Application Guide for Particle Accelerator Licenses

Medical

Item 1. a. Specify the name and address of the organization which will be responsible for ensuring that the accelerator program complies with the conditions of the license and with the Department regulations.

b. If the actual location of the particle accelerator is different from that in Item 1. a., specify the address of this location.

Item 2. Self-explanatory

Item 3. Self-explanatory

Item 4. State the name(s) of all individual(s) who will use the particle accelerator. For human use, each user must be a physician who is licensed to dispense drugs in the practice of medicine by a state or territory of the United States, the District of Columbia, or the Commonwealth of Puerto Rico. (Training and experience of physician-users is addressed under Item 8.)

Authorized physician-users have the following responsibilities:

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

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

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

d. Actual use of, or direction of therapists or other paramedical personnel in the use of, the particle accelerator, and

e. Provision of necessary follow-up medical care.

Item 5. State the name and title of the person designated by, and responsible to, the institution's radiation safety program (Sometimes designated "Radiation Safety Officer"). A summary description of the Radiation Safety Officer training and experience should be submitted under Item 8.

In programs where the Radiation Safety Officer will have assistance in the routine, day-to-day radiation safety program, specify the name(s) of the individual(s) who will provide this assistance. Include a brief resume of the assistant(s) training and experience.

If a consultant provides assistance in the radiation safety program, state the consultant's name and describe the duties, responsibilities, and amount of time devoted to the program by the consultant.

Item 6. Particle Accelerator(s)

a. Identify each particle accelerator by manufacturer and model number. Indicate the number of accelerators of each model which will be at the facility.

b. Specify the following operating characteristics for each accelerator listed. The specifications should be keyed to the appropriate line number of the accelerators (e.g. accelerator listed in Item 6.a. (1) should have specifications listed in Item 6.b. (1)). The following specifications should be described:

(1) Operating modalities available with each accelerator (e.g. x-ray, electron, neutron, proton, etc.). All available operating modalities should be specified, regardless of whether or not all will be routinely used.

(2) Specify which of the available operating modalities will actually be used in the treatment program. All available modalities might not be included (e.g., a given accelerator may be capable of producing x-ray and electron beams, but only the x-ray beam will be used.)

(3) For each operating modality which will be used, specify the maximum radiant energy attainable through that modality.

Item 7. Paragraph RH-5203(a)(1) of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation specifies the requirement for medical institutions applying for a license for human use of particle accelerators with regard to establishing a medical committee to evaluate all proposals for research, diagnostic, and therapeutic use of particle accelerator(s) with that institution.

Medical institutions with an existing medical isotopes committee, as required by a Radioactive Material License, may not need to establish a second committee, but should expand the existing committee's duties and responsibilities to include particle accelerator operations.

a. Specify the name and specialty of each member of the committee. The committee must be composed of at least three members, with the following specialties represented:

(1) Physicians expert in internal medicine, hematology, and therapeutic radiology, at least one of whom will use the licensed particle accelerator for the treatment of humans.

(2) A person experienced in depth dose calculations and protection against radiation.

(3) A representative of the institution's management.

b. Appendix A to this guide contains an example of typical duties and responsibilities for a medical committee. Indicate, by checking the appropriate box on the application form whether the duties, responsibilities, and meeting frequency will be as described in Appendix A or if an alternative is proposed. Any description submitted in lieu of using Appendix A should address, as a minimum, the same material covered in the Appendix.

Item 8. Training and Experience

a. For each physician-user listed in Item 4, the applicant should submit:

(1) Appendix B Form. If already on file with the Department; the name of the licensee, the license number where the documentation may be found and a copy of current Arkansas State Medical License need be submitted. If a proposed user is certified by the American Board of Radiology or Therapeutic Radiology, Appendix B Form needs to be submitted, specifying the branch of radiology and the year in which certification was received.

