RADIOACTIVE MATERIALS PROGRAM

GUIDE AND APPLICATION FOR LICENSING OF TELETHERAPY

State of Georgia
Dept. Of Natural Resources
Environmental Protection Div.

Radioactive Materials Program
4244 International Parkway
Atlanta, GA. 30354

Rev:Date 3:6/30/98
Telephone (404) 362-2675
Fax (404) 362-2653

Table of Contents

APPENDICES

I. PURPOSE OF GUIDE

The purpose of this regulatory guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments, and license renewals that authorize possession of radioactive material in a teletherapy unit for the treatment of human beings. This type of license is provided for in Rule 391-3-17-.05(4) of the Georgia Department of Natural Resources Rules and Regulations for Radioactive Materials, Rule 391-3-17-.05, "Use of Radionuclides in the Healing Arts. Amended."

The Department will issue a single material license to cover an institution's teletherapy program; the license will include the needed authorization for source material* (i.e., depleted uranium) contained as shielding in many teletherapy units. An institution's other medical programs will be covered in a separate license.

This guide is intended to provide you, the applicant or licensee, with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to medical teletherapy licenses. The following Georgia Regulations apply and should be used in conjunction with this guide. The applicant or licensee should carefully read the applicable Regulations. This guide should not be considered as an all inclusive and complete substitution for understanding the Regulations, training in radiation safety or developing and implementing an effective Radiation Protection Program.

Rule 391-3-17-.01 "General Provisions, Amended."

Rule 391-3-17-.02 "Licensing of Radioactive Materials, Amended."

Rule 391-3-17-.03 "Standards for Protection Against Radiation, Amended."

Rule 391-3-17-.05 "Use of Radionuclides in the Healing Arts, Amended."

Rule 391-3-17-.06 "Transportation of Radioactive Materials, Amended."

Rule 391-3-17-.07 "Notices, Instructions and Reports to Workers; Inspections, Amended."

AS LOW AS IS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Georgia Rule 391-3-17-.03 (4)(b) states "The licensee shall use, to the extent practicable, procedures and engineering controls based upon sound radiation protection principles to achieve occupational doses and doses to members of the public that are as low as is reasonably achievable (ALARA)." As an applicant, you must have an ALARA plan that embraces this philosophy when developing plans for working with radioactive materials.

This radiation safety program must be reviewed at least annually for the effectiveness of implementation. Licensees are required to maintain records of their radiation protection program until the Department terminates the pertinent license. Licensee must maintain records of audits and other reviews of their program and implementations for at three (3) years after the record has been made.

*The term "source material" is defined in Rule 391-3-17-.01(12)(ssss).

II. FILING AN APPLICATION

Complete the form "Application for a Radioactive Materials License"(Appendix A). Complete Items 1 through 4 on the form itself. For items 5 through 13 submit the information on supplementary pages. Each separate sheet or document submitted with the application needs to be identified and keyed to the item number on the application to which it refers. All typed pages, sketches, or drawings should be on 8-1/2 X 11 inch paper to facilitate handling and review. All items should be completed and detailed enough for the Department to determine that your equipment, facilities, training and experience, and radiation safety program are adequate to protect health and minimize danger to life and property.

All license applications and documents submitted to the Department will be available for review by the general public. Do not submit proprietary information unless it is absolutely necessary for it to be used to evaluate your application. The Department may withhold any document or part of a document from public inspection if disclosures of its contents is not required by law.* Any request for withholding is subject to a determination by the State of Georgia as to whether the document may actually be withheld in accordance with applicable laws and regulations.

Personal information about employees should not be submitted unless it is necessary. For example, the training and experience of employees need to be submitted to demonstrate their ability to manage radiation safety programs and to work safely with radioactive materials. Home addresses, home telephone numbers, dates of birth, social security numbers, and radiation dose information should not be submitted unless the Department specifically request it.

Prepare the application and supplements in duplicates. Submit the original copy to the Radioactive Materials Program. It will become a part of the license if approved. Keep an identical copy for your records.

III. CONTENTS OF AN APPLICATION

Item 1. License Information

Indicate whether this is an application for a new license, an amendment, or a renewal. If this is an amendment or a renewal, please identify the license number. An amendment request may be submitted in a letter form without using the application. For an amendment, the licensee must identify the GA. license number and give the business name. In all cases, the appropriate license fee must accompany the application in order to process the request. (See Item 12., License Fees, for the correct fee and mailing address.)

Item 2.A. Name and Mailing Address of Applicant

Enter the applicant's name, mailing address, county, telephone number, and **Internet address** if applicable. The applicant should use the legal name of the corporation and/or should be the legal entity with direct control over the use of the radioactive material. If the applicant is a private practice, the individual should be acting in a private capacity.

---

*A copy of the Georgia Open Records Law is available from the Georgia Law Library, for the cost of the photocopy. The telephone number for the library is (404) 656-3468.

Item 2.B. Street Address(es) of Use.

List each permanent facility used as a location of storage by the street address, city and state, or another descriptive address (such as on Highway 2 miles east of the intersection of Highway 10 and state Route 234, Any town State). The descriptive address should be sufficient to allow a Department inspector to find the location. A Post Office Box is not acceptable for Item 2.B. **A storage address must be an in-state storage address.**

If the device will be used at a permanent facility or facilities, give the specific address of each. Please identify the latitude and longitude coordinates of your facility(s).

Item 3. Person to Contact

Enter the name and telephone number of the contact person(s) for this application and license. This individual should be familiar with the proposed radioactive materials program and be able to answer questions regarding the application. This is usually the person responsible for the radiation safety program. This person will serve as the point of contact during the application review process and after issuance of the license. Notify the Department if the contact person changes. This change **will not be considered as an amendment**, unless it is a change of the Radiation Safety Officer.

The person named in Item 3. above may or may not be the same person who signs the application. Any commitments made by the applicant, must be approved and signed by the authorizing official named in Item 13 of the application. The Department considers this individual as having the authority to make commitments on behalf of the applicant.

Item 4. Location(s) Where Records Will Be Retained

Indicate where records are to be maintained. If multiple locations are being requested, records for each site's operation must be maintained at that site, and at the main Georgia facility location as indicated in Item 2.A.

Item 5. Radioactive Material

1. Identify each radionuclide (e.g., Cobalt-60), the chemical or physical form, the number of sources, and the maximum activity requested. You may specify activity in terms of Curies.

2. Identify the manufacturer's name and model number of each sealed source that will be used in the teletherapy unit.

3. Identify the manufacturer's name and model number of the teletherapy unit in which the sealed sources will be housed.

Item 6. Purpose For Which Licensed Material Will Be Used

Specify whether the teletherapy source will be used for treatment of patients only or whether it will also be used for other purposes. If you request other uses, describe them (e.g., irradiation of animals). The requested uses should be keyed to the sources listed in Item 5.

Item 7. Individuals Responsible For Radiation Safety Program--Their Training And Experience

7.1 Proposed Authorized Users - Human Use

Rule 391-3-17-.02(8)(a) specifies that before an application is approved, users must be qualified by training and experience to use the material for the purposes requested in such a manner as to protect health and minimize danger to life or property. Similar requirements that pertain specifically to teletherapy are found in Rule 391-3-17-.05(16)(a) and (b), and Rule 391-3-17-.05(16)(i). Accordingly, you should describe the training and experience of your proposed authorized users and proposed radiation safety officer (RSO). Proposed users for human use should have the training and experience that meet or exceed that described in Part I of Appendix C of this guide. Submit the training and experience for the above users.

7.2 Radiation Safety Officer

The Radiation Safety Officer (RSO) should have training and experience that meet that described in Part II of Appendix C of this guide. List the full name and title of the individual designated by and responsible to your management for the coordination of your radiation safety program (the RSO). If the on-site RSO is assisted by a consultant or part-time employee, also state the consultant's name and describe his or her duties, responsibilities, and the amount of time to be devoted to the radiation safety program. (Note that when a consultant is employed to assist the RSO, you (as the licensee ~ will still be responsible for the proper performance of your radiation safety program as required by the license, and your on-site RSO will be expected to review the consultant's work and sign the required reports and records.)

If the proposed RSO is not one of the proposed authorized users, you should submit a complete description of the individual's training and experience. If the on-site RSO is assisted by a consultant, provide similar information on the consultant's qualifications..

7.3 Teletherapy Physicist

A licensee’s teletherapy physicist must have the qualifications specified in Rule 391-3-17-.05(16)(j). Your teletherapy physicist should meet the criteria specified in this Rule or should have training and experience at least equivalent this requirement. Specify the full name of the teletherapy physicist and describe the individual's training and experience. Refer to Part III of Appendix C of this guide.

Item 8. Training For Individuals Working In Or Frequenting Restricted Areas

You must establish and agree to follow written procedures for instructing individuals as required by Rule 391-3-17-.07(3), Instructions To Workers. As a minimum, these written procedures should require:

1. That individuals who work in or frequent restricted areas (e.g, physicians, technologists) be instructed in the items specified in Rule 391-3-17-.07(3) at the time of initial employment and at least annually thereafter.

2. That this instruction include all written procedures developed as a prerequisite for obtaining your Department license and other terms of the license pertinent to radiation safety.

3. That other individuals whose duties may require them to work in the immediate vicinity of licensed material (e.g., housekeeping, security, clerical personnel) be informed about radiation safety hazards and appropriate precautions at the time of their initial employment and at least annually thereafter.

4. That until the Department terminates your teletherapy license, you maintain records documenting initial and refresher training and that, as a minimum, these records identify the individual who conducted the training, the individuals who were trained, the date and duration of the training, and the topics covered.

Submit a copy of the personnel training program that you have established and that you agree to follow for instructing individuals as required by the above Rule or, submit a statement that you have adopted the training program described in Appendix D of this Guide (submit a copy of the appendix). The personnel training program in Appendix D fulfills the criteria in Item 8.

