Arkansas Department Of Health
Medical Particle Accelerator
Licensing Guide Part Two: Application Supporting Documentation

Complete the Application Supporting Documentation Form in its entirety for both new and renewed Medical Accelerator Licenses.

Provide the information listed below, referring to the applicable appendices and the Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3 for additional guidance.

After gathering all documentation number each page at the bottom. Complete this form by filling in the page number next to each item listed.

Items 1-7 completed on Application for Medical Particle Accelerator License Form

1. FACILITY NAME

Provide the legal name of the applicant's corporation or company, including the designation "doing business as," or other legal entity that will be responsible for ensuring that the particle accelerator program complies with the conditions of the license and with the Arkansas State Board of Health (ASBH) Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3.

2. FACILITY CONTACT INFORMATION

Provide the facility's main telephone number and e-mail address.

3. FACILITY MAILING ADDRESS

Provide the mailing address where correspondence should be sent.

4. FACILITY PHYSICAL ADDRESS

If the physical location of the particle accelerator is different from the mailing address, list the physical street, city, state, and zip code for each permanent facility where a particle accelerator is used and/or stored. Do not list an address with a Post Office Box.

5. PERSON TO CONTACT REGARDING THIS APPLICATION

Identify the individual who can answer questions regarding this application. This is typically the proposed Radiation Safety Officer (RSO). The Department will contact this individual if there are any questions. Provide the individual's name, phone number and e-mail address.

6. TYPE OF APPLICATION

Mark the appropriate type of application. If the application is for renewal, list the current Medical Particle Accelerator License Number.

7. PARTICLE ACCELERATOR(S)

List the manufacturer, model number and maximum energy of each modality (x-ray, electron) for each particle accelerator on the license application. If additional space if needed, attach a list of the accelerators. Describe the purpose of use for the accelerators (e.g., for treatment of humans, research, etc.)

8. RADIATION SAFETY OFFICER (RSO)

The Radiation Safety Officer (RSO) is an individual who has the knowledge and responsibility to apply appropriate radiation protection rules and has been assigned such responsibility by the licensee. The RSO is responsible for the day-to-day oversight of the radiation safety program. Appendix A of this Licensing Guide contains a list of duties and responsibilities of the RSO. The applicant may either commit to Appendix A or submit equivalent duties and responsibilities.

Licensee management shall appoint an RSO and must provide the RSO with sufficient authority to stop unsafe operations. Provide the name of the individual that has been appointed the RSO.

A written agreement showing that this individual was appointed by the licensee management must be submitted. Complete and submit Appendix A, Form A "RSO Delegation of Authority" of this Licensing Guide. This demonstrates that the licensee has identified a responsible, qualified person and that the named individual is aware of his/her designation and fully aware of the responsibilities of the RSO. If the RSO is not an Authorized User or Qualified Medical Physicist listed in Item 9 of the application, the applicant must submit a summary description of the RSO's training and experience.

The RSO is usually a full-time employee at the licensed facility; however, the Department has authorized individuals who are not employed by the licensee, such as a consultant, to fill the role of the RSO or to provide support to the facility RSO. In order to fulfill the duties and responsibilities, the RSO should be on site periodically to have person-to-person interactions with licensee staff and ensure that operations are being conducted safely and policies and procedures are being followed.

In programs where the RSO 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 summary description of each assistant's training and experience.

9. INDIVIDUAL USERS WHO WILL USE OR SUPERVISE THE USE OF THE PARTICLE ACCELERATOR(S)

AUTHORIZED USER(S)

State the name(s) of all physicians who will use or supervise the use of the particle accelerator(s). These individuals will be listed on the license. For human use, each user must be a physician who possesses a current Arkansas State Medical License.

The responsibilities of the Authorized Users involved in medical use include the following:

- Examination of the patient and his or her medical records to determine if radiation therapy is appropriate.
- Prescription (written directive) of the radiation dose and how it is to be administered (total dose, dose per fraction, specified conditions, etc.).
- Approval of treatments plans that were developed by a Qualified Medical Physicist or Dosimetrist.
- Review of patient's progress and modification of the originally prescribed dose as warranted by the patient's reaction to the radiation.
- Provision of necessary follow-up medical care.

A physician shall not act as an Authorized User until the physician's training has been reviewed and approved by the Department, with the exception of Visiting Authorized Users.

VISITING AUTHORIZED USERS

In the event that additional authorized users are temporarily needed, a licensee may permit a physician to act as a Visiting Authorized User under the terms of the license for up to 60 days per calendar year under the following conditions (RH-10200.h.):

A. The Visiting Authorized User has the prior written permission of the licensee's management and the facility's Radiation Safety Committee; and
B. The Visiting Authorized User meets the training requirements established for Authorized Users in RH-10200.c.1.; and
C. The licensee maintains copies of all records generated pursuant to RH-10200.h.1. and h.2. for five (5) years from the date of the last visit.