(2) For each non-certified physician-user, additional statements from each physician under whom the individual has received training and experience in the use of a particle accelerator, describing the scope and extent of training and experience and including an appraisal of the proposed user's competence to independently use a particle accelerator. Criteria of acceptable training and experience are contained in Appendix B.

b. Radiation Safety Officer

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

Item 9. Instrumentation

The applicant should describe the radiation detection instruments available for use in the particle accelerator therapy program. Such instrumentation should include:

(1) A portable survey meter. Survey meters for accelerator therapy programs should be appropriate to the type of radiation being produced and devoted exclusively to the program (i.e. not shared with other programs at the facility).

(2) An area radiation monitor permanently mounted in the treatment room and equipped with a back up battery power supply.

(3) A dose measurement system if the applicant plans to perform full calibrations or spot checks as required by Paragraph RH-1608(d)(2) and (3). (If a consultant is used, a dose measurement system is not necessary.)

(4) If the accelerator is capable of producing neutrons, instrumentation should be available either on the premises or through a consultant to detect and quantify neutrons. These instruments may be portable survey meters designed for neutron detection and/or an instrument capable of measuring neutron contaminants in the treatment beam.

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

Appendix C to this guide is a form that may be used to describe these instruments. If this form is used, check the appropriate box on Item 9 of the application. If Appendix C is not used, equivalent information should be attached.

Item 10. Calibration of Radiation Detection Instruments

NOTE: Item 10 refers only to calibration of radiation detection instruments. Calibration of the particle accelerator itself is addressed in Item 16.

a. Survey Instruments

Appendix D to this guide contains an acceptable set of procedures for the calibration of survey instruments. The form in Appendix D may be used to describe the procedures used. (Note that Item 3.c. of the form applies to calibration by consultants or outside firms.) If the form from this Appendix is not used, be certain to address all of the applicable information from this form.

b. Other Instruments

(1) Area Monitor

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

(2) Dose Measurement System

Dose measurement systems used for calibration of the therapy beam must be calibrated every two years as required by Paragraph RH-1608(d)(2)(C)(ii).

The calibration of the dose measurement system must be directly traceable to national standards of exposure or absorbed dose. If the applicant intends to perform calibration of the therapy beam in-house, describe the procedures which ensure that the dose measurement system is calibrated as described above. Dose measurement systems used solely for spot check measurements may either be calibrated as described above or be calibrated by an annual direct comparison with a system which has been calibrated in that manner. If the applicant plans to perform spot check measurements, describe the procedures for calibrating the dose measurement system used for this purpose.

Item 11. Facilities and Equipment

a. Facilities

(1) Plan and elevation drawings or sketches of the treatment room and surrounding areas should be submitted which shows:

A. The exact location of the particle accelerator within the room

B. The type, thickness, and density of shielding materials used on all sides of the room, including floor and ceiling. All treatment room walls, floors, and ceiling must be fixed barriers.

C. The location of entrance, windows, conduits, and other penetrations and voids in the shielding materials. Shielding used to compensate for these voids should be described.

D. The nature of and distances to all areas adjacent to, above, and below the treatment room. Adjacent areas should be designated as controlled or uncontrolled areas in accordance with Paragraph RH-1200. As an alternative to specifying distances to adjacent areas, drawings may be drawn to a specified scale. (e.g. ¼ inch = 1 foot) (NOTE: The control panel MUST be outside of the treatment room. See RH-1608(c)(2).)

E. The height of earth against outside walls, if possible.

F. The location of "scram" buttons inside the treatment room. These emergency switches must be easily accessible and capable of immediately stopping the primary beam of radiation.

G. The direction of North.

(2) Calculations (not actual survey measurements) should be submitted which project the maximum radiation levels that will exist in each area adjacent to and above and below the shielded facility. The calculations should include contributions due to primary, leakage, and scattered radiation and should clearly indicate all parameters used in the calculations. Such parameters include beam orientation, effect of beam stops, maximum field size, scatter angles, scatter ratios, distance from source to scatterer, distances to areas of concern, type of material and

thickness of barrier, and attenuation factor of the barrier. Radiation levels must be evaluated with respect to the requirements of RH-1200. Adjacent controlled and uncontrolled areas should be identified by the type of activity performed in that area (e.g. corridor, office, etc.).