Item 9. Facilities And Equipment

Rule 391-3-17-.02(8)(b) states that an application will be approved if, among other things, the applicant's proposed equipment, facilities and procedures are adequate to minimize danger to public health and safety or property. In order for the Department to evaluate the adequacy of your proposed facilities and equipment, you must submit a detailed description of each item as discussed below.

9.1 Description of Facility

Annotated plans and elevation drawings or sketches should provide sufficient information for the Department staff to evaluate the proposed facility. As a minimum, the plans and elevation drawings or sketches of the teletherapy facility* should show:

1. The scale to which the drawings are made. Use the same scale for all drawings; the recommended scale is 1/4 inch = 1 foot.

2. The direction of north.

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

4. The directions of primary beam usage and, in the case of an isocentric unit, the plane of beam rotation.

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

6. The location of doors, windows, conduits, and other penetrations and voids in the shielding materials.

*As used in this guide, the term "teletherapy facility" means the treatment room and its surroundings. The term "treatment room" refers to the room in which the teletherapy unit and source are located and patients are treated.

7. The nature of and distances to all areas adjacent to the treatment room (including above and below). Note that plans and elevation drawings are particularly helpful in showing the relationship among the treatment room, the roof, and the rest of the building.

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

9. The type of use of all areas adjoining the treatment room, including areas above and below. Note that areas should be described as restricted or unrestricted as defined in Rule 391-3-17-.01(2).

9.2 Viewing System

You must provide a viewing system that permits continuous observation of the patient from outside the treatment room while the patient is being treated. See Rule 391-3-17-.05(15)(h).

Describe the system you will use to view the patient continuously. If you will use a shielded viewing window, also specify the thickness, density, and type of material used. If you will use a closed circuit television system (or other electronic system) for viewing the patient, also describe the back-up system you will use in case the electronic system malfunctions or specify that treatments will be suspended until the electronic system is repaired and functioning again.

9.3 Warning Systems and Access Controls

Provide adequate equipment and controls to maintain exposures of radiation to workers within regulatory limits. Rule 391-3-17-.05(15)(e) requires that each door leading into the treatment room 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 to the treatment room is opened when the source is exposed. The mechanism must be wired so that the source cannot be returned to the "on" condition until the door is closed and the system is reset at the control panel.

Describe: 1) warning systems (e.g., locks, signs, warning lights and alarms, interlock systems) for each teletherapy treatment room and 2) methods for controlling occupancy for each restricted area. If other radiation-producing equipment (e.g.. linear accelerator, x-ray machine) is located in the treatment room, describe the steps that will be taken to ensure that no two units can be operated simultaneously.

9.4 Beam Stops

It may be necessary to restrict use of the teletherapy unit's primary beam because the treatment room's 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.

Equip your teletherapy unit with electrical or mechanical stops that limit use of the primary beam of radiation so as to ensure compliance with Rule 391-3-17-.03(5)(j)1. and 2.

Describe the mechanical or electrical beam stops that are operational and restrict beam orientation, specify the direction in which the teletherapy head can be moved, and describe the maximum angle (from vertical) of the beam orientation in each direction. Identify the angle orientation convention (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). If the teletherapy unit has an integral beam absorber (also called a beam catcher), provide similar information for those orientations in which (1) the primary beam is directed toward the integral beam absorber and (2) the primary beam is directed away from the integral beam absorber. You may use sketches to describe how beam stops limit the use of the primary beam.

Some applicants have found it helpful to have a "sample" response for guidance. The following is an example of an acceptable response on the use of a rotational unit with an integral beam absorber; the angle orientation convention described above applies.

For the primary beam directed toward the integral beam absorber, electrical or mechanical stops are set so that the primary bean must be centered (within plus or minus 2°) on the integral beam absorber and, in that configuration, the attenuated primary beam may be rotated 360° pointing toward the floor, east wall, ceiling and west wall.

For the primary beam directed away from the integral beam absorber, electrical or mechanical stops permit the unattenuated primary beam to be directed in a 95° arc from 5° toward the west wall to vertically down toward the floor to 90° toward the east wall.

Given this type of example, many applicants can make changes to accommodate their own situations (e.g., use of a vertical unit, use of a rotational unit without an integral beam absorber).

9.5 Adequacy of Shielding

Based on an evaluation of shielding and the planned use of each area, you must have determined whether each area adjacent to the treatment room will be maintained as a restricted or an unrestricted area, and you must demonstrate compliance with Department regulations. Accordingly:

1. Identify each area adjacent to the treatment room (including above and below) as a restricted or unrestricted area.

2. Submit calculations of the maximum radiation levels expected in each adjacent area. Your calculations should include:

    a. Maximum anticipated workload data (e.g., maximum number of patients treated per hour and per week; maximum dose and treatment time per patient; maximum "on time" per hour and per week).
    b. The value of each parameter used in your calculations. These parameters include such factors as beam orientation, maximum field size, scatter angle, scatter ratio, distance to scatterer, distance to area of concern, type and thickness of materials used in barrier, and transmission factor of barrier.
    c. Contributions from primary, leakage (with the source in the "on" position), and scattered radiation (including low-angle scatter that just misses the integral beam absorber).
    d. Calculations for each area adjacent to the treatment room, including above and below the room, and a statement as to whether the area will be maintained as a restricted or unrestricted area. Calculations need not be provided for areas that have not been excavated.
    e. "Worst case" situations (e.g., use of maximum beam size; all patients treated in 1 hour using the critical orientation that produces high radiation levels in an adjacent area; if the

integral beam absorber is not used for all patient treatments, calculations based on use of the unattenuated primary beam where appropriate; situations within the capabilities of the teletherapy unit that are not prohibited by electrical or mechanical stops, regardless of the clinical usefulness of these orientations).

f. A consideration of continuous occupancy (i.e., occupancy factor of unity) for unrestricted areas unless you request authorization for higher radiation levels pursuant to Rule 391-3-17-.03(5)(i)2.

g. The results of each calculation expressed in millirems in any 1 hour and millirems in any 1 day.

3. For each unrestricted area, state how you will meet the requirements of Rule 391-3-17-.03(5)(j)1. and 2. ,or request authorization for higher levels by providing the information specified in Rule 391-3-17-.03(5)(i)2.

4. For each restricted area, describe your program for meeting the requirements of Rule 391-3-17-.03 and Rule 391-3-17-.07. This description should include:

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. Your program for ensuring that personnel entering the restricted area receive proper instruction in accordance with Rule 391-3-17-.07(3).

d. Your program for ensuring that personnel entering the restricted area are monitored in accordance with Rule 391-3-17-.03(7)(a)3. and (b).

e. The surveys that will be performed in accordance with Rule 391-3-17-.03(7)(a)1. and 2.

Appendix E of this guide discusses the requirements for unrestricted and restricted areas and the calculations needed to show compliance with the regulations.

Rule 391-3-17-.05(15)(l)1. and (o) requires that certain surveys and tests be made and the results reported to the Department. Appendix F of this guide describes the minimum information and measurements that should be included in a survey report to meet the license conditions.

Item 10. Radiation Safety Program

The licensee is responsible for the conduct of its teletherapy program and for the actions of its employees. The Department is permitted to incorporate in licenses any additional requirements and conditions that it deems appropriate or necessary to protect health or minimize danger to life or property. Accordingly, you must provide information about your radiation safety program.

10.1 Personnel Monitoring Program

You must establish and submit written procedures for personnel monitoring. As a minimum, these written procedures must require:

1. That whole-body badges (i.e., film or thermoluminescent dosimeters, also called "TLDs") be provided to personnel who enter restricted areas under the circumstances described in Rule 391-3-17-.03(7)(b).

2. That whole-body badges be exchanged for processing at intervals not to exceed 1 month.
3. That whole-body badges be processed by a commercial personnel dosimetry service company, preferably one accredited by the National Voluntary Laboratory Accreditation Program (NVLAP).
4. That any pocket dosimeters used to measure exposure from licensed material be operable, calibrated, and tested for drift at intervals not to exceed 1 year. Records of calibration and drift tests must be maintained as described in Rule 391-3-17-.03(13)(g)3.

10.2 Radiation Detection Instruments

You must specify and agree to have the following radiation detection instruments in your possession and available for use:

1. A portable low-range survey meter capable of detecting 0.2 milliroentgen per hour.
2. A beam-on radiation monitor permanently mounted in each teletherapy room that is equipped with an emergency power supply separate from the power supply for the teletherapy unit. The beam-on monitor must be capable of providing a visible indication (e.g., flashing light) of an exposed or partially exposed source, and the visible indicator must be observable by a person entering the teletherapy room.
3. A dosimetry system for making full calibration and spot-check measurements (or have access to it).
4. An instrument of sufficient sensitivity to count leak-test samples, e.g., a NaI(Tl) well crystal connected to a single or multichannel analyzer (or have access to it).
5. A high-range portable survey meter such as an ionization-type instrument capable of reading at least 1 roentgen per hour (or have access to it).

10.3 Calibration of Portable Survey Instruments

Rule 391-3-17-.03(7)(a)1. requires each licensee to make such surveys as are necessary to evaluate the extent of radiation hazards that may be present during possession and use of licensed material. Rule 391-3-17-.03(7)(c) requires that in order to perform appropriate surveys, the instruments used must be operable and calibrated.

10.3.1 Licensing Criteria for Applicants That Will Not Calibrate Their Own Survey Instruments

If you will not calibrate your own instruments , you should specify that:

1. Your survey instruments will be returned to the manufacturer for calibration or provide the name, address and the NRC or Agreement State license number of the organization that will provide the service.
2. Your survey instruments will be calibrated at intervals not to exceed 1 year and following repair.
3. Records of each calibration will be maintained for at least 3 years after the calibration. These records will show the date and results of the calibration and the name of the organization that provided the service.

