ARKANSAS DEPARTMENT OF HEALTH
MEDICAL PARTICLE ACCELERATOR
LICENSING GUIDE

INTRODUCTION

A. PURPOSE OF GUIDE

This document provides guidance and instruction to an applicant when preparing an application for a particle accelerator for therapeutic human use. A particle accelerator is defined as "any machine capable of accelerating electrons, protons, deuterons or other charged particles in a vacuum and of discharging the resultant particulate or other radiation into a medium at energies usually in excess of 1 MeV." Therapeutic radiation machines capable of generating energies at or above 500 kV/keV shall be considered particle accelerators.

The information in this guide is not intended to impose any conditions beyond those required by the rules but provide specific guidance on the information that must be submitted in an application to satisfy Department requirements. Written procedures are required to be submitted as part of the license application.

B. APPLICABLE RULES

The following sections of the Arkansas State Board of Health (ASBH) Rules for Control of Sources of Ionizing Radiation should be reviewed and used in conjunction with this licensing guide.

- Section 3 — Standards for Protection Against Radiation (Applicable portions of Parts A through G and L through N
- Section 5 — Rules of Practice
- Section 6 — Licenses and Radiation Safety Requirements for Particle Accelerators
- Section 11 — Therapeutic Radiation Machines

The Department periodically revises these rules and licensees will be notified of proposed changes.

FILING AN APPLICATION

A. GENERAL

Complete the "Application for Medical Particle Accelerator License" in its entirety. Please select if supplemental information is attached and label any attachments with the appropriate item number from the application. Submission of incomplete or inadequate information will result in delays in the approval process for the license. Additional information will be requested, if necessary, to ensure that an adequate radiation safety program will be established and implemented.

The Department requires that a member of management review and sign the license application to acknowledge management's overall commitment to the radiation safety program.

Send one (1) copy of the completed application to:

Arkansas Department of Health
Radiation Control Section
4815 West Markham Street, Slot #30
Little Rock, Arkansas 72205

Retain at least one copy of the submitted application form with all attachments. When issued, the license will require that the particle accelerator be possessed and used in accordance with statements, representations and procedures provided in the application and supplemental information. Regulatory requirements specified in the ASBH Rules for Control of Sources of Ionizing Radiation shall govern unless the submitted documents set forth in the license application and correspondence are more restrictive than the rules.

All license applications will be available for review by the general public, except those documents delineated in RH-4040 "Public Records – Exceptions." Employee or patient information such as address, phone number, social security number, date of birth, etc. should not be submitted.

B. LICENSE FEES

New License Application Fee
The non-refundable administrative fee for processing a new license application for a non-hospital medical particle accelerator is $450.00 per unit and $300.00 for each additional unit. ***The license application will not be reviewed until the fee is received by the Department.***

Annual Fee
In accordance with RH-5003., annual fees for licensing shall be paid by January 1 of each year, which are $450.00 per unit and $300.00 for each additional unit. An invoice will be mailed out each November for the following year.

C. LICENSE AMENDMENTS

RH-8011 requires that a licensee shall apply for and must receive a license amendment before any change listed in RH-8011.a.-h. is made. A non-refundable administrative fee for processing the request to amend an existing license is $50.00 per amendment. ***The amendment request will not be reviewed until the fee is received by the Department.***

D. LICENSE RENEWAL

Once approved by the Department, the medical particle accelerator license will be issued for a period of ten (10) years. A renewal application will be mailed approximately 90 days before the license expires. A fee is NOT required when submitting a renewal application. Only the annual fee must be paid for each calendar year.

E. TERMINATION

If the licensee wishes to terminate the medical particle accelerator license, a written request must be submitted to the Department. Note that surveys for residual activity shall be conducted for accelerators capable or producing energies above 10 MV (10 MeV) prior to machining, removing, or working on components which may have become activated due to photon-neutron production. In the event of decommissioning an accelerator, the survey results shall be submitted along with the termination request to the Department for review.

CONTENTS OF AN APPLICATION

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.

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 a 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 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 prescribe 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 is 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 in 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.

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 ensuring 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 will be 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 facility 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 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.

APPENDIX A
FORM A

RADIATION SAFETY OFFICER

DELEGATION OF AUTHORITY

MEMORANDUM

DATE: _____

SUBJECT: Delegation of Authority

You, _____, have been appointed the Radiation Safety Officer and are responsible for the radiation safety program at _____. The Radiation Safety Officer duties and responsibilities consists of ensuring radiological safety and compliance with the ABSH Rules for Control of Sources of Ionizing Radiation and the conditions of the medical particle accelerator license. You are hereby delegated the authority necessary to meet the duties and responsibilities listed in Appendix A, including restricting or terminating particle accelerator operations if such action is deemed necessary to minimize danger to health and safety, property, or the environment. You are required to notify management if staff members fail to cooperate and are not following the policies and procedures of the Radiation Safety Program. In addition, you are allowed to contact the Arkansas Department of Health at any time with questions and/or concerns.