Calculations should show maximum radiation level to be expected in any one hour and in one week. In this regard, the following should be considered:

A. Anticipated workload data should be specified (e.g., maximum number of patients treated per hour and per week, treatment time per patient, on time per hour and per week, average dose per patient).
B. Continuous occupancy should be used (i.e., occupancy factor equal to unity) since the regulation assumes that a person is continuously present in this area. If the occupancy factor used is less than 1 then a detailed description of the area and the rationale must be included with the application.
C. "On-time" may be considered as a factor in calculations (i.e., that fraction of an hour or week during which the primary beam of radiation is on.)
D. Fractional use factors (i.e., that fraction of the time during which the primary beam of radiation is directed at a particular barrier) should <u>not</u> be considered in calculations. If the use factor used is less than 1 then the rationale must be included in the application.
E. If the particle accelerator will be operated in more than one treatment modality, calculations should be made for each modality, as applicable.

b. Equipment

(1) Beam stops

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

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

directed toward the integral beam absorber and (b) the primary beam is directed away from the integral beam absorber. The applicant may use sketches to describe beam stops that limit the use of the primary beam.

(2) Patient viewing system

A system for providing continuous viewing of the patient from outside the treatment room during therapy is required. If a shielded viewing window is used, the applicant should specify the thickness, density, and type of material. If electronic means are used to view the patient (e.g., TV monitor) the applicant should specify the backup system that will be used in the event the system malfunctions or should confirm that patient treatment will be suspended until the systems are repaired and functioning again. Two-way aural communication shall be established between the patient and the operator at the control console.

(3) Control of access to restricted areas

Describe the area security safeguards (e.g., locks, signs, warning lights and alarms, and interlocking systems) for each treatment room and the method of controlling occupancy of all restricted areas. Each door leading into the treatment room must be provided with an interlock to control the on-off mechanism of the accelerator. The interlock must cause the accelerator to turn off if the door is opened when the accelerator is operating. The mechanism must be so wired that the accelerator cannot be turned on until the door is closed and the system is reset at the control. Interlocks must be so designed so that all entrances to the treatment room must be closed before treatment can be initiated or continued. If the beam is interrupted by any door opening, treatment shall only be reinitiated by closing that door and the system reset at the control panel.

All entrances to the treatment room must be provided with warning lights, which will indicate when the beam is on, in a readily observable position near the outside of each access door.

(4) Particle accelerator operating specifications

Paragraph RH-1608(b) contains several requirements in regard to operating characteristics for particle accelerators. Describe the specifications for the particular applicant accelerator, addressing all nineteen areas listed in this paragraph. In most cases, commissioning (acceptance testing) of the accelerator will address these topics. Please submit a copy of the most recent tests which define the accelerator specifications.

Item 12. Describe the in-house training program for all personnel who work with or in the vicinity of the particle accelerator, including both radiation workers (e.g., technologists, in-house service personnel, physics personnel) and ancillary personnel (e.g., clerical, housekeeping, nursing, security personnel).

Training should be provided:

(1) Before a new employee assumes duties with or in the vicinity of the accelerator

(2) During the annual refresher training for all employees; and

(3) Whenever a significant change occurs in duties, regulations, or terms of the license.

Topics which should be covered in such training include:

A. Potential hazards associated with accelerator operations
B. Radiological safety procedures appropriate to their respective duties
C. Pertinent Arkansas Department of Health regulations
D. Pertinent Policies and Procedures of the licensee;
E. Pertinent conditions of the license, including specific conditions of operation and the application itself that is incorporated as part of the license;
F. Their obligation to report unsafe conditions and the individual to whom unsafe conditions should be reported;
G. Appropriate response to emergencies or unsafe conditions
H. Their right to be informed of their radiation exposure; and
I. Locations where the licensee has posted or made available notices, copies of pertinent regulations, and copies of pertinent licenses and license conditions (including applications and applicable correspondence) as required by Part N of Section 3 of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation.