10.3.2 Licensing Criteria For Applicants That Will Calibrate Their Own Survey Instruments

If you will calibrate your own survey instruments, you should provide a description of the standards, frequency and procedures used to calibrate your instruments. You must establish and submit written

procedures for calibrating your survey instruments. As a minimum, these written procedures must require that:

1. Survey instruments be calibrated at intervals not to exceed 1 year and following repair.
2. Calibration be performed with radionuclide sources at distances sufficient to approximate point sources.
3. Survey instruments be calibrated on every scale or range that the instrument offers, up to 1 roentgen per hour. (Note that calibration requires the following minimum activities of typical radionuclide sources: 85 millicuries of cesium-137, 21 millicuries of cobalt-60, or 30 millicuries of radium-226.)
4. For each scale that shall be calibrated calibrate two (2) separate readings at 1/3 and 2/3 of full scale rating.
5. Survey instruments be adjusted to provide readings on all calibrated scales or ranges within ±10% of true value (or ±20%, provided a calibration chart or graph is prepared, attached to the instrument, and used to interpret readings).
6. A record of each instrument calibration, showing the date and the results of the calibration, be maintained for at least 3 years after the calibration.

   Or,

7. Provide a statement that you will calibrate your survey instruments in the manner described in Appendix G of this Guide(submit a copy of the appendix). The standards, frequency, and procedures for calibrating survey instruments described in Appendix G fulfill the criteria in Item 10.3.2.

For detailed information on survey instrument calibration, refer to ANSI N323-1978, "Radiation Protection Instrumentation Test and Calibration."*

10.4 Leak-Test Program

10.4.1 Licensing Criteria for Applicants That Will Use a Consultant To Perform Leak Tests

The consultant or commercial organization should take the leak-test samples (smears), evaluate the samples, and report the results to you. Confirm that records of each leak test will be maintained for at least 3 years after each leak test. These records must identify the sealed source manufacturer's name, model number, serial number, estimated activity, the measured activity (in microcuries) of each test sample, the date of the test, and the name of the consultant or commercial organization that provided the service.

If you will use a consultant or commercial organization, state the name, address, and NRC or Agreement State license number of the consultant or commercial organization that will perform the entire leak-test process for you.

* Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

10.4.2 Licensing Criteria for Applicants That Will Use Commercial Leak-Test Kits

If you will use commercial leak-test kits, identify the leak-test kit by supplier's name and kit model number. State that you will follow the suppliers instructions for taking the samples and sending them to the supplier and specify the name of the person who will use the kit. A person with adequate training and experience will use a commercial leak-test kit (in accordance with the supplier's instructions) for taking leak-test samples that are sent to the supplier for evaluation and the results will be reported to you. The leak-test kit should have been approved for licensing by NRC or an Agreement State. For at least 3 years after each leak test, records of each leak test must be maintained that identify the source, manufacturer's name, model number, serial number, estimated activity, the measured activity (in microcuries) of each test sample, the date of the test and the name of the person who took the samples.

An individual identified in your application who meets the Department's training and experience criteria as a user, radiation safety officer, or teletherapy physicist has adequate training and experience to use a commercial leak-test kit. If the individual who will use the leak-test kit is not one of those identified in the application, submit the person's name and a description of his or her training and experience, which the Department staff will review on a case-by-case basis.

10.4.3 Licensing Criteria for Applicants That Will Perform the Entire Leak-Test Procedure Themselves

If you will perform your own leak tests submit your procedures. You should establish and agree to follow your written procedures for performing the entire leak-test sequence. As a minimum, these procedures should include the following:

1. Describe the materials to be used in taking the leak-test samples and the points on the equipment that will be tested. Samples are not normally taken directly from the surface of a source, but rather from the nearest accessible surface, e.g., collimator blades.

2. Describe the radiation safety procedures to be followed during the leak test and the method for handling and disposing of the samples.

3. Describe the instrument to be used to evaluate the samples and state its sensitivity and accuracy. Rather than specify the manufacturer's name and model number of the instrument, describe its characteristics (e.g., NaI(Tl) well crystal connected to a single-channel or multichannel analyzer). Survey instruments are not acceptable for evaluating leak-test samples.

4. Describe the calibration and standardization procedures and provide a sample calculation showing conversion of results to the required microcurie units. Describe procedures to evaluate or count samples using a calibrated instrument of sufficient sensitivity and accuracy to measure 0.005 microcuries.

5. Identify each individual who will take or evaluate the leak-test samples and describe each person's training and experience if this information was not submitted . An individual identified in the application who meets Department's training and experience criteria as a user, radiation safety officer or expert has adequate training and experience to perform the entire leak-test procedure.

6. Specify that you will maintain records of leak tests for at least 3 years after each test and that, as a minimum, your records will identify the source manufacturer's name, model number, serial number, estimated activity, the measured activity of each test sample, the date of the test and the name of the person who performed the test.

10.5 Operating Procedures

You must establish and submit written procedures governing the operation of your teletherapy unit. You should have written operating procedures directed to and given to specific groups of staff members (e.g., technologists) outlining the responsibilities of each group to ensure your compliance with the Department's regulations, the terms and conditions of the license, and the commitments made in license applications and correspondence with the Department. Many topics pertaining to radiation safety should be addressed in the operating procedures. As a minimum these written procedures should:

1. Require that the teletherapy unit, room, and console be secured when unattended.

2. Describe the actions to be taken to ensure that only the patient is in the treatment room when the primary beam is turned on.

3. Require that safety devices be checked for proper operation (including identifying the devices to be checked and by whom, how the checks are to be performed and the frequency), that malfunctions or defects be corrected promptly, and that the dates and results of the checks and a notation of the date on which each malfunction or defect was corrected be maintained for at least 3 years after each check and each correction of a malfunction or defect.

Appendix H contains a list of topics that may be addressed in a set of operating procedures.

10.6 Emergency Procedures

Rule 391-3-17-.05(15)(d)1. requires that emergency procedures be established and that the procedures be posted at the control console. You must establish and agree to follow written procedures for emergencies that may occur, e.g., the teletherapy source fails to return to the "off" position. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should as a minimum:

1. Specify when they are to be followed.

2. Describe step-by-step actions that are to be taken by whom.

3. Give first consideration to minimizing the exposure to the patient, usually by removing the patient from the room (rather than using tools to attempt to return the source to the off position). If a first step of the emergency procedures specifies pressing the "emergency bar" on the teletherapy unit console, this action may cause the source to return to the off position but may also cut power to the entire teletherapy unit or to the gantry or the couch--these possibilities must be considered in developing emergency procedures.

4. Instruct the staff to act quickly and calmly and to avoid the primary beam of radiation.

5. Require that, as soon as the patient and staff are out of the treatment room, the area be secured (i.e., door locked or guard posted) and a sign posted to alert others to the problem.

6. Specify who is to be notified. Provide the names of at least two individuals who can be notified and their on-duty and off-duty telephone numbers.

You should submit a copy of your emergency procedures, or state that you will follow the emergency procedures described in Appendix I of this guide (submit a copy of the appendix). The emergency procedures shown in Appendix I fulfill the criteria established above.

10.7 ALARA Program

You should establish and agree to follow a written program for ensuring that occupational radiation exposures are maintained as low as reasonably achievable (ALARA). As a minimum, the ALARA program should:

1. Contain management's formal commitment to the ALARA philosophy, recognizing the importance of keeping individual and collective doses ALARA.

2. Include periodic review of the teletherapy program and provide continuing education and training for all personnel who work with or in the vicinity of the teletherapy facility. (This review and education program must ensure that all personnel make every reasonable effort to maintain individual and collective doses ALARA.)

3. Specify the duties of various persons (e.g., technologists, authorized users, radiation safety officer (RSO), radiation safety committee (RSC), licensee management) within the licensee's organization as they apply to ALARA.

4. Establish Investigational Levels (IL) at approximately 10% and 30% of the maximum permissible doses specified in Rule 391-3-17-.03(5)(a) and describe the actions to be taken if radiation exposures exceed the ILs (e.g., investigation by the RSO of the cause of the exposure; consideration of actions that might be taken to reduce probability of recurrence).

5. Specify that, at intervals not to exceed 3 months, radiation exposures of all personnel will be reviewed, compared to ILs, and appropriate actions taken.

6. Include a formal annual review by management, the RSO, and the RSC of the entire radiation safety program, including ALARA considerations.

Submit a copy of your ALARA program, or state that you have adopted the model ALARA program described in Appendix J of this guide (submit a copy of the appendix).

10.8 Radiation Safety Committee

If the application is for a hospital or other medical institution, you must establish and maintain a Radiation Safety Committee (RSC) to oversee the use of licensed material throughout your institution and to review your institution's radiation safety program. As a minimum, the membership of your RSC must include an authorized user for each type of use permitted by the license, a representative of the nursing

staff, a representative of the institution's management, and the Radiation Safety Officer.

You should submit one of the following:

1. A statement that specifies:

   a. The name of each member of your radiation safety committee, with sufficient additional information to show that the RSC includes the individuals specified in rule 391-3-17-.05(6)(f)1.(i). To prevent the need for future license amendments when RSC members are changed, also state that, if you change individual members of the RSC, you will (1) ensure that the membership includes all the personnel specified in the above Rule and (2) maintain records of the membership until the Department terminates your teletherapy license.

   b. The meeting frequency and the responsibilities and duties of the RSC. As a minimum, the RSC should meet as often as necessary to conduct its business but not less than once in each calendar quarter.

2. A statement that your RSC's responsibilities, duties, and meeting frequency will be as described in Appendix K of this guide (submit a copy of the appendix). Appendix K meets the licensing criteria in Item 10.8 .