_____ _____
Printed name of member of management Title

_____ _____
Signature Date

I have reviewed the duties and responsibilities listed above and in Appendix A, and I accept the responsibility of the Radiation Safety Program at _____.

_____ _____
Signature of appointed Radiation Safety Officer Date

APPENDIX A

DUTIES AND RESPONSIBILITIES
OF THE
RADIATION SAFETY OFFICER

The Radiation Safety Officer's (RSO) duties and responsibilities consists of ensuring radiological safety and compliance with the Department and the conditions of the medical particle accelerator license, which includes the following:

- Stopping unsafe activities involving the operation of a medical particle accelerator
- Radiation exposures are maintained As Low As Reasonably Achievable (ALARA)
- Ensuring that radiation safety procedures (operating and emergency procedures) are up to date and implemented
- Ensuring that operators are properly trained by establishing and implementing a personnel training program, and maintaining documentation of training records
- When necessary, personnel monitoring devices are used and exchanged at the proper intervals and records are maintained
- The particle accelerator(s) are properly secured when not in use
- Radiation areas are posted in accordance with RH-1303
- Documentation is maintained to demonstrate that the total effective dose equivalent to a member of public does not exceed the dose limits specified in RH-1208
- The Radiation Safety Program is reviewed at least annually, and findings and corrective actions, if any, are documented
- Ensuring that the Medical Particle Accelerator license is up to date and amendment requests are submitted as needed, and submits any additional information requested by the Department
- Ensuring that the Radiation Safety Committee meets at the frequency specified in the license and documentation of the meeting minutes is maintained
- Radiation monitoring equipment (area monitor, survey meter, etc,) is calibrated before first use, at least annually, and following any repair that will affect the calibration
- Ensures that records generated for approving Visiting Authorized Users, if any, is maintained on file for review and tracks the number of days per calendar year that each physician acts as a Visiting Authorized User
- Properly notifies the Department of any incidents described in RH-10200.k., RH-10201.b. and RH-1502.a. and RH-1504.
- Ensuring that renewal applications are submitted in a timely manner and any additional information requested by the Department is submitted
- Ensuring that all records required by Section 6 and Section 11 of the ASBH Rules for Control of Sources of Ionizing Radiation are maintained and available for review

AUTHORIZED USER TRAINING AND EXPERIENCE FOR MEDICAL PARTICLE ACCELERATORS (RH-10200.c.)

Name of Proposed Authorized User:

PART 1 – TRAINING AND EXPERIENCE

Previously Approved Authorized User

☐ The proposed Authorized User has been previously approved by the Department. The physician is currently listed on or has been formerly listed on a Medical Particle Accelerator License as an Authorized User.

Name of licensee: _____

License Number: _____

Provide a copy of the license that lists the individual as an Authorized User, if available.
NOTE: If the individual is or was listed on a license in a different state, a copy of the license must be provided, or the training documentation must be submitted using one of the methods below.

Proposed Authorized User Not Previously Approved
(Select one of the options below)

☐ **1. Board Certification**

The proposed Authorized User must be currently certified by one of the certification boards listed in RH-10200.c.1.A. Please provide a copy of the board certification.

☐ **2. Education, Training and Experience** (for those that do not have the required board certification)

If more than one supervising individual is necessary to document training and experience, submit a copy of this form for each preceptor.

Is a physician who is in the active practice of therapeutic radiology and has completed 200 hours of instruction in basic radiation techniques applicable to the use of an external beam radiation therapy unit, 500 hours of supervised work experience, and a minimum of 3 years of supervised clinical experience.

a. Classroom and Laboratory Training:

Description of Training	Location of Training	Hours	Dates of Training
Radiation Physics and Instrumentation			
Radiation Protection			
Mathematics pertaining to the use and measurement of ionizing radiation			
Radiation biology			
Total Hours of Training:			

b. Supervised Work Experience:

Description of Experience	Location of Experience/License Number of Facility	Hours	Dates of Experience
Review of full calibration measurements and periodic quality assurance checks			
Evaluation of prepared treatment plans and calculation of treatment times/patient treatment settings			
Using administrative controls to prevent misadministrations			
Implementing emergency procedures to be followed in the event of the abnormal operation of an external beam radiation therapy unit or console			
Checking and using radiation survey meters			
Total Hours of Supervised Work Experience:			

c. Supervised Clinical Experience

Clinical experience shall include 1 year in an approved formal training program and an additional 2 years in therapeutic radiology under the supervision of an Authorized User.

Description of Experience	Location of Experience/License Number of Facility	Dates of Experience
Examining individuals and reviewing their case histories to determine their suitability for external beam radiation therapy treatment, and any limitations/contraindications		
Selecting proper dose and how it is to be administered		
Calculating the therapeutic radiation machine doses and collaborating with the Authorized User in the review of patients' progress and consideration of the need to modify originally prescribed doses and/or treatment plans as warranted by the patients' reaction to radiation		
Post-administration follow-up and review of case histories		
Total Years/Months of Supervised Clinical Experience:		

PART II – PRECEPTOR ATTESTATION
(Only for training and experience option)

This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the receptor provides, directs, or verifies the training and experience required.

If more than one preceptor is necessary to document experience, obtain a separate preceptor statement for each and have them select the applicable attestations below:

☐ I attest that _____ has satisfactorily completed the 200 hours of classroom and laboratory training as required by RH-10200.c.1.B.i.

☐ I attest that _____ has satisfactorily completed 500 hours of supervised work experience as required by RH-10200.c.1.B.ii.

☐ I attest that _____ has satisfactorily completed a minimum of 3 years of supervised clinical experience as required by RH-10200.c.1.B.iii.

AND

☐ I attest that _____ has achieved a level of competency sufficient to function independently as an Authorized User for medical particle accelerators.

Complete the following for preceptor attestation and signature:

☐ I meet the requirements in RH-10200.c. or equivalent State requirements for an Authorized User of medical particle accelerators.

Name of Preceptor:		Signature:
Phone Number:	License Number/Facility Name:	Date:

APPENDIX B

TRAINING AND EXPERIENCE

AUTHORIZED USER(S)

RH-10200.c. outlines the training and experience required for a physician to act as an Authorized User for therapeutic radiation machines. The AU Form in this appendix should be used to demonstrate the required training and experience for each proposed Authorized User. For those Authorized Users that have already been approved by the Department for therapies using a medical particle accelerator, provide the facility name and particle accelerator license number so the prior approval can be verified. For new proposed Authorized Users, there are a couple ways to demonstrate the required training and experience. Select one of the following options:

OPTION 1. Board Certification

The applicant or licensee may use this pathway if the proposed Authorized User is a physician certified by a board listed in RH-10200.c.1.A. The following board certifications are accepted:

1. The American Board of Radiology in Radiation Oncology or Therapeutic Radiology
2. The American Board of Radiology in Radiology, prior to 1976 (combined diagnostic and therapeutic radiology program)
3. The American Osteopathic Board of Radiology in Radiation Oncology
4. The Faculty of Radiologists of the Royal College of Surgeons in Ireland in Radiation Oncology
5. The Royal College of Radiologists in Clinical Oncology
6. The Royal College of Physicians and Surgeons of Canada in Radiation Oncology or Therapeutic Radiology

Please submit a copy of the board certification for each proposed Authorized User.

OPTION 2. Education, Training and Experience

The applicant or licensee may use this pathway if the proposed Authorized User is a physician who is not certified by a board listed in Option 1 above (RH-10200.c.1.A.). Option 2 of the AU Form outlines the requirements for this pathway. Fill out the table in this form to demonstrate that each proposed Authorized User has completed the required classroom and laboratory training, supervised work experience, and supervised clinical experience. Part II Preceptor Attestation must be submitted for this pathway. The proposed Authorized User is not required to receive the training and experience at any one location or at one time. The required training may be obtained in any number of settings, locations, and educational situations.

QUALIFIED MEDICAL PHYSICISTS

RH-10200.d. outlines the training and experience required for an individual to act as a Qualified Medical Physicist for external beam radiation therapy. The QMP Form in this appendix should be used to document each Qualified Medical Physicist's training and experience. For those Qualified Medical Physicists that have already been approved by the Department for therapies using a medical particle accelerator, provide the facility name and particle accelerator license number so the prior approval can be verified. For new proposed Qualified Medical Physicists, there are a couple ways to demonstrate the required training and experience. Select one of the following options:

OPTION 1. Board Certification

The applicant or licensee may use this pathway if the proposed Qualified Medical Physicist is certified by a board listed in RH-10200.d.1.A. The following board certifications are accepted:

1. The American Board of Radiology in:
    a. Therapeutic Medical Physics; or
    b. Therapeutic Radiologic Physics; or
    c. Roentgen-Ray & Gamma-Ray Physics; or
    d. X-Ray and Radium Physics; or
    e. Radiologic Physics
2. The American Board of Medical Physics in Radiation Oncology Physics
3. The Canadian College of Physicists in Medicine in Radiation Oncology Physics

OPTION 2. Education, Training and Experience

The applicant or licensee may use this pathway if the proposed Qualified Medical Physicist is not certified by a board listed in Option 1 above (RH-10200.d.1.A.). Option 2 of the QMP Form outlines the requirements for this pathway. Fill out the table in this form to demonstrate that each proposed Qualified Medical Physicist has completed the required education and supervised full-time medical physics training and work experience. Part II Preceptor Attestation must be submitted for this pathway. The proposed Qualified Medical Physicist is not required to receive the training and experience at any one location or at one time. The required training may be obtained in any number of settings, locations, and educational situations.

QUALIFIED MEDICAL PHYSICIST TRAINING AND EXPERIENCE FOR MEDICAL PARTICLE ACCELERATORS (RH-10200.d.)

Name of Proposed Qualified Medical Physicist:

PART 1 – TRAINING AND EXPERIENCE

Previously Approved Qualified Medical Physicist

☐ The proposed Qualified Medical Physicist has been previously approved by the Department. The medical physicist is currently listed on or has been formerly listed on a Medical Particle Accelerator License as Qualified Medical Physicist.

Name of licensee: _____

License Number: _____

Provide a copy of the license that lists the individual as a Qualified Medical Physicist, if available.
NOTE: If the individual is or was listed on a license in a different state, a copy of the license must be provided, or the training documentation must be submitted using one of the methods below.

Proposed Qualified Medical Physicist Not Previously Approved
(Select one of the options below)

☐ **1. Board Certification**

The proposed Qualified Medical Physicist must be currently certified by one of the certification boards listed in RH-10200.d.1.A. Please provide a copy of the board certification.

☐ **2. Education, Training and Experience** (for those that do not have a board certification)

a. Education: Holds a master's or doctor's degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university

Degree:	Major Field:
College or University:	

b. Supervised Full-Time Medical Physics Training and Work Experience – *must be conducted in clinical radiation facilities that provide high-energy external beam radiation therapy (photons and electrons with energies greater than or equal to 1 MV / 1 MeV.*

☐ Completed one (1) year of full-time training in physics under the supervision of _____ who meets the requirements for a Qualified Medical Physicist.

AND

☐ Completed one (1) year of full-time work experience under the supervision of _____ who meets the requirements for a Qualified Medical Physicist.

If more than one supervising individual is necessary to document supervised training and work experience, please provide a copy of this page for each supervising individual.

During the year of work experience, the following tasks shall have been performed under the supervision of an individual who meets the requirements for a Qualified Medical Physicist:

Description of Work Experience	**Location of Experience/License Number of Facility**	**Dates of Work Experience**
Radiation Protection Surveys as required by RH-10300.a.		
Acceptance testing, commissioning and full calibration measurements as required by RH-10301.p. and RH-10302.t.		
Periodic quality assurance checks as required by RH-10301.q. and RH-10302.u.		

PART II – PRECEPTOR ATTESTATION
(Only for training and experience option)

This part must be completed by the individual's preceptor. The preceptor does not have to be the supervising individual as long as the receptor provides, directs, or verifies the training and experience required. If more than one preceptor is necessary to document experience, obtain a separate preceptor statement from each.

☐ I attest that _____ has satisfactorily completed the 1-year of full-time training in medical physics and an additional year of full-time work experience as required in RH-10200.d.1.B. The training included hands-on device operation, safety procedures, clinical use, and the operation of a treatment planning system.

☐ I attest that _____ has achieved a level of competency sufficient to function independently as a Qualified Medical Physicist for medical particle accelerators.

Complete the following for preceptor attestation and signature:

☐ I meet the requirements in RH-10200.d. or equivalent State requirements for a Qualified Medical Physicist

Name of Preceptor:		Signature:
Phone Number:	License Number/Facility Name:	Date:

APPENDIX C

PERSONNEL TRAINING PROGRAM

The training described in this Appendix shall be provided:

- Before a new employee assumes duties with or in the vicinity of the accelerator
- At intervals not to exceed twelve (12) months, and
- Whenever a significant change occurs in duties, rules, or terms of the license

Training records shall be maintained for five (5) years and available for review during Department inspection.

PARTICLE ACCELERATOR OPERATORS

NOTE: This includes Radiation Therapists, Qualified Medical Physicists and Dosimetrists that may operate the accelerator.

In accordance with RH-5401 and RH-5410, no licensee shall permit any individual to act as a particle accelerator operator until such individual:

A. Has been instructed in the subjects listed below and has demonstrated an understanding thereof:

1. Fundamentals of Radiation Safety

   - Characteristics of particulate and electromagnetic radiation
   - Units of radiation dose and quantity of radioactivity
   - Biological hazards of exposure to radiation
   - Measurement of radiation
   - Methods of controlling radiation dose
   - Radiation safety procedures, interlock systems and warning systems

2. Radiation Detection Instrumentation

   - Use of radiation survey instruments
   - Survey technique
   - Use of personnel monitoring equipment

3. Equipment

   - Remote handling equipment
   - Handling of activated materials (if applicable)
   - Use of shielding
   - Identification of radiation hazards associated with the use of the equipment

B. Has received copies of and instruction in the following and has demonstrated an understanding thereof:

1. Applicable requirements of Section 6 and Section 3 of the ASBH Rules for Control of Sources of Ionizing Radiation

2. Pertinent license conditions

3. Facility's operating and emergency procedures

C. Has demonstrated competence to use the particle accelerator, related equipment, and survey instruments that will be utilized by the individual.

ANCILLARY PERSONNEL

NOTE: This includes any personnel that might work in the vicinity of the particle accelerator (e.g., clerical, housekeeping, nursing, and security personnel)

Topics that will be covered during radiation awareness training:

- Potential hazards associated with accelerator operations
- Radiological safety procedures appropriate to their respective duties
- Pertinent policies and procedures of the facility
- Their obligation to report unsafe conditions and the individual to whom unsafe conditions should be reported
- Appropriate response to emergencies or unsafe conditions
- Locations of where the emergency procedures and Notice to Employees (Section 3, Part N) are posted

APPENDIX D

DUTIES AND RESPONSIBILITIES
OF THE
RADIATION SAFETY COMMITTEE

The Radiation Safety Committee is responsible for the following:

- Reviewing the training and experience of all individuals who work with the particle accelerator(s) (physicians, technologists, physicists) to determine that their qualifications are adequate to perform their duties safely and in accordance with the Arkansas Department of Health Rules and the conditions of the license.
- Ensuring that all use of the particle accelerator(s) is conducted in a safe manner and in accordance with the Arkansas Department of Health Rules and the conditions of the license.
- Being familiar with all pertinent Arkansas Department of Health Rules, the terms of the license, and information submitted in support of the request for the license and its amendments.
- Ensuring that the particle accelerator license is amended when necessary prior to any changes in facilities, equipment, policies and procedures and personnel, as specified in the license.
- Ensuring that all individuals whose duties may require them to work in the vicinity of the particle accelerator (nurses, security, housekeeping personnel, etc.) are properly instructed.
- Reviewing any elevated or abnormal occupational doses and recommending corrective actions as needed and ensuring that the Department was notified of any doses exceeding the annual occupational dose limits.
- Reviewing the results from the annual radiation safety program audits and Department inspections, and ensuring adequate corrective actions are taken for any deficiencies identified in the radiation safety program.
- Ensuring that the committee meets at least every six (6) months, or as often as necessary, and that the required members are in attendance as required by RH5203.a.1.
- Ensuring that meeting minutes are maintained and include the following:
    1. The date of the meeting;
    2. Members present;
    3. Members absent; and
    4. Summary of deliberations and discussions.

APPENDIX E

FACILITIES AND EQUIPMENT

Applicants must completely describe the proposed facilities and equipment as required by RH-5202.b. in order for the Department to ensure that the applicant is protecting health and minimizing danger to public health and safety or property.

The *National Council on Radiation Protection and Measurements (NCRP) Report No. 151 "Structural Shielding Design and Evaluation for Megavoltage X – and Gamma-Ray Radiotherapy Facilities"* should be used and referenced to adequately determine the design and shielding required to limit radiation exposure to members of the public and employees to an acceptable level. If another guidance document is used for this assessment, provide the name of the guidance document.

A. Facilities

1. The applicant must submit a facility diagram of the treatment room(s) and surrounding areas that includes the following:

    a. Exact location of the accelerator within the room for each unit

    b. Location of the door to the accelerator vault

    c. Location of the control panel for each accelerator
    NOTE: The control panel must be outside of the treatment room

    d. All adjacent areas and the distance to these areas (also includes above and below the treatment room). As an alternative to specifying distances, drawings may be drawn to a specified scale (e.g., ¼ inch = 1 foot) Adjacent areas should be designated as controlled or uncontrolled areas.

    e. Height of earth against outside walls, if applicable

    f. 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.