Item 13. Operating Procedures

The applicant should establish a set of operating procedures for particle accelerator operations which address, as a minimum, the following:

(1) Procedures for ensuring that no one except the patient is in the treatment room during treatment of a patient.

(2) If other radiation-producing equipment (e.g., x-ray machine) is located in the treatment room, the applicant should describe the steps that will be taken to ensure that no two units can be operated simultaneously. (The exact location of such equipment should be specified in Item 11.)

(3) If a patient must be held in position during treatment, the use of mechanical supporting or restraining devices should be described.

(4) Procedures for securing the particle accelerator against unauthorized use when not in operation.

(5) Procedures for checking safety and warning devices for proper operation. Paragraph RH-5405(c) requires that such tests be performed at intervals not to exceed three months and that records be maintained of the checks.

(6) Safety procedures to be followed whenever an interlock has been either tripped or intentionally bypassed. Intentionally bypassing any safety interlock must be:

A. Authorized by the medical committee

B. Recorded in a permanent log and a notice posted at the accelerator control console

(7) Copies of the following must be maintained:

A. Electrical circuit diagrams of the accelerators and the associated interlock systems shall be kept current and on file at the facility.

B. A copy of the operating procedures shall be maintained at the control panel.

Item 14. Emergency Procedures

The applicant must establish and submit a set of emergency procedures to be followed in the event of an incident, including:

(1) Procedures for minimizing exposures

(2) Procedures for shutting off the power supply to the accelerator and occasions when this would be necessary (e.g., should the beam fail to terminate at either the preselected time or dose)

(3) Procedures for notifying proper persons, including the Arkansas Department of Health. (The emergency notification phone number for the Department of Health is (501) 661-2136). A copy of the emergency procedures must be posted at the control panel, including names and phone number of individuals to be contacted. A statement should be included which indicated that this will be done.

Item 15. Radiation Surveys

a. Routine Radiation Survey Program

Paragraph RH-5407(g) requires that procedures for performing area surveys be established by a qualified expert (See Item c. below) or the facility radiation safety officer

and be in written form. A copy of such survey procedures should be submitted with the application and should include areas to be surveyed, frequency of surveys, applicable action levels, and the records to be maintained.

b. Radiation Protection Survey (Initial and after changes in facility) Paragraph RH-1608(d)(1) requires that all new facilities and existing facilities not previously surveyed, have a survey performed by a qualified expert to ascertain that the particle accelerator facility can operate under safe conditions. Paragraph RH-5407(b) requires that such surveys also be performed when changes have been made in shielding, operation, equipment, or occupancy of adjacent areas, as well as periodically to check for unknown changes and malfunctioning equipment. Provide the following information regarding these surveys:

(1) Name of the qualified expert performing these surveys (An evaluation of this individual's training and experience must be maintained at the facility. Guidelines for training and experience are found in c. below).

(2) Frequency with which protection surveys will be performed

(3) A copy of the most recent survey, indicating areas which in the opinion of the qualified expert, the facility is either in violation of applicable regulations or deficient in radiation safety procedures. Any cracks or voids discovered in the shielding should be identified, even though an actual violation or unsafe condition might not exist.

c. Qualified Expert

Paragraph RH-5501(w) details the necessary training and experience for individuals to be considered as "qualified experts" for the purpose of this application. (While this paragraph deals with radioisotope teletherapy, similar qualifications are applicable to individuals performing this service for particle accelerator therapy.) Licensees must review the individual's training and experience in light of these requirements. If a person who does not meet these minimum qualifications is being considered, the following information should be submitted:

(1) Name of the individual
(2) A description of this individual's training and experience, including information similar to that in RH-5501(w)(4)
(3) Reports of at least one calibration and spot-check program for particle accelerator therapy based on measurements personally made by this individual within the last ten years
(4) Written endorsement of the technical qualifications of this individual from personal knowledge by a physicist certified as specified in RH-5501(w)

Item 16. Calibration of Particle Accelerators

Paragraph RH-1608(d) (2) requires that particle accelerators used for treatment of humans be calibrated before initiating a treatment program and at intervals not to exceed twelve (12) months thereafter. Additionally, the particle accelerator must be calibrated after any changes which might alter the characteristics of the therapy beam. Such calibrations must be performed by a qualified expert as described in Item 15.c. above.