The licensee must be able to show the number of days that each Visiting Authorized User practiced at the facility per calendar year. This documentation along with the training requirements listed above will be reviewed during inspections. These individuals are not listed on the license, but if it is anticipated that the 60 days will be exceeded, an amendment request must be submitted to add the physician as an Authorized User to the license.

QUALIFIED MEDICAL PHYSICISTS

State the name(s) of the medical physicists that are responsible for the following duties at the facility (RH-10302.r.1.:

- Full calibrations required by RH-10302.t.
- Radiation protection surveys required by RH-10300.a.
- Supervision and review of beam and clinical dosimetry
- Beam data acquisition and transfer for computerized dosimetry, and supervision of its use
- Establishment of quality assurance procedures and performance of quality assurance check review required by RH-10302.u.
- Consultation with the Authorized User(s) in treatment planning, as needed
- Performing of calculations/assessments regarding patient treatments that may constitute misadministrations

If a vendor is used for physics support, state the name of the vendor and their Arkansas State Vendor Registration Number. Please note that it is the facility's responsibility to confirm that each medical physicist providing services at their facility is listed on the vendor's registration and has been approved as a Qualified Medical Physicist.

If the licensee only has one Qualified Medical Physicist that not a full-time employee, the operating procedures required by RH-10302.s. shall also specifically address how the Qualified Medical Physicist is to be contacted for problems or emergencies, as well as the specific actions, if any, to be taken until the Qualified Medical Physicist can be reached for instruction.

RADIATION THERAPTISTS

These individuals will not be listed on the license.

10. TRAINING AND EXPERIENCE OF USERS

Appendix B "Training and Experience" of this licensing guide may be used to assist the applicant with providing training and experience documentation.

AUTHORIZED USERS

An Authorized User shall be a physician who is certified by a specialty board that is listed in RH-10200.c.1.A. or has completed the required training and experience delineated in RH-10200.c.1.B.

If a proposed Authorized User was previously identified as an Authorized User on another medical particle accelerator license, submit a copy of the license or provide the license number.

Complete the AU Form of Appendix B for each proposed Authorized User. Again, a physician shall not act as an Authorized User for any therapeutic radiation machine until the physician's training has been reviewed and approved by the Department.

QUALIFIED MEDICAL PHYSICISTS

The licensee shall require the Qualified Medical Physicist to be certified by a specialty board that is listed in RH-10200.d.1.A. or has completed the education, training and work experience as required in RH-10200.d.1.B.

If a proposed Qualified Medical Physicist was previously identified as a Qualified Medical Physicist on another medical particle accelerator license, submit a copy of the license or provide the license number.

Complete the QMP Form of Appendix B for each proposed Qualified Medical Physicist. An individual shall not act as a Qualified Medical Physicist until the individual's training has been reviewed and approved by the Department.

RADIATION THERAPISTS

Even though not listed on the license, these individuals shall meet the appropriate Radiologic Technology Licensure requirements and must provide the facility with a current copy of his or her License. It is the facility's responsibility to ensure that each radiation therapist's state license is current.

In accordance with RH-5401, no licensee shall permit any individual to act as a particle accelerator operator until appropriate training has been performed. Initial and refresher training for operators must be described in the applicant's personnel training program in Item 11 below.

11. PERSONNEL TRAINING PROGRAM

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, medical physicists, dosimetrists) and ancillary personnel (e.g., clerical, housekeeping, nursing, security personnel). The applicant may either commit to the training program in Appendix C or submit equivalent procedures.

In addition, RH-5401 requires specific training for particle accelerator operators (e.g., radiation therapists). The applicant may either commit to the procedures contained in Appendix C or submit equivalent procedures. Note that equivalent procedures must contain, at minimum, the items and topics listed in RH-5401 and RH-5410.

12. RADIATION SAFETY COMMITTEE

In accordance with RH-5203.a., a license for use of a particle accelerator in medical therapy will be issued only if the applicant has appointed a medical committee of at least three members to evaluate all proposals for research, diagnostic, and therapeutic use of a particle accelerator within that facility.

Specify the title of each member of the Radiation Safety Committee (RSC). Membership must include the following:

A. Physician experts in internal medicine, hematology, and therapeutic radiology;

B. A person experienced in depth dose calculations and protection against radiation; and

C. A representative of the facility's management

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

Appendix D of this guide contains an example of typical duties and responsibilities of a Radiation Safety Committee. Check the appropriate box on the application form, indicating whether the duties, responsibilities, and meeting frequency will be as described in Appendix D or if alternative procedures will be used. Any procedures submitted in lieu of using Appendix D should be substantially equivalent to those in the Appendix.