3. If you already have an RSC because you hold another Department license (e.g., for nuclear medicine procedures), you may (1) submit the information on membership outlined in a above and (2) specify that your existing RSC's duties and responsibilities have been amended to include teletherapy.

Item 11. Waste Management

Rules 391-3-17-.03(12)(a) provides the Department's general requirements for disposal of radioactive material. Most teletherapy licensees dispose of unneeded sealed sources by transferring them to an authorized recipient (e.g., the source manufacturer). Note that Rule 391-3-17-.05(15)(b) requires that certain work, including source removal or source exchange, may be performed only by persons specifically authorized by the NRC or an Agreement State to do the work. Note also that some teletherapy units contain source material in the form of depleted uranium used as shielding material in the unit. Before transferring radioactive material, you must verify that the recipient is properly authorized to receive it by using one of the methods described in 391-3-17-.02(19)(d). Describe how you will dispose of unneeded teletherapy units and sources.

Item 12. License Fees

The applicant should refer to the DNR Radioactive Materials License Fee Schedule (Appendix B) to determine the appropriate licensing fee and category. (Note that, in addition to licensing fees licensees are required to pay inspection fees and annual fees. No action will be taken on applications filed without the proper fee. Checks for the fees should be made payable to the **Department of Natural Resources, Radioactive Materials Program**, and mailed to the following address:

Radioactive Materials Fees
P.O. Box 101161

Atlanta, Georgia 30392

Note: Prior approval from the Department must be obtained before Small Entity classification can be used.

Mail license applications, amendment, renewal requests, and terminations of license to the following address:

Radioactive Materials Program
4244 International Parkway
Atlanta TradePort, Suite 114
Atlanta, GA. 30354

Item 13. Certification

If you are an individual applicant acting in a private capacity, you must sign the completed application form, otherwise, the application should be dated and signed by a representative of organization or legal entity that has authority to make binding commitments and sign off on official documents. The signing official must certify that the application contains information that is true and correct to the best of the his/her knowledge and belief. The Department will not process an unsigned application, and it will be returned for proper signature.

IV. AMENDMENTS TO A LICENSE

After you are issued a license, you must conduct your program in accordance with (1) the statements, representations, and procedures contained in your application and other correspondence with the Department (2) the terms and conditions of the license, and (3) the Department's regulations.

It is your obligation to keep your license current. If any of the information provided in your application is to be modified or changed, submit an application for a license amendment. In the meantime, you must comply with the terms and conditions of your license until it is actually amended. Department regulations do not allow you to implement changes solely on the submission of an amendment request.

An application for a license amendment may be prepared either on the application form, Appendix A, or in a letter. It should be submitted in duplicates as stated in Section 2 of this guide. Retain one copy , the license requires that you possess and use licensed material in accordance with the statements and representations in your amendment request and in any additional attachments.

Your application should specify your license number and clearly describe the nature of the changes, additions, or deletions. References to previously submitted information and documents should be clear and specific. Identify the pertinent information by date, page, and paragraph. For example, if you wish to change the RSO, your application for a license amendment should specify the proposed RSO's name, training, and experience. The qualifications of the proposed RSO should be equivalent to those specified in Item 7 of this guide.

You need to include the appropriate fee with an amendment request. The Department will not issue the amendment prior to receipt of the proper fee as specified in the Fee Schedule, Appendix B.

V. RENEWAL OF A LICENSE

Licenses are issued for a period of up to 5 years. Send an application for renewal, in duplicates, to the address specified in Section 2 of this guide. Retain one copy, the license requires that you possess and use licensed material in accordance with the statements and representations in your renewal request and in any supplements to it.

It is important that the appropriate fee, accompany your application for license renewal. The Department will not issue the license renewal prior to receipt of the fee.

You may submit an entirely new application for renewal as if it were for a new license without referring to previously submitted information. The Department prefers this method for renewals, especially for those applicants who reference a large number of documents and/or old documents. Submitting an entirely new application allows you to reevaluate your program periodically and consolidate the description of your program into one or two current documents. A new application ensures that your program contains all needed information as requested in current licensing guide.
As an alternative to a new application, you may:

1. Review your current license to determine whether the information about sealed sources and teletherapy units accurately represents your current and anticipated program. Identify any necessary additions, deletions or changes and then prepare information as appropriate for the change(s).

2. Review the documents submitted to the Department in the past to determine whether the information is up to date and accurately represents your facilities, equipment, personnel, radiation safety procedures, locations of use, etc. The documents considered to represent your current program must be identified by date. Also identify any out-of-date and superseded documents and indicate the changes that are necessary. Documents referenced in your license should not be older than 5 years unless all the information in the document accurately represents your current program. If you need to update information in documents 5 years old or older, you should submit a new application.

3. Review current Department regulations to ensure that any changes in the regulations are appropriately covered in your program description.

4. After you have completed your review, submit a letter to the Department in duplicates, with the proper application fee for a license renewal. Provide the information in items 1, 2, and 3 as necessary.

5. Include the name and telephone number of the person to be contacted about your renewal application and include a current mailing address if it is not indicated correctly on your license.

If you file an application for a license renewal at least 30 days before the expiration date of your license, include the appropriate application fee and your current license will automatically remain in effect until the Department takes final action on your renewal application.

If you do not wish to renew your license, dispose of all licensed radioactive material possessed in a manner authorized by 391-3-17-.02(19). Complete the Department's form, "Request to Terminate Radioactive Materials License" (see Appendix L) and send it to the Department before your license expires.

If you cannot dispose of all the licensed radioactive material in your possession before the expiration date, you must request a license renewal for "storage only" of the radioactive material. The renewal is necessary to avoid violating the Department's regulations that do not allow possession of licensed material without a valid license.

VI. TERMINATION OF A LICENSE

You may request termination of your license at any time. This notification should include a request to terminate the license and must include a completed Department's form, "Request to Terminate Radioactive Materials License" (see Appendix L) , certifying that all sources have been disposed of properly. Note that a license is not terminated until the Department takes action to terminate the license. An application for license termination does not relieve the licensee from its obligations to comply with Department's regulations and the terms and conditions of the license.

APPENDIX A

Georgia Department of Natural Resources

Environmental Protection Division

Radioactive Materials Program

APPLICATION FOR RADIOACTIVE MATERIALS LICENSE

INSTRUCTIONS - Complete Items 1 through 13 if this is an initial application or renewal of a license. Use supplemental sheets where necessary. Item 13 on the application must be completed and signed. Retain one copy for your records. Submit original application to: Georgia Department of Natural Resources, Radioactive Materials Program, 4244 International Parkway, Suite 114, Atlanta, Georgia, 30354. Upon approval of this application, the applicant will receive a Georgia Radioactive Materials License. Georgia Radioactive Materials Licenses are issued in accordance with the general requirements contained in the Georgia Department of Natural Resources Rules and Regulations, Chapter 391-3-17. **The Department can be reached via the Internet. The address is rad_materials @ mail.dnr.state.ga.us.**

1.This is an Application for: (Check appropriate item) A.☐ New License B. ☐ Amendment to License C. ☐ Renewal of License
If B or C , Please indicate GA. License Number _____

2.a. Name and Mailing Address of Applicant Name: Address: City, State, Zip Code: County: Telephone Number ( ) _____ -_____ Internet Address:	2.b. Address where licensed material will be stored and/or used (Street Address) A. Permanent B. Coordinates 1. Latitude: 2. Longitude: C. Temporary sites throughout Georgia? Yes _____ No_____
3. Person to Contact Regarding this Application Name: Title: Telephone Number ( ) _____ - _____	4. Locations where records will be kept:
SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.	
5. RADIOACTIVE MATERIAL a. Element and mass number, b. Chemical and/or physical form; and c.. maximum amount which will be possessed at any one time.	6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED
7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING EXPERIENCE	8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS
9. FACILITIES AND EQUIPMENT	10. RADIATION SAFETY PROGRAM
11. WASTE MANAGEMENT	12. LICENSEE FEES (SEE DEPARTMENT'S FEE SCHEDULE) FEE CATEGORY : AMOUNT ENCLOSED $ CHECK MAILED ☐ PLEASE INVOICE ☐
MAKE CHECKS PAYABLE TO: DEPARTMENT OF NATURAL RESOURCES RADIOACTIVE MATERIALS PROGRAM	**MAIL FEES TO: RADIOACTIVE MATERIALS PROGRAM, P.O. BOX 101161 ATLANTA, GEORGIA 30392**

13. CERTIFICATION (Must be completed by the applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATE ON BEHALF OF THE APPLICANT NAMED IN ITEM 1, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH GEORGIA DEPARTMENT OF NATURAL RESOURCES RULES AND REGULATIONS, DESIGNATED CHAPTER 391-3-17 AND THAT ALL INFORMATION CONTAINED HEREIN, INCLUDING ANY SUPPLEMENTS ATTACHED HERETO, IS TRUE AND CORRECT TO THE BEST OF OUR KNOWLEDGE AND BELIEF.