If particle accelerator therapy beam calibrations will be performed by a consultant or an outside organization, this individual or organization must be registered with the Arkansas Department of Health pursuant to Paragraph RH-34(b) and part D of Section 1 of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation. Outside organizations should be contacted to make certain that they are registered. If so, it will be necessary only to specify the name and address of the individual or organization, the Arkansas Department of Health registration number, and the frequency of calibration. If a consultant is not registered with the Department, the registration forms should be obtained from the Department and application made for registration by the consultant. If the applicant intends to perform particle accelerator therapy beam calibrations in-house, provide the following information:

(1) Name of the individual who will perform calibrations. This person must meet the requirements described in Item 15.c. above.
(2) Frequency of calibration.
(3) Measurement instruments used for therapy beam calibration. The calibration of these instruments should be detailed under Items 9 and 10 of this application.
(4) Procedures used for calibration, including:

A. Verification that the accelerator is operating in compliance with the design specifications. Specifications which should be considered, as a minimum, in these measurements are:

(i) Light localizer

(ii) Side light and back-pointer alignment with the isocenter

(iii) Variation in the axis of rotation for the table, gantry, and jaw system

(iv) Beam flatness and symmetry at specified depths

B. Measurement of the exposure rate or dose rate in air and/or at various depths of water for:

(i) The range of field sizes used

(ii) Each effective energy of the modalities used

(iii) Each treatment distance used

C. Determination of congruence between the radiation field and the field indicated by the localizing device.

D. Determination of the radiation field uniformity and its dependence upon the direction of the useful beam.

E. Measurements made in sufficient detail to allow the absorbed dose to tissue in the useful beam to be calculated to within +/- 5%.

(5) Recordkeeping procedures, including:

A. Maintaining records of calibrations for at least five (5) years after completion of the calibration.

B. Maintaining a copy of the most recent calibration at the control panel for reference by the operator.

NOTE: If an outside consultant performs calibration of the particle accelerator, records must still be maintained as described in (5) above.

Item 17. Spot Check Measurements

Paragraph RH-1608(d) (3) requires that particle accelerators used for treatment of humans have spot check measurements made at periodic intervals between calibrations described in Item 16 above. Submit a copy of the written spot check procedures, as developed by a qualified expert (See Item 15.c.), which address at lease the following:

(1) Name of the individual to perform spot check measurements (If an outside company or consultant will perform spot check measurements, specify the name, address, and registration number of this individual or organization.)

(2) Measurements to be taken during spot checks which demonstrate the degree of consistency in operating characteristics of the accelerator which can affect radiation output of the system or radiation delivered to the patient.

(3) Frequency of spot check measurements.

(4) Beam quality checks, as described in Item 11.b. (4) above, for systems in which beam quality may vary significantly.

(5) When built-in devices provide self-checks during irradiation, such parameters must be independently verified at specified time intervals.

(6) Procedures for investigating spot check results which are erratic or inconsistent. Investigation and correction, if needed, must be performed prior to patient irradiation.

(7) Recalibration, as described in Item 16, whenever a significant change is noted in spot check measurements.

(8) Recordkeeping procedures. Spot check measurement records must be maintained for at least two (2) years.

Item 18. Special Considerations for Particle Accelerator Licensees

Appendix E to this guide contains a list of several paragraphs from Section 3 of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation which are requirements for all licensees and are not addressed elsewhere in this application. Complete the Appendix E form and submit it as a part of the application, indication that these requirements are understood and will be followed.

Item 19. Personnel Monitoring

Personnel monitoring devices (film badges, thermoluminescent, or optical stimulated luminescence dosimeters) which monitor whole body exposures should be provided to individuals who work with, or in the vicinity of, the particle accelerator. Specific requirements are given in Paragraph RH-5406. Pocket ionization chambers (pocket dosimeters) are not appropriate monitoring devices in light of the requirements of RH-5406(b).

Item 20. The application should be signed by an individual empowered to act on behalf of the applicant. If the applicant is a hospital, the hospital administrator should complete Item 20. Any application received unsigned will be returned.

APPENDIX A

RADIATION SAFETY COMMITTEE

Responsibility

The committee is responsible for:

1. Ensuring that all individuals who work with or in the vicinity of the particle accelerator(s) have sufficient training and experience to enable them to perform their duties safely and in accordance with Arkansas Department of Health regulations and the conditions of the license.

2. Ensuring that all use of the particle accelerator(s) is conducted in a safe manner and in accordance with Department regulation and the conditions of the license.

Duties

The committee shall:

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

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

3. Establish a program to ensure that all individuals whose duties may require them to work in the vicinity of the particle accelerator (e.g., nursing, security, and housekeeping personnel) are properly instructed as required by Part N of the Arkansas State Health Department's Rules and Regulations for Control of Sources of Ionizing Radiation.

4. Review the entire radiation safety program at least annually to determine that all activities are being conducted safely and in accordance with Department regulations and the conditions of the license. The review shall include an examination of all records, reports from the radiation safety officer, results of Department inspection, written safety procedures and the adequacy of the institution's management control system.

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

6. Maintain written reports of all committee meetings, actions, recommendations, and decisions.

7. Ensure that the particle accelerator license is amended, when necessary, prior to any changes in facilities, equipment, policies, procedures, and personnel, as specified in the license.

Meeting Frequency

The radiation safety committee shall meet as often as necessary to conduct its business but not less than every six (6) months.

APPENDIX B

SUGGESTED TRAINING FOR THERAPY PROCEDURES INVOLVING PARTICLE ACCELERATORS

In the context of this application "physician" means any individual possessing a valid physician's and surgeon's certificate issued by this state (See Paragraph RH-200(ak)).

To qualify as adequately trained, a physician should have:

1. Training in basic radiation safety techniques (200 hours) applicable to the use of particle accelerators for therapy procedures, consisting of lectures, laboratory sessions, discussion groups, or supervised experience in the following areas:

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

    (The hours listed next to each of the four (4) subjects above are suggested values and should not be interpreted as specific requirements.)

2. Experience with the energies and modalities of the particle accelerator for which the application is made, or equivalent (500 hours).

3. Clinical training procedures:
    Active practice in therapeutic radiology with a minimum of three (3) years experience in a formal training program accredited by the Residency Review Committee of Radiology and Liaison Committee on Graduate Medical Education.

APPENDIX B FORM

AUTHORIZED USER (PHYSICIAN) / RADIATION SAFETY OFFICER TRAINING AND EXPERIENCE

For the use of medical particle accelerators for human use

1. Name of Authorized User (Physician) / Radiation Safety Officer (RSO)

2. The Authorized User (Physician) current Arkansas State Medical License number

3. Certification

☐ American Board of Radiology
Date Certified _____

☐ Therapeutic Radiology
Date Certified _____

4. Authorized User (Physician) / RSO Training and Experience (check the appropriate box)

☐ A statement of the using physician's / RSO's clinical training and experience, signed by preceptor, is submitted in support of the application

☐ The using physician/RSO is currently authorized as a user of Medical Particle Accelerators for human use under License No. _____

☐ Not applicable - (explain)

Field of Training	Location of Training	Hours of Training	Dates of Training
Radiation Physics & Instrumentation			
Radiation Protection			
Mathematics Pertaining to the use and measurement of Radioactivity			
Radiation Biology			
Clinical Training			
Particle Accelerator Experience			

APPENDIX C

INSTRUMENTATION

1. Survey Meters

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

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

2. Area Monitor

      Manufacturer's name: _____
      Manufacturer's model number: _____
      Number of instruments available: _____
      Backup battery power supply: Yes _____ No _____