13. FACILITIES AND EQUIPMENT

Facilities and equipment must be adequate to protect occupational workers and members of the public, and to keep doses As Low As Reasonably Achievable (ALARA). Appendix E contains guidance that may be used to provide the necessary information to adequately describe the facilities and equipment.

Include a scale drawing

14. PARTICLE ACCELERATOR QUALITY ASSURANCE PROGRAM

Quality Assurance procedures must be established for any therapeutic radiation machine, to include acceptance testing, full calibrations, periodic quality assurance checks, and safety quality assurance checks. The Qualified Medical Physicist(s) are responsible for establishing these procedures and ensure that the quality assurance checks are performed as required. The applicant must submit a copy of these procedures for review.
Appendix F may be used as guidance for establishing Quality Assurance Program procedures.

If full calibrations are performed by a consultant or an outside organization, this individual or organization must be registered with the Arkansas Department of Health. Please provide the name of the individual or organization and their Arkansas Vendor Registration Number.

15. QUALITY MANAGEMENT PROGRAM

In accordance with RH-10201, each licensee shall develop, implement, and maintain a quality management program to provide high confidence that radiation will be administered as directed by the Authorized user.

The Quality Management Program shall address, at minimum, the following specific objectives:

1.	Written Directives	RH-10201.a.1.
2.	Procedures for administrations	RH-10201.a.2.
3.	Reports and notifications of misadministrations	RH-10201.b.
4.	Records of misadministrations	RH-10201.c.

The applicant must submit a copy of their Quality Management Program procedures for review and approval by the Department.

16. RADIATION DETECTION INSTRUMENTS

Each facility location authorized to use a photon therapy system (500 kV and above) and electron therapy system (500 keV and above) shall possess a calibrated and operable portable radiation survey instrument capable of measuring dose rates over the range of 1 mrem (10 μSv) per hour to 1000 mrem (10 mSv) per hour. Complete Item 16 of the license application for radiation survey instruments by providing the requested information in the specified format.

In accordance with RH-10303 and RH-10304, portable monitoring equipment shall be tested for proper operation and shall be calibrated before first use, at intervals not to exceed twelve (12) months, and following any repair that will affect the calibration.

17. PERSONNEL MONITORING PROGRAM

Licensees are required to develop a program for monitoring and assessing the radiation dose to occupationally exposed individuals. The licensee must evaluate the radiation exposure to all occupational radiation workers (radiation therapists, medical physicists, etc.) to demonstrate compliance with RH-1302.

Appendix G provides guidance that may be used to develop and implement a personnel monitoring program.

18. RADIATION SURVEY PROGRAM

The licensee shall ensure that radiation protection surveys of all new facilities, and existing facilities not previously surveyed are performed with an operable radiation measurement survey instrument calibrated in accordance with RH-10304. The radiation protection survey shall be performed by, or under the direction of, a Qualified Medical Physicist to verify that:

- Radiation levels in restricted areas are not likely to cause personnel exposures in excess of the limits specified in RH-1200.a.
- Radiation levels in unrestricted areas do not exceed the limits specified in RH-1208.b.

Appendix H contains guidance that may be used to develop and implement a radiation survey program. The applicant may commit to these procedures or submit equivalent procedures for review.

19. OPERATING AND EMERGENCY PROCEDURES

In accordance with RH-1004, each licensee shall develop, document, and implement a radiation protection program to ensure compliance. This program must include a set of operating and emergency procedures. Appendix I includes a list of required items that must be addressed in the facility's operating and emergency procedures. Submit a copy of your operating and emergency procedures for review.

In accordance with RH-5405.g., a copy of the current operating and emergency procedures shall be maintained at the accelerator control panel.

20. MANAGEMENT CONTROL

Licensee management is responsible for ensuring that the Radiation Safety Program is implemented and maintained. RH-1004 states that the licensee shall periodically (at least annually) review the radiation protection program content and implementation. The review must ensure that the licensee is in compliance with the applicable sections of the ASBH Rules for Control of Sources of Ionizing Radiation, 20 CAR Pt. 3 and the terms and conditions of the license. The applicant must confirm in writing that the annual audit results will be reviewed and approved by Senior Management.

The applicant must develop and implement procedures for the required review or audit. These procedures should include an outline of items reviewed during the audit, a summary of deficiencies, and a corrective action plan to correct any deficiencies.

21. CERTIFICATION

The application for a medical particle accelerator license and the license itself are legal documents. License applications and correspondence must be signed by individuals who are authorized to make legally binding statements or act on behalf of the applicant. This individual is the Certifying Official.

I, , attest to adherence to the Rules for Control of Sources of

Ionizing Radiation, 20 CAR Pt. 3, on this date .

This Medical Accelerator License Application/Renewal has been reviewed by two reviewers within the Radiation Control Section.

Primary Reviewer: Date:

Secondary Reviewer: Date: