Radioactive Material License Guide

Gamma Stereotactic Radiosurvey (GSR) Module

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LICENSING GUIDE FOR
GAMMA STEREOTACTIC RADIOSURVEY (GSR) MODULE

The specific items identified below should be addressed in addition to the more general items identified in the "Instructions and Licensing Guide – Medical Use", which applies to all medical use licensees and applicants.

PURPOSE:

The purpose of this guide is to provide assistance to applicants and licensees in preparing applications for new licenses, license amendments and license renewals that authorize the possession of radioactive material for use as sources for patient procedures using a gamma stereotactic radiosurgery device (GSR). This type of license is provided for in Environmental Regulatory Code Part XV. Radiation Protection, Chapter 7. This guide is to provide you with information that will enable you to understand specific regulatory requirements and licensing policies as they apply to GSR. Specifically, guidance is provided on operating and emergency procedures, conduct of required surveys of the GSR unit, and survey instruments and radiation monitors.

Item 4.A – INDIVIDUALS RESPONSIBLE FOR RADIATION SAFETY

GSR PHYSICIST:

List the name of the individual proposed as a GSR physicist. Individuals not previously authorized by an Agreement State or the NRC as a GSR physicist or medical physicist, must submit a complete description of their training and experience.

Item 4.B - TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS:

TRAINING PROGRAM:

TRAINING PROGRAM FOR INDIVIDUALS RESPONSIBLE FOR GSR TREATMENT OF PATIENTS:

It has been determined that there is a need for a "team approach" for the use of this device. As a minimum, the team should include a qualified medical physicist who can make the detailed dose calculations involved in the use of this device and physicians with expertise in radiation therapy and neurosurgery and persons with any other speciality deemed appropriate. You must provide a description of your procedure for a "team approach" in the treatment of patients. In this

procedure, include the names of the individuals and a description of the extent of each individual's involvement in the use of the GSR treatment of patients.

Training in the use of the GSR has been accomplished by apprenticeship and on the job training. The manufacturer contracts with experienced GSR users to train new users. The neurosurgeons or radiation oncologists usually spend a couple weeks at a GSR facility learning about the use of the GSR and participating in treatments. The medical physicists often go to a different site than the physicians and will spend approximately one week at one facility and one week at a second facility. The manufacturer generally has a physician and physicist present for the first few treatments in a new facility with new users. It is required that all personnel involved in patient treatment attend the training recommended by the manufacturer.

Personnel should be instructed in the topics above as follows:

1. Before assuming duties with, or in the vicinity of, radioactive materials;
2. During annual refresher training;
3. Whenever there is a significant change in duties, regulations, the terms of the license, equipment, procedures, or protocol.

Licensees should tailor their training programs according to their specific needs.

TRAINING FOR NURSING STAFF:

Nurses providing care for patients during treatment should be instructed in the following topics, commensurate with their duties:

1. Basic radiation biology;

2. Basic radiation physics, to include concepts of time, distance, and shielding;

3. Risk estimates, including comparison with other health risks so that nurses will have an understanding of the risks involved and response appropriately, rather than react based on excessive fear or lack of concern;

4. ALARA concept;

5. Posting requirements;

6. Proper use of personnel dosimetry (when applicable);

7. Licensee's Quality Management Program – To ensure that each administration is in accordance with the written directive. Attention to correct positioning of the helmet to ensure that treatment is to correct site;

8. Instruction in procedures for reacting to medical emergencies or patient death, including notification of appropriate medical personnel and the RSO (the intent of these procedures should in no way interfere with or be in lieu of appropriate patient care);

9. Occupational dose limits;

10. Dose to the embryo/fetus limits including instruction about declaration of pregnancy;

11. Dose to individual members of the public;

12. Workers right to be informed of occupational radiation exposure;

13. Each individuals obligation to report unsafe conditions to the RSO;

14. Applicable regulations, license conditions, information notices, bulletins, etc.;

15. Location where copies of the applicable regulations and the radioactive material license are posted or made available for examination;

16. Proper record keeping;

17. Previous incidents, events and/or accidents; and

18. Questions and answers.

TRAINING FOR THE MEDICAL PHYSICS STAFF (including medical physicist, therapists, and dosimetrists)

In addition to the topics identified above for nursing staff and individuals involved in the GSR treatment of patients, individuals should be instructed in the following, commensurate with their duties:

1. Appropriate surveys to be conducted, and when;

2. Leak testing;

3. Emergency procedures to include drills of emergency extraction of patients from the unit;

4. Operating instructions to include daily preventative maintenance procedures as well as patients treatment;

5. Computerized treatment planning system; and

6. Dosimetry protocol.

TRAINING FOR ANCILLARY PERSONNEL (housekeeping, dietary services, security, etc.)

Individuals should be instructed in the following topics (licensees may choose to prohibit ancillary personnel from entering restricted areas, and train accordingly).

1. Posting/labeling;

2. Precautions

RECORDS:

Records of worker training should include date and duration of training; topics covered, names of individuals(s) providing training and attendees, and should be maintained for 3 years.

ITEM 7.B – WASTE DISPOSAL

RETURNING SOURCES

Because of the nature of the licensed material contained in GSR units, the only option for disposal is to transfer the material to an authorized recipient. The transfer should be done as soon as practical after there is no further use for the sources.

Authorized recipients are the original supplier of the sealed sources, a commercial firm licensed by the NRC or an Agreement State to accept radioactive waste from other persons, and another specific licensee authorized to possess the licensed material. No one else is authorized to dispose of licensed material.

It is required 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.

ITEM 9.a – HEALTH PHYSICS PROGRAM

The licensee is responsible for the conduct of its GSR program and for all actions of its employees. Accordingly, you must provide information about your radiation safety program. Please note that the Radiation Licensing Section can incorporate in licenses such additional requirements and conditions that it deems appropriate or necessary to protect health or to minimize danger to life or property.

Emergency Instructions:

It is required that instructions be posted at the GSR unit console that inform the operator of procedures to be followed if the operator is unable to turn the primary beam of radiation off with the controls outside the treatment room or any other abnormal operation occurs. You must establish and agree to follow written procedures for emergencies that may occur, e.g., the treatment couch fails to retract. It is recommended that a copy of the manufacturer's instructions be given to each responsible individual and that actual practice of emergency procedures for patient removal be performed every six months. In your response, you should submit a copy of your emergency procedures. These procedures, designed to minimize radiation exposure to patients, workers, and the general public, should as a minimum:

a. Specify when they are to be followed.

b. Describe step-by-step actions that are to be taken and by whom;

c. Give first consideration to minimizing the exposure to the patient; usually by removing the patient from the room.

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

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

f. 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.

GSR SURVEY REPORTS:

It is required that you perform a radiation survey and to submit a survey report each time your GSR sources are replaced or after making any change such as

the shielding, location or use of the GSR 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.

In order to fulfill this requirement for reporting the results of the radiation survey to the appropriate section within 30 days following completion of the action that initiated the record requirement, the survey report should:

1. Provide the name, address and license number of the person or organization that possesses the GSR 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 new sources, relocation of the GSR 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 paragraphs 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 GSR unit.

8. Provide the manufacturer’s name and model number of the GSR sources.

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

10. Specify the intensity of the primary beam of radiation at the isocenter of the sources as measured after the sources have been installed in the protective source housing of the licensee's GSR unit and the date that this intensity was measured.

11. Provide the maximum and average radiation levels measured at one meter from the sources in the off position. The average radiation level may be obtained by averaging measurements taken at 14 to 26 points on the surface of a sphere 1 meter in radius centered on the isocenter of the sources. Describe the locations of the 14 to 26 points and the radiation levels measured at each of the points.

12. For measurements of radiation levels in adjacent areas, which should be made during irradiation of a phantom with normal treatment parameters, describe the phantom used, including the material of which it is made and its size.