2. A Qualified Expert shall be consulted in the shielding design of a particle accelerator installation. Each accelerator installation shall be provided with such primary and/or secondary barriers as are necessary to ensure compliance with RH-1200 (Occupational Dose Limits for Adults) and RH-1208 (Dose Limits for Individual Members of the Public). Shielding calculations should project the maximum radiation levels that will exist in each area adjacent to, above, and below the accelerator. These calculations should also 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 on concern type of material and thickness of barrier, and attenuation factor of the barrier.

Calculations must show the maximum radiation level to be expected in any one hour and in one week, and shall describe the type, thickness and density of shielding materials used on all sides of the room, including the floor and ceiling. All treatment room walls, floors, and ceiling must be fixed barriers, except for access doors to the treatment room or movable beam interceptors. 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 per hour and per week, average dose per patient).

b. Continuous occupancy factor should be used (i.e., occupancy factor equal to unity) since the rules assume that a person is continually 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 calculations.

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 time during which the primary beam of radiation is directed at a particular barrier) should not be considered in these calculations. If the use factor is less than 1, then the rationale must be included in the calculations.

e. If the accelerator will be operated in more than one treatment modality, calculations should be made for each modality, if applicable.

f. 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.

B. Equipment

Each photon therapy system operating at 500 kV and above, and electron therapy systems operating at 500 keV and above shall be equipped with the components and devices described in RH-10302. Some equipment/devices to point out are listed below and will be verified during Department inspection. A description of this equipment does not need to be submitted with the application; however, operational checks must be described in the applicant's written Quality Assurance procedures discussed in Item 14.

Controls and Interlock Systems	RH-5403. RH-10302.q.7. – 9.
Warning Devices	RH-5404, RH-10302.q.5.
Area Monitoring Devices	RH-5407, RH-10302.a.
Viewing Systems	RH-10302.q.3.
Aural Communication	RH-10302.q.4.

APPENDIX F

QUALITY ASSURANCE PROGRAM

Acceptance Testing and Commissioning

Acceptance testing and commissioning shall be performed by, or under the direct supervision of a Qualified Medical Physicist who is physically present at the facility during the calibration. These tests shall be performed in accordance with the AAPM Report No. 47 "AAPM Code of Practice for Radiotherapy Accelerators" and the manufacturer's contractual specifications. Acceptance testing and commissioning shall be conducted before the first medical use and following installation or reinstallation. Records will be reviewed during Department inspection.

Full Calibrations

In accordance with RH-10302.t., full calibrations shall include measurement of all applicable parameters recommended in the AAPM Report No.142 "Quality Assurance of Medical Accelerators." Full calibrations must also be performed in accordance with the AAPM Report No. 47 "Code of Practice for Radiotherapy Accelerators." Although it is not necessary to complete all elements of a full calibration at the same time, all applicable parameters (for all energies) shall be completed at intervals not exceeding twelve (12) months. Full calibrations must also be performed following any component replacement, major repair, or modification of components that could significantly affect the characteristics of the beam.

The Qualified Medical Physicist shall perform or directly supervise, while being physically present at the facility, all elements of a full calibration necessary to determine that all parameters are within acceptable limits according to RH-10302.t.4. A dosimetry system described in RH-10300.c.1. must be used to measure radiation output. A copy of the most recent calibration performed shall be available at a designated area within the therapy facility. Each calibration record shall be maintained for five (5) years, and contain the information delineated in RH-10302.t.7.

Periodic Quality Assurance Checks

Periodic quality assurance checks shall be performed in accordance with AAPM Report No. 142 "Quality Assurance of Medical Accelerators" at intervals not to exceed those specified in Report No. 142. The licensee shall perform periodic checks in accordance with written procedures established by the Qualified Medical Physicist. These procedures shall include a description of the daily spot checks and monthly spot checks that will be performed and shall specify, at minimum, the following:

1. Frequency at which tests, or measurements are to be performed
2. Acceptable tolerance for each parameter measured in the quality assurance check when compared to the value for that parameter determined in the full calibration
3. Immediately notifying the Authorized User and Qualified Medical Physicist if any parameter is not within its acceptable tolerance. The accelerator shall not be made available for medical use until the Qualified Medical Physicist has determined that all parameters are within their acceptable tolerances.

4. If all quality assurance check parameters appear to be within their acceptable range, the results shall be reviewed and signed by either the Authorized User or Qualified Medical Physicist within three (3) treatment days
5. The Qualified Medical Physicist shall review and sign the results of each quality assurance check at intervals not to exceed thirty (30) days.

Safety Quality Assurance Checks

Applicable safety quality assurance checks shall be performed at intervals not to exceed those specified in the AAPM Report 142 "Quality Assurance of Medical Accelerators." The checks performed pursuant to RH-10302.u.7. shall be performed at intervals not to exceed three (3) months, unless a more frequent interval is referenced in Report No. 142.