CERTIFYING OFFICER -- TYPED PRINTED NAME AND TITLE	SIGNATURE	DATE

FOR DEPARTMENT USE ONLY

TYPE OF FEE	FEE CATEGORY	AMOUNT RECEIVED	INVOICE DATE	COMMENTS
APPROVED BY			DATE:	

License Category	Licensing Fees				Inspection Fees		Annual Fees		
	Code	Application	Renewal	Amendment	Routine	Non-Routine	Nominal	Small Entity	Lower Tier
Medical Teletherapy	A.1	3,400	790	430	1,200	1,900	3,200	600	135
Institutional Medical-Mult. Use	A.2	710	1,000	430	1,000	1,500	1,200	600	135
Institutional Medical-Single Use	A.3								
Private Practice	A.4								
In-Vitro Studies Only	A.5	500	500	380	1,200	1,200	500	500	135
In-Vitro General Licenses	A.6	0	0	0	0	0	100	100	100
Bone Mineral Analyzers	A.7	710	1,000	430	1,000	1,500	1,200	600	135
Medical Manufacturer for Distribution	A.8.a.	3,400	1,400	460	1,400	1,900	2,900	600	135
Medical Distribution or Redistribution Only	A.8.b.	1,100	500	310	800	1,200	900	600	135
Mobile Nuclear Medicine	A.9	710	1,000	430	1,000	1,500	1,200	600	135
Broad Medical	A.10	2,300	2,000	360	1,600	1,800	3,300	600	135
Eye Applicators	A.11	710	1,000	430	1,000	1,500	1,200	600	135
Depleted Uranium	A.12	110	110	110	290	350	130	130	130
Special Nuclear Material(sealed sources in devices)	B.1	500	500	380	460	1,300	400	400	135
Special Nuclear Material(other)	B.2	690	690	230	690	800	1,000	600	135
Industrial Mfg. for Distribution	C.1	1,300	2,300	550	1,000	2,000	1,500	600	135
In-house Industrial Radiography	C.2	3,000	1,800	490	1,200	2,500	2,600	600	135
Multiple Job-Site Industrial Radiography	C.3								
Gamma Irradiators (Self-Shielded)	C.4.a.	500	480	250	460	690	400	400	135
Gamma Irradiators (<10K Ci)	C.4.b.1.	1,000	750	250	500	1,000	1,000	600	135
Gamma Irradiators (>10K<100K Ci)	C.4.b.2.	5,000	3,750	1,250	1,200	2,400	5,000	600	135
Gamma Irradiators (>100K<1M Ci)	C.4.b.3.	10,000	7,500	2,500	2,500	5,000	10,000	600	135
Gamma Irradiators (>1M Ci)	C.4.b.4.	30,000	22,500	7,500	5,000	10,000	30,000	600	135
Broad Scope Distribution, Specific	C.5.a.	2,300	1,400	230	2,100	2,100	2,100	600	135
GL Distribution (source and/or device evaluation)	C.5.b.	2,500	580	390	690	690	1,700	600	135
GL Distribution (no source and/or device evaluation)	C.5.c.	1,900	940	290	690	690	1,400	600	135
NARM Exempt Distribution (device evaluation)	C.6.a.	2,100	1,100	250	690	690	1,500	600	135
NARM Exempt Distribution (no device evaluation)	C.6.b.	2,600	1,200	350	460	690	1,700	600	135
Well Logging/Tracers	C.7	3,400	2,000	540	800	800	2,300	600	135
Nuclear Laundries	C.8	1,400	1,400	350	1,200	1,900	1,600	600	135
Industrial Research & Development	C.9	1,100	1,100	630	800	930	1,300	600	135
Gas Chromatograph, Installed Gauges, etc.	C.10	500	500	380	1,200	1,200	500	500	135
Portable Moisture Density Gauges,Pb analyzers,etc.	C.11								
Calibration Sources	C.12								
Industrial (other)	C.13								
Broad Scope (Academic)	D.1	2,300	2,000	500	930	1,200	2,100	600	135
Broad Scope (Industrial R&D)	D.2								
Civil Defense	E.	580	400	310	690	690	500	500	135
Teletherapy Service Co.	F.	1,400	1,100	630	800	690	1,500	600	135
Consultants (Leak Testing Service)	G.	500	500	380	1,200	1,200	500	500	135
Storage Only	H.								
Academic (Non-Broad)	I.								
Device Evaluation	J.1	3,300	0	1,200	0	0	2,100	600	135
Source Evaluation	J.2	690	0	230	0	0	500	500	135
Reciprocity	K.	0	0	0	0	0	Appropriate License Renewal Fee		
Radioactive Waste Disposal-Burial	L.1	50,000	50,000	5,000	12,000	24,000	30,900	600	135
Radioactive Waste Disposal-Incineration	L.2								
Radioactive Waste-Storage,Packaging or Transfer	L.3	2,800	1,900	200	2,100	2,200	3,600	600	135
G L Devices(except tritium safety signs)	GL	0	0	0	0	0	100	100	100

APPENDIX C

TRAINING AND EXPERIENCE FOR TELETHERAPY USERS

PART I. TRAINING AND EXPERIENCE FOR PROPOSED USERS--HUMAN USE

1. General Criteria

Any human use of byproduct material (i.e., the internal or external administration of byproduct material, or the radiation therefrom, to human beings) must be carried out by or under the supervision of a physician. As defined in Rule 391-3-17-.01(2)(vvv), a physician means any person who is licensed to engage in the practice of medicine under the authority of O.C.G.A. 43-34-20 or the limited practice of medicine under O.C.G.A. 43-35-1.

Rule 391-3-17-.05(16)(i) requires that a physician designated as an authorized user have adequate training and experience. Outlined below are criteria for training and experience that the Department has found acceptable for physicians who will use, supervise, or direct the use of radioactive materials in teletherapy units.

2. Previous Approval by NRC or an Agreement State

Physicians specifically listed as authorized users on a teletherapy license previously issued by Department, NRC, or an Agreement State are considered to have adequate training and experience. Specify the teletherapy license number issued by the Department or submit a copy of the NRC or Agreement State license on which the applicant physician was specifically listed as an authorized user.

3. Medical Specialty Board Certification

The following certifications will be accepted as evidence that a physician has had adequate training and experience [Refer to Rule 391-3-17-.05(16)(i)1.]:

a. Certification by the American Board of Radiology (ABR) in oncology or therapeutic radiology.

b. Certification by the American Board of Radiology (ABR) in radiology if certified prior to 1979.

c. Certification by the American Osteopathic Board of Radiology (AOBR) in radiation oncology.

d. Certification by the Canadian Royal College of Physicians and Surgeons (RCPS) in therapeutic radiology.

e. Certification in radiology , with specialization in radiotherapy, as a British "Fellow of the Faculty of Radiology" (FFR) or "Fellow of the Royal College of Radiology" (FRCR).

Physicians holding one of the medical specialty certifications listed above should submit a copy of their certificates along with the application.

4. Physicians Who Do Not Meet the Criteria in Sections 2 or 3--Minimum Training and Experience

The training and experience described below should have been received within 5 years of the date of application or the applicant physician must provide evidence of (1) continuing clinical involvement in radiotherapy or (2) having taken refresher or continuing education courses in radiation therapy.

a. Training in basic radioisotope handling techniques applicable to the use of sealed sources (200 hours) consisting of lectures, laboratory sessions, discussion groups, or supervised on-the-job training (OJT) experience (note that OJT must have been received in a formal training program) in the following areas [Refer to Rule 391-3-17-.05(16)(I)2.(i)]:

(1)	Radiation physics and instrumentation	(110 hours)
(2)	Radiation protection	(40 hours)
(3)	Mathematics pertaining to the use and measurement of radioactivity	(25 hours)
(4)	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.)

b. 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 [Refer to Rule 391-3-17-.05(16)(i)2.(ii)]:

(1) Review of initial full calibration and periodic spot-check measurements of teletherapy units;
(2) Preparation of treatment plans and treatment times for teletherapy and brachytherapy;*
(3) Using administrative controls to prevent misadministrations;
(4) Implementing emergency procedures to be followed in the event of the abnormal operation of a teletherapy unit or console; and
(5) Checking and using survey meters.

c. Clinical training in teletherapy procedures: Active practice in therapeutic radiology with a minimum of 3 years of experience, at least 1 year of which should have been spent in a formal training program accredited by the Residency Review Committee for Radiology of the Accreditation Council for Graduate Medical Education or the Committee on Postdoctoral Training of the American Osteopathic Association and an additional 2 years of clinical experience in radiation oncology or therapeutic radiology under the supervision of an authorized user at a medical institution. [Refer to Rule 391-3-17-.05(16)(i)2.(iii)]

5. Documenting Training and Experience To Meet The Criteria In Section 4

The qualifications of each applicant physician who has not been previously approved by a licensing agency (see Section 2) and who is not certified (see Section 3) will be reviewed on a case-by-case basis with the assistance of the Medical Advisory Committee. The following is a checklist of materials that should be submitted, with suggestions on their preparation:

a. Document at least 200 hours of training in basic radioisotope handling techniques, as described in Section 4.a. For each subject covered in this basic training, state where the training was obtained, the dates, total number of hours, and type of training. Hours of training should be broken down into lecture, laboratory, or OJT. OJT must have been obtained in a formal training program. Be sure that hours of training can be traced to the institution where the training was received. Each hour of training should be listed under only one subject category (i.e., the most applicable subject category). Document at least 500 hours of experience with the types and

* Although brachytherapy procedures are not authorized on a teletherapy license, information on the applicant physician's experience with these procedures is important because the normal method of treatment of some patients (e.g., patients with cervical cancer) involves use of both brachytherapy and teletherapy.

quantities of radioactive materials being requested as described in Section 4.b.

b. Submit a completed and signed letter by an authorizing official from the institution which the applicant physician gained training and experience as described in 5.A. above. The letter should describe the scope and extent of the applicant physicians training and experience and competency to independently use teletherapy and brachytherapy sources for patient treatment.

c. For applicant physicians who completed their training and experience more than 5 years before the date of the application, evidence of (a) continuing clinical involvement in radiation therapy from the time the training was completed to the date of the application or (b) having taken refresher or continuing education courses in radiation therapy.

PART II. TRAINING AND EXPERIENCE FOR PROPOSED USERS--NONHUMAN USE AND RADIATION SAFETY OFFICER (RSO)

1. General Criteria

Rule 391-3-17-.02(8)(a) requires that the applicant for a license be qualified by "training and experience to use the material for the purpose requested in such manner as to protect health and minimize danger to life or property." Proposed RSOs and proposed users for nonhuman uses of teletherapy units are expected to meet these requirements. Outlined below are training and experience criteria that have been found acceptable for these two categories of applicants.

Physicians whose training and experience meet the criteria in Part I have sufficient training and experience to be authorized to use a teletherapy unit for nonhuman use or to act as RSO or both. However, proposed users for nonhuman use (e.g., instrument calibration) of a teletherapy unit and proposed RSOs need not be physicians.

2. Minimum Training and Experience

a. Training in basic radioisotope handling techniques applicable to the use of sealed sources (200 hours) as described in Section 4.a of Part I of this appendix.

b. 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:

(1) Learning appropriate radiation safety, quality control, and emergency procedures for handling and using sealed sources.
(2) Calibration of ion chambers and survey meters and performance of operational checks of these instruments.
(3) Performance and evaluation of leak tests of sealed sources.

3. Documenting Training and Experience

Document training and experience. See the discussion in Part I of this appendix.

PART III. TRAINING FOR TELETHERAPY PHYSICIST

The following describes the training and qualifications for a teletherapy physicist [Refer to Rule 391-3-17-.05(16)(j)]:

1. Must be certified by the American Board of Radiology in:

a. Therapeutic radiological physics;
b. Roentgen-ray and gamma-ray physics;
c. X-ray and radium physics;
d. Radiological physics; or

2. Hold a master's or doctor's degree in physics, biophysics, radiological physics or health physics, and have 1 year of full-time training in therapeutic radiological physics and also 1 year of full-time work experience under the supervision of teletherapy physicist at medical institution. To meet this requirement, the individual shall have performed the tasks listed in Rule 391-3-17-.05(7)(g) and Rule 391-3-17-.05(15)(j) (k) and (l) under the supervision of a teletherapy physicist during the year of work experience.

APPENDIX D

PERSONNEL TRAINING PROGRAM

1. Schedule for Training

   Training will be provided:

   a. Before an employee assumes duties with or in the immediate vicinity of radioactive materials;

   b. Annually as refresher training for all employees; and

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

2. Description of the Training Program

   Training will be sufficient to ensure that:

   a. Individuals who work in or frequent restricted areas are instructed in the items specified in rule 391-3-17-.07(3); and

   b. Individuals whose duties may require work in the immediate vicinity of radioactive materials are informed about radiation hazards and appropriate precautions.

3. Content of the Training Program

   The program of instruction will include:

   a. Pertinent terms and conditions of the Department license, including procedures developed as a prerequisite for obtaining the license and commitments incorporated into the license by condition.

   b. Appropriate response to emergencies or unsafe conditions, including participation by appropriate staff in "dry runs" of emergency procedures conducted as a part of the initial and annual refresher training.

   c. Areas where radioactive material is used or stored. Potential hazards associated with radioactive material.

   e. Radiological safety procedures appropriate to the duties of the employee.

   f. Pertinent Department regulations.

   g. The obligation of all personnel to report unsafe conditions to the radiation safety officer.

   h. The right of all personnel to be informed of radiation exposure and bioassay results.

   i. The locations where the licensee has posted or made available notices, copies of regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by rule 391-3-17-.07.

4. Records That Document Training

Records of initial and refresher training will be maintained until the Department terminates the teletherapy license and will include:

a. The name of the individual who conducted the training;

b. The names of the individuals who received the training;

c. The dates and duration of the training session; and

d. A list of the topics covered.

APPENDIX E

DISCUSSION OF UNRESTRICTED AND RESTRICTED AREAS FOR TELETHERAPY APPLICANTS AND LICENSEES

Each area adjacent to a teletherapy facility must be identified and maintained either as an unrestricted or as a restricted area. As a part of your application for a new teletherapy license, you as an applicant have to use calculated values of maximum anticipated radiation levels to show how you will comply with the Department's regulations on restricted and unrestricted areas. After your license is issued and your teletherapy unit and source installed, you as a licensee must conduct surveys and use measured radiation levels in showing how you are complying with the Department's requirements. The following discusses pertinent Department regulations and factors to be considered in showing compliance with these regulations.

1. Unrestricted Areas:

   a. A standard teletherapy license requires that radiation levels in unrestricted areas meet the requirements of Rule 391-3-17-.03(5)(j)1. and 2. 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 50 millirems in one year.

   b. In showing compliance with Rule 391-3-17-.03(5)(j)1. and 2., you:

      (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. You may use a fractional use factor to show compliance with Rule 391-3-17-.03(5)(j)1. and 2. if you maintain records to support your assumptions about use of the teletherapy unit. You should keep these records until Department terminates your teletherapy license.

   d. If compliance with Rule 391-3-17-.03(5)(j)1. and 2. cannot be demonstrated, you have several options:

      (1) You may restrict beam orientation (e.g., by using electrical or mechanical stops) to limit the anticipated radiation level.
      (2) You may add shielding to the barrier in question.
      (3) You may request authorization for higher radiation levels and demonstrate that the requirements of Rule 391-3-17-.03(5)(i)2. are met. In this case, you must include information on average radiation levels and anticipated occupancy times for each unrestricted area. You must also maintain records to support the assumptions used in justifying your request until the Department terminates your teletherapy license.
      (4) You may designate and maintain the area as restricted.

2. Restricted Areas:

   a. The Department's regulations do not specify maximum exposure rates for restricted areas in a manner similar to Rule 391-3-17-.03(5)(j)1. and 2. Rather, the regulations refer to the ALARA

---

*The phrase "occupancy factor" is used as in NCRP Report No. 49: a factor used to correct for the degree of occupancy of the area in question while the primary beam is "on."

philosophy [Rule 391-3-17-.01(2)(k)] and specify certain maximum permissible doses that individuals may receive in a restricted area [Rule 391-3-17-.03(5)(a)].

b. For each restricted area, you must describe:

(1) The physical and administrative controls used to restrict access to the restricted area;

(2) The number, wording, size, and location of warning signs to be placed in the vicinity of the restricted area;

(3) Your program for ensuring that personnel entering the restricted area receive proper instruction in accordance with rule 391-3-17-.07(3);

(4) Your program for ensuring that personnel entering the restricted area are monitored in accordance with Rule 391-3-17-.03(7)(a)3. and (b); and

(5) The surveys that will be performed in accordance with Rule 391-3-17-.03(7)(a)1. and 2.

The details regarding controls, signs, training and monitoring programs, and surveys will vary depending on the magnitude of possible exposure rates and other factors that pertain to your teletherapy unit. The Department will review each situation on a case-by-case basis.

APPENDIX F

TELETHERAPY SURVEY REPORTS

Rule 391-3-17-.05(15)(l)1. and (o) requires you to perform a radiation survey and to submit a survey report to the Department each time your teletherapy source is replaced or whenever any changes are made in the shielding, location, or use of the teletherapy unit 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 on 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.

CONTENTS OF SURVEY REPORT

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

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

2. Provide the name and address of each person conducting the survey.

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

4. Provide the date on which the work described in Item 3 was completed.

5. Provide the date or dates on which the survey was conducted.

6. Provide the following information for each radiation detection instrument used for the measurements reported in items 10, 11, and 15 (or 16) of the survey report:

   a. The manufacturer's name and model number,
   b. The date of the last calibration before making these measurements, and
   c. The standards (i.e., radionuclide, activity, and accuracy) and procedures used in the calibration.

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

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

9. Specify the activity of the source (in curies) and the corresponding assay date.

10. Specify the intensity of the primary beam of radiation at a specific distance (e.g., roentgens per hour at a meter (RHM) or roentgens per minute at a meter (RMM)) as measured after the source has been installed in the protective source housing of the licensee's teletherapy unit and the date that this intensity was measured. (Note that Rule 391-3-17-.05(15)(j) provides for full calibration measurements to be made by an expert using a properly calibrated dosimetry system, as well as for monthly spot checks. Records demonstrating compliance with these sections of the Department’s regulations must be maintained by the licensee as required by Rule 391-3-17-.05(15)(j)7. These records need not be submitted with the required survey report.)

11. Provide the maximum and average radiation levels measured at 1 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 1 meter in radius centered on the source; the diagram in Figure F-l 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 points. (Note that Department agrees with Section 4.2.2 of NCRP Report No. 33, "… small areas of reduced protection are acceptable in evaluating the maximum exposure rate providing that the average over 100 square centimeters at one meter from the source does not exceed 10 milliroentgens per hour.")

12. 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). You 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.

13. 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:

    a. The phantom used, including the material of which it is made and its size,
    b. The source-to-phantom distance, and
    c. The field size (field size should be the maximum permitted by the collimators unless physical means are used to restrict field size).

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

    a. Indicate the direction of north,
    b. Show the location of the teletherapy unit and source within the treatment room,
    c. Identify each area adjacent to the treatment room (including above and below),
    d. Indicate the directions of primary beam usage and, in the case of an isocentric unit, the plane of rotation, and
    e. Identify the locations at which radiation levels were measured (see items 15 and 16 below).

15. Rotational units:

    a. For the primary beam directed toward the integral beam absorber, determine the rotational position of the teletherapy unit that causes the maximum radiation level in each area adjacent to the treatment room (including above and below the treatment room). 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 to the barrier in question.

    b. For the primary beam directed away from the integral beam absorber and for units without an integral beam absorber, report the maximum radiation levels that are measured in each area adjacent to the treatment room (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 12 of the survey report.

16. For vertical units, report the maximum radiation levels measured in each area adjacent to the treatment room (including above and below) and specify the orientations (i.e., angulation toward each area) that produce 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 12 of the survey report.

17. For each measured radiation level reported in items 15 or 16 of the survey report that exceeds 2 milliroentgens per hour, explain how you are complying with the Department's regulations and the terms of your license. See Appendix E for further guidance.

18. Describe (1) the tests that were conducted and (2) the results of these tests that ensure proper operation of the safety systems described below.

All tests should use a radiation detection instrument to confirm the "on-off" status of the source.

a. Teletherapy treatment room door interlock. The test should be sufficient to ensure that the door interlock operates.
b. Teletherapy "on-off" indicators, both mechanical and electrical (e.g., lights or mechanical indicator on protective source housing of teletherapy unit, over door to room, at console).
c. Electrical or mechanical stops installed to limit use of the primary beam of radiation. The test should be sufficient to ensure that beam stops at in the manner described in item 12.
d. 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.

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

a. The date of removal and
b. The name, address, and license number of the person or firm who took possession of the unit or source.

20. If the surveyor recommends any changes to improve the safety of the operation of the teletherapy facility, describe the recommendations and your response to these recommendations.

INSTRUCTIONS FOR FILING SURVEY REPORTS

1. A report of the results of the required survey should be sent to the Department.

These reports must be sent no later than 30 days after the installation of a new source or completion of the changes requiring the survey.

2. The licensee should keep a copy of the survey report in its files for at least 5 years from the date on which the survey was conducted.

APPENDIX G

PROCEDURES FOR CALIBRATION OF SURVEY INSTRUMENTS

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

   a. The sources will be approximate point sources.
   b. The source used will be one of those listed in Table G-l.

Table G-1

SOURCES USED FOR SURVEY INSTRUMENT CALIBRATION

Radionuclide	Minimum Activity (To give at least 700 milliroentgens per hour at 20 cm)
Cesium-137	85 millicuries
Cobalt-60	21 millicuries
Radium-226	34 millicuries

   c. The source activities or exposure rates at given distances will be traceable by documented measurements to a standard source certified within 5% accuracy to the National Institute Of Standard and Technology (NIST) calibration sources.
   d. Calibration will be performed at intervals not to exceed 12 months and after servicing.
   e. Instruments will be calibrated on every scale or range of the instrument, up to 1 roentgen per hour.
   f. For each scale that shall be calibrated. Calibrate two (2) separate readings at 1/3 and 2/3 of full scale rating.
   g. The exposure rate measured by the instrument will differ from the true exposure rate by less than +10% at the calibration points (read the appropriate section of the instrument manual to determine how to make necessary adjustments to bring the instrument into calibration). Readings within +20% will be considered acceptable if a calibration chart, graph, or response factor is prepared, attached to the instrument, and used to interpret meter readings.

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

   a. Before each use and after each survey to ensure that the instrument was operational during the survey;
   b. After each maintenance or battery change; and
   c. At intervals not to exceed 3 months.

   If any reading with the same geometry is not within +20% of the reading measured immediately after calibration, the instrument will be recalibrated.

3. Records of items 1, 2.b, and 2.c above will be maintained for a least 3 years after each calibration or check.

4. The use of the small check source that is in some survey meters is not appropriate or acceptable for

calibration purposes.

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

   a. 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.

      (1) The inverse square law may be used with any point source to calculate the exposure rate at other distances.

      (2) The radioactive decay law may be used to calculate the output at any time.

   b. Inverse Square Law

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

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

      <u>Note</u>: R_a and R_b must be in the same units of dose rate (e.g., milli rem per hour, rem per hour) 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:

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

   c. Radioactive Decay Law

      The dose rate of a standard source at a time t after a specified calibration date is given by:

$$R_t = R_O \times e^{-(0.693 \times \frac{t}{T_{½}})}$$

where: R_t is the dose rate at a time t after the source calibration date
R_O is the dose rate on the day the standard source was calibrated
t is the time elapsed since the calibration date
T½ is the radionuclide half-life

<u>Note</u>: R_t and R_O must be in the same units of dose rate (e.g., millirem per hour, rem per hour), and t and $T_{½}$ must be in the same units of time (e.g., seconds, days, years).

APPENDIX H

TOPICS THAT MAY BE INCLUDED IN OPERATING PROCEDURES

Good health physics practice dictates that you provide your personnel with operating procedures to give them clear and specific directions in their duties and responsibilities. These duties may include, but are not limited to, safety device checks, instrument calibration, monthly spot checks, and leak tests. 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 technologists.

The operating procedures should be designed for the program proposed in your application. Procedures should be complete and self-contained. Pertinent information contained in equipment manuals and other publications should be extracted and included in your operating procedures.

The following topics may be included in your operating procedures:

1. Receipt and Disposal of Radioactive Materials. Teletherapy licenses specify exactly the radioactive material by chemical and physical form (including manufacturer's name and model number) and the maximum activity that may be possessed and used in a specific teletherapy unit (manufacturer's name and model number). When radioactive materials are no longer needed, they may be transferred to a person or firm authorized to receive them as provided in Rule 391-3-.02(19). Further, you must notify the Department in writing when you decide to permanently discontinue all activities involving radioactive materials authorized by your license; see Rule 391-3-17-.02(18).

   Accordingly, operating procedures should be sufficient to ensure that radioactive materials received are within the limits specified in your license, that radioactive materials are transferred to appropriately licensed persons in accordance with the requirements of Rule 391-3-17-.02(19), and that the Department is notified in writing when you decide to permanently discontinue all activities authorized by your license.

2. Use of the Teletherapy Unit. The operating procedures should specify who may operate the unit, how the unit may be used (i.e., in what orientations, for what purposes), and how the unit is to be operated (i.e., the sequence of steps to be followed to turn the beam on and off). The operating procedures should include instructions to ensure that only the patient is in the room when the primary beam is on and may specify certain daily checks of the unit to ensure its proper operation.

3. 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, door interlocks, 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, prompt correction of any malfunctions or defects noted, and retention of appropriate records (see Item 10.5 of this guide). A simple checklist may be used to complete the task and record keeping 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 operating procedures should describe the steps 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.

   Documents such as ANSI N449-1974, "Guidelines for Maintaining Cobalt-60 and Cesium-137 Teletherapy Equipment";* ANSI N449.1-1978, "Procedures for Periodic Inspection of Cobalt-60 and Cesium-137

Teletherapy Equipment";* and NCRP Report No. 69, "Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV,"** recommend frequency and procedures for making certain tests. If the recommendations in these documents conflict with the Department's regulations or license conditions, the minimum acceptable frequency is that specified in the regulation or license condition.

4. Personnel Dosimetry. Operating procedures should require teletherapy personnel to wear personnel monitoring devices (film or TLD badges); they should also contain instructions about the manner in which the devices should be worn and about proper storage of the devices when they are not in use. 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 or TLD of the affected person to be processed immediately.

5. Procedures for Securing the 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.

6. Instrument Calibration and Checks. Instruments must be calibrated and checked for proper operation in accordance with the Department's regulations [e.g., Rule 391-3-17-.05(15)(f)] and other commitments of the licensee [e.g., response to Item 10.3 of this guide]. Operating procedures should identify who will calibrate survey instruments, specify the frequency of calibration, and describe the methods and radioactive standards used in the calibration.

   Rule 391-3-17-.05(15)(g)4. and 6. requires that the beam-on monitor and survey instrument (or audible-alarm personal dosimeter) be checked daily for proper operation. The operating procedures should specify who is to make these checks and how they are to be made.

   Rule 391-3-17-.05(15)(i) specifies how and by whom dosimetry systems used for full calibration and spot-check measurements are to be calibrated and the frequency of calibration. Operating procedures should be sufficient to ensure compliance with this Rule.

7. Full Calibration of Teletherapy Units. Rule 391-3-17-.05(15)(j)2. specifies what measurements must be made during a full calibration; Rule 391-3-17-.05(15)(j)3. and 6. requires that a properly calibrated dosimetry system must be used and a teletherapy physicist must perform the full calibration measurements. Operating procedures should identify who will make the full calibration measurements and describe the procedures to be followed and the instruments to be used.

8. Monthly Spot-Check Measurements of Teletherapy Units. Rule 391-3-17-.05(15)(k) specifies that tests must be conducted as monthly spot checks and Rule 391-3-17-.05(15)(i) describes the characteristics of a properly calibrated dosimetry system needed to make the spot-check measurements. The operating procedures should specify when, how, and by whom the spot-check measurements will be made. If the spot checks are not done by the expert, the operating procedures should describe how and when the results of the spot checks are reviewed by the expert.

9. Leak Tests. Leak tests must be conducted in accordance with the requirements of Rule 391-3-17-.05(7)and the commitments in your response to Item 10.4 of this guide. Operating procedures should specify who will perform the tests, how often the tests will be conducted, and the procedures to be followed in taking and evaluating the samples. If commercial leak-test kits are used, the operating procedures should include the supplier's instructions.

---

* Copies may be obtained from the American National Standards Institute, 1430 Broadway, New York, NY 10018.

** Copies may be obtained from NCRP Publications, 7910 Woodmont Avenue, Bethesda, MD 20815.

10. Inspection and Servicing of the Teletherapy Unit. Rule 391-3-17-.05(15)(p) requires that teletherapy units be fully inspected and serviced during source replacement or at intervals not to exceed 5 years, whichever comes first. This work to ensure proper functioning of the source exposure mechanism must be done by a person or firm specifically licensed to do so by the Department, the NRC, or an Agreement State. Operating procedures should be sufficient to ensure compliance with this Rule.

11. Limitations on Work Done on Teletherapy Unit. Rule 391-3-17-.05(15)(b) requires that only persons or firms specifically authorized by the Department, the NRC or an Agreement State can:

    - Install, relocate, or remove teletherapy units containing sources;
    - Perform source exchanges; and
    - Perform any maintenance or repair of the teletherapy unit that involves work on the source drawer, the shutter, or other mechanism that expose the source, reduce the shielding around the source, or compromise the safety of the unit and result in increased radiation levels.

    Operating procedures should be sufficient to ensure compliance with the requirements of this license condition.

12. Survey Reports. Rule 391-3-.05(15)(l) and (o) specifies when a formal survey must be made, what measurements and tests must be performed, and when and to whom formal reports must be submitted. The operating procedures should specify who will perform the formal surveys, how and when they will be conducted, and when and to whom copies of the formal report will be sent. The operating procedures should require that, as a minimum, the survey reports contain the information identified in Appendix F of this guide.

13. Relocation of Teletherapy Unit. Rule 391-3-17-.05(15)(c) requires that the Department approve your plans and proposed location before a teletherapy unit is relocated. The operating procedures should ensure that the needed amendment to the Department license is obtained before the teletherapy unit is relocated.

14. Record keeping. You must maintain certain records to comply with the Department's regulations, the conditions of your license, and commitments made in your license application and correspondence with the Department. Operating procedures should identify the individuals within your organization who are responsible for maintaining which records. Operating procedures should consider, but not be limited to, maintenance of the documents listed below.
    - Copies of the Department licenses, your license applications, and correspondence with the Department in support of a license request[1]
    - Record of results of safety device checks[2]
    - Personnel dosimetry records[3]
    - Records of survey instrument calibrations and daily checks[2]
    - Records of daily checks of beam-on monitor[4]
    - Records of daily checks of audible-alarm personal dosimeters[4]

---

[1]Maintenance of these records is required. Because this regulation does not specify how long to keep the records, you should maintain them until the department terminates your license.

[2]Maintain for at least 3 years from the date of each safety device check (see Item 10.5), 3 years for survey instrument calibration and check (see Item 10.3), and 5 years for leak test (see Item 10.4)

[3]See Rule 391-3-17-.03(13)(g).

[4]Maintenance of these records is required by Rule 391-3-17-.03(13)(g)5.

- Records of calibration of the dosimetry system used for full calibration measurements[5]
- Records of calibration or intercomparison of the dosimetry system used for spot-check measurements[5]
- Results of full calibration measurements[5]
- Results of spot-check measurements[5]
- Record of evaluation of the training and experience of the "teletherapy physicist" as defined in Rule 391-3-17-.05(16)(j)[5]
- Records of training of new personnel and annual refresher training of personnel[6]
- Records of leak-test results
- Records of full inspection and servicing of the teletherapy unit[5]
- Copies of reports of surveys conducted in accordance with Rule 391-3-17-.05(15)(l) and (o)[7]
- Records of receipt and disposal of radioactive material[8]

15. Emergency Procedures. Rule 391-3-17-.05(15)(d)1. requires that emergency instructions be posted at the teletherapy machine control and that these instructions inform the operator of procedures to be followed if the primary beam of radiation cannot be turned off by using the controls outside the room.

    Emergency instructions should be developed that cover not only the situation outlined above but any other unusual occurrence (e.g., source does not return to the fully off position). In developing emergency instructions, you must be sure that they are clear and concise and that potential adverse consequences have been considered.

    Operating procedures should require that written emergency instructions be established, be posted at the teletherapy unit console, and be followed when necessary. The emergency instructions should specify when they are to be implemented and describe specific actions to be taken and specific persons to be notified. Operating procedures should also require that new teletherapy personnel be trained in emergency procedures as soon as they report for duty and that practice drills in emergency procedures be conducted with all appropriate personnel at least once a year.

    See Item 10.6 for criteria used to evaluate emergency instructions.

[5]See Rule 391-3-17-.05(15)(I)3., Rule 391-3-17-.05(15)(j)7., Rule 391-3-17-.05(15)(k)10. and Rule 391-3-17-.05(15)(p)3.

[6]See Rule 391-3-17-.05(15)(I)3., Rule 391-3-17-.05(15)(j)7., Rule 391-3-17-.05(15)(k)10. and Rule 391-3-17-.05(15)(p)3.

[7]Maintain for the duration of the license [Refer to Rule 391-3-17-.05(15)(l)3].

[8]See Rule 391-3-17-.01(4).

APPENDIX I

EMERGENCY PROCEDURES FOR BEAM CONTROL FAILURE OR MALFUNCTION

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 by the Radiation Therapy Technologist:

1. Open the door to the treatment room.
2. If the patient is ambulatory, tell him or her to get off the table and leave the room.
3. 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.
4. Close the door and secure the area by locking the door to the treatment room or posting a guard at the entrance.
5. Turn off the main switch at the control panel.
6. Notify the radiation therapist and radiation safety officer at once.
7. 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* _____

*Copies of emergency procedures posted at the teletherapy console will contain up-to-date information on the names and telephone numbers of personnel to be contacted.

APPENDIX J

MODEL PROGRAM FOR MAINTAINING OCCUPATIONAL RADIATION EXPOSURES AT MEDICAL INSTITUTIONS ALARA

1. Management Commitment

   a. We, the management of this (medical facility, hospital, private practice, etc.), are committed to the program described in this document for keeping exposures (individual and collective) as low as is reasonably achievable (ALARA). In accordance 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 that person has applied to ensure that the applicant will be able to take appropriate measures to maintain exposure ALARA.

      (2) When considering a new use of byproduct material, the RSC will review the efforts of the applicant to maintain exposure ALARA. The user should have systematized procedures to ensure ALARA and should have incorporated the use of special equipment.

      (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

---

[1] Private practice physician licenses do not require an RSC.

[2] The RSO identified on private practice physician licenses will assume the responsibilities of the RSC.

assert authority. When the RSO has been overruled, the RCS will record the basis for its action in the minutes of its 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 J-l 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.

(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 6 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

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 authorized 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

[3]Emphasis on 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 investigation.

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 workers under his or her supervision are trained and educated in good health physics practices and in maintaining exposures ALARA.

5. Workers

a. Workers will be instructed in the ALARA concept and its relationship to their working procedures and working conditions.
b. Workers will know what recourses are available if they believe that ALARA is not being promoted on the job.

6. Establishment of Investigational Levels 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 RSC, the RSO, or both. The Investigational Levels apply to the exposure of individual workers.

TABLE J-l

	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

The RSO will review and record the results of personnel monitoring at least once in any calendar quarter. The exposures will be compared with the Investigational Levels in Table J-l 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 J-l values for Investigational Level I.

b. Quarterly 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 RSC. The RSC 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 RSC's minutes.

c. Quarterly personnel 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 radiation exposure record 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 RSC's minutes. The RSC's minutes will be sent to the management of the institution for review. The minutes, containing details of the investigation, will be made available to Department inspectors for review at the time of the next inspection.

d. Establishment of an individual worker's Investigational Level II above that listed in Table J-l

If a 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 RSC 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.

*Not normally applicable to nuclear medicine or teletherapy operations

APPENDIX K

RADIATION SAFETY COMMITTEE

Responsibilities

The Radiation Safety Committee is responsible for:

1. Overseeing the use of the department-licensed radioactive materials throughout the institution.
2. Reviewing the institution's radiation safety program to ensure that the Department-licensed materials are used safely and in accordance with the Department regulations, the conditions of the licenses, and the ALARA philosophy [expressed in Rule 391-3-17-.01(2)(k)].

Duties

The Radiation Safety Committee will:

1. Be familiar with all pertinent Department regulations, the terms of the licenses, and information submitted in support of the request for the licenses and amendments.
2. Review the training and experience of all individuals who use Department licensed 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 Department regulations and the conditions of the licenses.
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 Department-licensed radioactive material (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by Rule 391-3-17-.07(3).
4. Review and approve all requests for use of Department-licensed 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 the Department regulations and the conditions of the licenses. (The review will include an examination of all records, reports from the radiation safety officer (RSO), results of the Department inspections, written safety procedures, and management control system.)
6. Recommend remedial action to correct any deficiencies identified in the radiation safety program.
7. Maintain, until the Department terminates our licenses, written records of all Radiation Safety Committee meetings, actions, recommendations, and decisions.
8. Ensure that the Department radioactive material license is amended, when necessary, before any changes are made in facilities, equipment, policies, procedures, and personnel (i.e., authorized user and RSO).

Meeting Frequency

The Radiation Safety Committee will meet as often as necessary to conduct its business but not less than once each calendar quarter.

*The phrase "radiation workers" as used in this appendix means those individuals who may receive an occupational dose as defined in Rule 391-3-17-.01(2)(ppp).

APPENDIX L

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
REQUEST TO TERMINATE RADIOACTIVE MATERIAL LICENSE

1. Licensee Name _____ 2. License Number _____

3. Address _____
No. Street City, State Zip code

4. Contact Person _____ 5. Telephone Number _____

6. Request is hereby made that the Radioactive Material License described above be terminated for the following reason:

_____

_____

7. Radioactive Material possessed under this license has been disposed of as indicated below:

☐ No materials have been possessed or procured by the licensee under this licensee.

☐ All material was used for the licensed purposes, none remains.

☐ All material was leased, and has been returned to lessor.

Name of lessor: _____ License No. _____

☐ Copy notice of receipt attached

☐ Material has been transferred to the following licensee:

Licensee Name _____ License No. _____

Address _____
No. Street City, State Zip code

Date of transfer: _____

☐ Copy of receipt attached

☐ Material has been disposed of in the following manner:

_____

_____

☐ A radiation survey was conducted to confirm the absence of radioactive material and to determine whether any contamination remains at the facility covered by the license.

☐ Copy of survey results attached.

6. Management Official or Radiation Safety Officer

_____ _____
Signature of certifying officer Date

_____ _____
Print name Title

Keep one copy for your records and send original to:

GEORGIA DEPARTMENT OF NATURAL RESOURCES
RADIOACTIVE MATERIALS PROGRAM
4244 INTERNATIONAL PARKWAY, SUITE 114
ATLANTA, GEORGIA 30354