13. Submit the plan and elevation drawings or sketches of the GSR facility; a scale of ¼ inch = 1 ft. is recommended. The drawings or sketches should:

    a. Indicate the direction of north,
    b. Show the location of the GSR unit and source housing within the treatment room,
    c. Identify each area adjacent to the treatment room (including above and below),
    d. Identify the locations at which radiation levels were measured.

14. 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. GSR treatment room door interlock. The test should be sufficient to ensure that the door interlock operates in the manner required; and

    b. GSR treatment timing device. The tests should be sufficient to ensure that the timer is accurate, that the treatment couch retracts and shielding doors close at the end of the preset time, and that the shielding door does not open nor does the

treatment couch move to the treatment position until the timer is reset.

15. If the GSR unit or its sources were 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 sources.

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

OPERATING PROCEDURES FOR GSR:

Personnel should be provided 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 fails to 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:

USE OF THE GSR UNIT:

The operating procedures should specify who may operate the unit, how the unit may be used, how the unit is to be operated (i.e., the sequence of steps to be followed to begin treatment), and who must be present during the treatment. 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.

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, helmet position indicator microswitches, safety switches, door interlocks, 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 promptly correction of any malfunctions or defects noted, and retention of appropriate records. A simple checklist may be used to complete the task and recordkeeping 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 GSR unit might be prohibited until the problem is corrected, or alternative procedures such as requiring personnel to enter the room with an operable survey meter might be implemented.

PERIODIC SPOT-CHECK MEASUREMENTS OF GSR UNITS:

It is required that output spot-checks tests must be performed once in each calendar month. The operating procedures should specify when, how, and by whom the spot-check measurements will be made. The measurements required shall be performed in accordance with procedures established by a GSR physicist. The GSR physicist need not actually perform the spotcheck measurements, but must review and initial the spotcheck results.

INSPECTION AND SERVICING OF THE GSR UNIT:

It is required that GSR 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 may only be done by a person or firm specifically licensed to do so by the NRC or an Agreement State. Preventative maintenance should also be addressed to ensure that as systems deteriorate from use, they are identified and repaired. These items related to the GSR should be included in these sections such as hydraulic system maintenance; collimator helmet supports, holes, plugs, bushings, and other helmet positioning equipments; and the systems related to the patient couch and the shielding door.

LIMITATIONS ON WORK PERFORMED ON GSR UNIT

It is required that only persons or firms specifically authorized by the NRC or an Agreement State can:

Install, relocate or remove a GSR sealed source or a GSR unit that contains sources;

Perform any maintenance, adjustment, or repair of the GSR unit that involves work on mechanisms that could expose the source, reduce the shielding around the source, or result in increased radiation levels.

SURVEY REPORTS:

Identify 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.

RELOCATION OF GSR UNIT:

It is required that the Department approve your plans and proposed location before a GSR unit is relocated. The operating procedures should ensure that the necessary approval is obtained before the GSR unit is relocated.

RECORDKEEPING:

You must maintain certain records to comply with 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 license, license applications, and correspondence with the Department in support of license request;

Records of results of safety device checks;

Personnel dosimetry records;

Records of survey instrument calibrations and daily check;

Records of daily checks of audible-alarm personal dosimeter;

Records of daily checks of beam-on monitor;

Records of calibration of the dosimetry system used for full calibration measurements;

Records of calibration or intercomparison of the dosimetry system used for spot-check measurements;

Results of full calibration measurements;

Results of sport-check measurements;

Results of leak test results;

Records of training of new personnel and annual refresher training of personnel;

Records of full inspection and servicing of the GSR Unit;

Copies of reports of surveys conducted in accordance with Regulations and conditions of your GSR license; and

Records of receipt and disposal of radioactive material

SAFETY INSTRUCTIONS

It is required that operating instructions be posted at the GSR machine control and that these instructions inform the operator of procedures to be followed to ensure that only the patient is in the treatment room before the treatment is initiated or after a door interlock interruption; and the procedure if the treatment cannot be terminated by using the controls outside the room or any other abnormal operation occurs.