In accordance with RH-10302.u.7., Safety quality assurance checks, at a minimum, must ensure the proper operation of:

1. Electrical interlocks at each external beam radiation therapy room entrance
2. Proper operation of the "BEAM-ON," interrupt, and termination switches
3. Beam condition indicator lights on the access doors, control console, and in the radiation therapy room
4. Viewing and intercom systems
5. Radiation area monitors
6. Electrically operated treatment room door(s) from inside and outside the treatment room
7. At least one emergency power cutoff switch. If more than one is installed and not all switches are tested at once, each switch shall be tested on a rotating basis.

If the results of the safety quality assurance checks indicate the malfunction of any system, the control console must be secured in the OFF position and patients shall not be treated until the system is adequately repaired or replaced.

A copy of the most recent quality assurance checks performed shall be available at a designated area within the facility. Each record shall include the results of the check plus the information described in RH-10302.u.10.

APPENDIX G

PERSONNEL MONITORING PROGRAM

This Appendix provides information that may be used to develop and implement, or revise, or amend a personnel monitoring program to correctly the measure radiation dose to occupationally exposed workers. Applicants may use this information to establish a personnel monitoring program to meet the requirements of RH-1302 and other requirements of Section 3 of the ASBH Rules for Control of Sources of Ionizing Radiation. This information includes guidance as well as discussion of rule requirements that are to be reflected in the elements of personnel monitoring program.

"Dosimetry" is a broad term commonly applied to the use of monitoring devices and other methods to measure or otherwise quantify radiation doses to individuals. The licensee must control occupational doses and demonstrate compliance with radiation dose limits. RH-1200 provides the occupational dose limits for adults. RH-1302 states that individuals entering a high or very high radiation area must be provided with dosimetry.

Definitions of relevant terms such as Total Effective Dose Equivalent (TEDE), deep-dose equivalent (DDE), and committed effective dose equivalent (CEDE) can be found in RH-1100, "Definitions".

Radiation Dose Limits

There are three dose limits included in RH-1200 that apply to external exposure:

- Deep dose to the whole body 5 rem or (0.05 Sv),
- Shallow dose to the skin or extremities 50 rem or (0.5 Sv), and
- Dose to the lens of the eye 15 rem or (0.15 Sv).

According to the definitions in RH-1100, the deep dose equivalent (DDE) to the whole body is considered to be at a tissue depth of 1 cm (1000 mg/cm^2), shallow dose equivalent to the skin or extremities at 0.007 cm (7 mg/cm^2), and eye dose equivalent at 0.3 cm (300 mg/cm^2). In evaluating the eye dose equivalent, it is acceptable to take credit for the shielding provided by protective lenses.

Paragraph RH-1302 requires the use of individual monitoring devices for the following:

- Adults likely to receive, in one year, from sources external to the body, a dose in excess of 10 percent of the occupational dose limits in RH-1200. Monitoring devices are accordingly required for adults with an annual dose in excess of
    - 0.5 rem (0.005 Sv) DDE
    - 1.5 rem (0.015 Sv) eye dose equivalent
    - 5 rem (0.05 Sv) shallow dose equivalent to the skin
    - 5 rem (0.05 Sv) shallow dose equivalent to any extremity.
- Minors who are likely to receive an annual dose in excess of

- 0.1 rem (1.0 mSv) DDE
- 0.15 rem (1.5 mSv) eye dose equivalent
- 0.5 rem (5 mSv) shallow dose equivalent to the skin
- 0.5 rem (5 mSv) shallow dose equivalent to any extremity.

- Declared pregnant women likely to receive an annual dose in excess of 0.1 rem (1.0 mSv) DDE during the entire pregnancy.
- Individuals entering a high or a very high radiation area.

Radiation Dose Monitoring

External dose is determined by using individual radiation monitoring devices, such as **Film Badges, Optically Stimulated Luminescence Dosimeters (OSLD), and Thermoluminescent Dosimeters (TLDs)**. These devices must be evaluated by a processor that is National Voluntary Laboratory Accreditation Program (NVLAP)-approved, as required by RH-1301.

The applicant must describe the type of personnel dosimetry, specifically, film badges, OSLs, or TLDs, that personnel will use.

- Applicants must ensure that the personnel dosimetry program contains provisions that personnel monitoring devices be worn so that the part of the body likely to receive the greatest dose will be monitored. The device for monitoring the whole body dose, eye dose, skin dose, or extremity dose shall be placed near the location expected to receive the highest dose during the year (RH-1201.c). When the whole body is exposed fairly uniformly, the individual monitoring device is typically worn on the front of the upper torso.

