guides were recommended by the Office of the Inspector and Auditor following an audit of what was then the Radioisotopes Licensing Branch (currently the Material Licensing Branch).

2.3 Value/Impact

2.3.1 NRC

The review and approval of applications for use of radioactive materials in teletherapy programs are considerably facilitated by the use of a standard format, the instructions for which will be provided in the regulatory guide. The guide will clearly detail the regulations to be followed and the information required for licensing and implementing an acceptable program for the use of teletherapy sources. Staff review time is shortened because of the use of the standard format and the reduction of unnecessary correspondence resulting from the lack of sufficient detail in license applications. Other than the allocation of staff resources to the development and production of the guide, no impact on the NRC is anticipated.

2.3.2 Other Government Agencies

Other government agencies should not be affected.

2.3.3 Industry

The regulatory guide will contribute to the reduction in time required for a physician or a medical institution to prepare a license application. The applicant will spend less time trying to interpret NRC regulations and requirements for submission of information. More importantly, the guide will provide information for the design and implementation of a more effective radiation safety program, thereby minimizing the radiation exposure to workers and, in the case of an emergency, to the patient.

2.3.4 Public

The public as potential patients will benefit from the use of the guide through reduced radiation exposure as discussed in 2.3.3.

2.3.5 Worker

The worker will benefit from the use of the guide through reduced radiation exposure as discussed in 2.3.3.

2.4 Decision

The development and publication of the guide should be initiated.

3. TECHNICAL APPROACH

This section is not applicable since only an administrative action is involved.

4. PROCEDURAL APPROACH

4.1 Alternatives

The procedural alternatives are as follows:

a. Publish a guide for the preparation of applications.

b. Publish a guide for the review of license applications describing what should be reviewed and the detail to which the various items of the application should be reviewed.

4.2 Discussion

A licensing guide is the more effective way to transmit information about regulations and licensing requirements to an applicant. A license application guide will ensure uniform transmission of information to the licensee. A review guide would not be as efficient. Use of a review guide by NRC staff would still require the use of individual letters to applicants whose submissions are incomplete. Consequently, a license application guide is the more effective alternative.

4.3 Decision

Development and publication of a license application guide should be initiated.

5. STATUTORY CONSIDERATIONS

5.1 NRC Authority

This guide interprets regulations promulgated principally in 10 CFR Part 35.

5.2 Need for NEPA Assessment

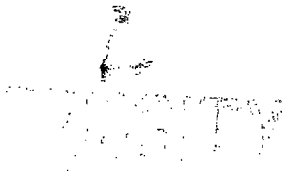
The proposed action is not a major Federal action significantly affecting the quality of the human environment and does not require an environmental impact statement.

6. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

No conflicts or overlaps appear to exist.

7. SUMMARY AND CONCLUSIONS

The proposed regulatory guide for the preparation of license applications for the use of sealed sources in teletherapy programs will provide an applicant with guidelines for submitting complete applications and implementing optimum radiation safety programs. The proposed action should be undertaken.



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