Emergency instructions should be developed that cover not only the situations outlined above but any other unusual occurrence (e.g., helmet does not retract following treatment, timer malfunction). In developing emergency instructions, you should 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 GSR 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 GSR 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.

The operating procedures should specify categories of occurrences (e.g., GSR unit malfunction, misadministration) that require notification and the names and telephone numbers of individuals or organizations to be notified in each category of occurrence (e.g., radiation safety officer, hospital administrator, GSR unit manufacturer or service representative of the Department).

You should submit a copy of your operating procedures. You must establish and agree to follow written procedures governing the operation of the GSR unit. You should have written operating procedures directed to and given to specific groups of staff members (e.g., technologists) outlining the responsibilities or each group to ensure your compliance with Radiation regulations, the terms and conditions of the license, and 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 GSR 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 treatment is initiated;

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 by maintained for at least 3 years after each check and each correction of a malfunction or defect.

ITEM 9.B – PHYSICAL FACILITIES:

It is required that the applicant's proposed facilities and equipment are adequate to protect health and minimize danger to life or property. In order for the Department to evaluate the adequacy of your proposed facilities and equipment, you must provide a detailed description as discussed below. Prior to receipt of licensed material, all proposed facilities and equipment must be available for use in accordance with the license application.

FACILITY DIAGRAM:

Annotated plans and elevation drawings or sketches should provide sufficient information for Department staff to evaluate the proposed facility. As a minimum, the plans and elevation drawings or sketches of the GSR suite and loading facility should indicate:

1. The scale to which the drawings are made. Use the same scale for all drawings; the recommended scale is ¼ inch = 1 foot.

2. The direction of north.

3. The principal use of each room or area (for example, in vitro, hot lab, waiting, examining, imaging, reading, office, film processor, toilet, closet, hallway). 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.

4. The location of the gamma stereotactic unit and source within the treatment room.

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.

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 amount the treatment room, the roof, and the rest of the building.

SURVEY INSTRUMETNS AND RADIATION MONITORS:

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

1. A portable survey meter;

2. A beam-on radiation monitor permanently mounted in each GSR suite that is equipped with an emergency power supply separate from the power supply for the GSR unit. The beam-on monitor must be capable of providing a visible indication (e.g., flashing light) or an exposed or partially exposed source, and the visible indicator must be readily observable by any person entering the GSR room.

3. A dosimetry system for making full calibration and spot-check measurements (or have access to a dosimetry system).

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).

TEMPORARY HOT CELL CONSTRUCTION AND SOURCE LOADING

GSR licensees are prevented from performing activities that could expose the sources, reduce the shielding around the sources, or result in increased radiation levels. Therefore, the construction of the temporary hot cell and installation of

sources must be performed by a service company specifically licensed to perform such activities. You must provide a copy of the service companies license, its operating procedures, and any agreements regarding radiation safety procedures that will be used during source installation procedures.

VIEWING SYSTEM:

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 or procedure 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.

WARNING SYSTEMS AND ACCESS CONTROLS:

Provide adequate equipment and controls to maintain exposures of radiation to workers ALARA and within regulatory limits.

It is required that each door leading into the treatment room be provided with an interlock to control the “on-off” mechanism of the GSR unit. The interlock must shield the sources of radiation if the door to the treatment room is opened when the source is exposed. The mechanism must be wired so that the treatment cannot restart until the door is closed and the system is reset at the control panel.

In response to the above, describe (1) warning systems (e.g., locks, signs, warning lights and alarms, interlock systems) for each GSR treatment suite and (2) methods for controlling occupancy for each restricted area. If other radiation-producing units (e.g., linear accelerator, X-ray machine) are located in the treatment room, describe the steps that will be taken to ensure that no two radiation producing units can be operated simultaneously.

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 the 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 maximum collimator diameter, fewest plugs used, 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.

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).

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 the Regulations.

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

3. For each restricted area, describe your program for meeting the following:

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

b. The number, working, 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 instructions.

d. Your program for ensuring that personnel entering the restricted area are monitored.