3. Dose Measurement System

   a. Electrometer
      Manufacturer's name:_____
      Manufacturer's model number: _____

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

APPENDIX D

CALIBRATION OF INSTRUMENTS

METHODS FOR CALIBRATION OF (X- AND GAMMA-RAY) SURVEY METERS,

INCLUDING PROCEDURES, STANDARDS, AND FREQUENCY

A. Calibration of survey meters shall be performed with radionuclide sources.

1. The sources shall be approximate point sources.
2. The source activities or exposure rates at given distances shall be traceable by documented measurements to a standard source certified within 5% accuracy to the U.S. National Bureau of Standards (NBS) calibrations.
3. The frequency shall be at least annually and after servicing.
4. Each scale of the instrument shall be calibrated at least at two (2) points located at approximately 1/3 and 2/3 of full scale.
5. The exposure rate measured by the instrument shall differ from the true exposure rate by less than 10% at the two (2) points on each scale (read appropriate section of the instrument manual to determine how to make necessary adjustments to bring instrument into calibration).

   NOTE:
   Sources of Cs-137, Ra-226, or Co-60* are appropriate for use in calibrations. The activity of the calibration standard should be sufficient to calibrate the survey meters on each scale to be used for radiation protection purposes. Scales up to 1 R/hr should be calibrated, but higher-range scales above 1 R/hr need not be calibrated when they will not be needed for radiation protection surveys. If there are higher ranges, they should at least be checked for operation and approximately correct response to radiation. Otherwise, a cautionary note that they have not been checked should be placed on the instrument.

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

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

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

    If any reading with the same geometry is not within +/- 20 % of the reading measured immediately after calibration, the instrument should be recalibrated (See Item A).

C. Records of the above Items A and B-2 must be maintained.

D. An adequate calibration of survey instruments cannot be performed with built-in check sources. Electronic calibrations that do not involve a source of radiation are also not adequate to determine proper functioning and response of all components of an instrument.

CALIBRATION OF SURVEY INSTRUMENTS

Check appropriate items.

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

☐ 2. Calibration will be performed at two (2) points on each scale used for radiation protection purposes (i.e., at least up to 1 R/hr).

The two (2) points will be approximately 1/3 and 2/3 of full scale. A survey instrument may be considered properly calibrated when the instrument readings are within +/- 10% of the calculated or known values for each point checked. When higher scales are not checked or calibrated, an appropriate precautionary note will be posted on the instrument.

3. Survey instruments will be calibrated:

☐ a. By the manufacturer

☐ b. At the licensee's facility

(1) Calibration source

Isotope (element and mass number) _____

Manufacturer's name_____

Model Number_____

Activity in millicuries_____

or

Exposure rate at a specified distance_____

Accuracy_____

Traceability to primary standard_____

☐ (2) The calibration procedures in Appendix D will be used.

or

☐ (3) The step-by-step procedures, including radiation safety procedures, are attached.

☐ c. By a consultant or outside firm

(1) Name_____

(2) Location_____

(3) Registration number*_____

(4) The consultant's report will contain the information on

☐ the attached "Certificate of Instrument Calibration".

☐ the consultant's reporting form as attached.

*****_Persons performing survey meter calibrations for Arkansas Licensees must be registered with the Arkansas Department of Health._

APPENDIX E

SPECIAL CONSIDERATIONS

Each paragraph of the Arkansas Rules and Regulations for Control of Sources of Ionizing Radiation referred to below must be read and understood. Completion of the application implies agreement to abide by, and comply with the regulations. Indicate that these particular paragraphs have been read and will be complied with by checking the box in front of each reference.

☐ 1. Paragraph RH-1305, Instruction of Personnel; Posting of Notice to Employees

☐ 2. Part F, Paragraphs RH-1500 through RH-1505, Records, Reports, and Notification

☐ 3. Part N, Paragraphs RH-2801 through RH 2808, Notices, Instructions and Reports to Workers Inspections

☐ 4. Paragraph RH-5210, Inalienability of Licenses

☐ 5. Paragraph RH-5601, Additional Requirements