- If, after the dose is received, the licensee somehow learns that the maximum dose to a part of the whole body, eye, skin, or extremity was substantially higher than the dose measured by the individual monitoring device, an evaluation shall be conducted to estimate the actual maximum dose.

Because evaluation of dose is an important part of the radiation protection program, it is critical that users return dosimeters on time. Licensees should be vigorous in their effort to recover any missing dosimeters. Delays in processing a dosimeter can result in the loss of the stored information.

Declared Pregnancy and Dose to Embryo/Fetus

The Rules, Paragraph RH-1207 states that the licensee shall ensure that the dose to an embryo/fetus during the entire pregnancy, due to occupational exposure of a declared pregnant woman, does not exceed 0.5 rem (5 mSv). The licensee shall make efforts to avoid substantial variation above a uniform monthly exposure rate to a declared pregnant woman. If the pregnancy is declared in writing and includes the worker's estimated date of conception, the dose equivalent to an embryo/fetus shall be taken as the sum of:

- The deep dose equivalent to the declared pregnant woman; and

- The dose equivalent to the embryo/fetus from radionuclides in the embryo/fetus and radionuclides in the declared pregnant woman.

Records of External Radiation Dose Monitoring

In order to demonstrate compliance with occupational dose limits of RH-1200, the Rules include specific requirements for documenting, maintaining, and retaining the results of personnel radiation dose monitoring. The requirements are summarized below:

A. Records of Prior Occupational Dose

Prior to assigning a personnel monitoring device to a worker the worker's occupational radiation dose received during the current year will be determined. In addition, every reasonable effort must be made to obtain the individual's records indicating the individual's cumulative occupational radiation dose. If a worker is unable to provide the information, records from their previous employer will be obtained. Prior occupational dose records shall include all of the information required by the Rules for Control of Sources of Ionizing Radiation, Paragraph RH-2826, "Cumulative Occupational Exposure History", Department Form Z, or an equivalent form.

B. Records of Individual Monitoring Results

Each licensee shall maintain records of doses received by all monitored individuals and these records must include, when applicable, the information contained in RH-1500.f.1. Records of doses received by each monitored worker shall be maintained as long as the facility's medical particle accelerator license remains in effect.

C. Annual Reports to Monitored Individuals

Each licensee shall make dose information available to workers as shown in records maintained by the licensee under the provisions of RH-1500.f. The licensee shall provide an annual report to each individual monitored under RH-1302 of the dose received in that monitoring year if:

- The individual's occupational dose exceeds 100 mrem (1 mSv) TEDE or 100 mrem to any individual organ or tissue; or
- The individual requests his or her annual dose report

D. Termination Reports to Monitored Individuals

Within 30 days of termination of employment, or within 30 days after the individual's exposure has been determined, whichever is later, each monitored worker will receive a written report summarizing the individual's occupational radiation dose, as required by Rules for Control of Sources of Ionizing Radiation, Paragraph RH-2804, "Notifications and Reports to Individuals". Records documenting that the reports have been furnished to monitored workers will be maintained for at least 3 years.

E. Records for Declared Pregnancies

The fetal dose will be closely monitored so as not to exceed 500 millirem. Recordkeeping requirements specified in the Rules for Control of Sources of Ionizing Radiation, Paragraph RH-1207, “Dose to an Embryo/Fetus” and RH-1500.f.5., “Records of Individual Monitoring Results”, will be met.

F. Occupational Dose Limits for Minors

Minors will not exceed an annual occupational dose of 500 millirem. Recordkeeping requirements specified in Rules for Control of Sources of Ionizing Radiation, Paragraph RH-1206, “Occupational Dose Limits for Minors” and Paragraph RH-2804, “Notifications and Reports to Individuals”, will be met.

G. Worker Overexposure Reports

When a report of an individual’s exposure is sent to the Arkansas Department of Health as required by Rules for Control of Sources of Ionizing Radiation, Paragraph RH-1505, “Notifications and Reports to Individuals”, the exposed individual will also be notified no later than when the report is sent out.

APPENDIX H

RADIATION SURVEY PROGRAM

Radiation surveys are performed to demonstrate compliance with the occupational dose limits in RH-1200.a. and to ensure that the licensee has made every reasonable effort to maintain exposures to radiation as far below the dose limits as practical. Surveys are used to verify that adequate shielding is in place to keep doses "as low as reasonably achievable" (ALARA). Surveys are also performed to demonstrate compliance with the dose limits for individual members of the public in RH-1208. Members of the public are not radiation workers but includes individuals who may work in the vicinity of the accelerator(s).

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. In addition, a radiation protection survey shall also be performed prior to any subsequent medical use and:

- After making any change in the treatment room shielding
- After making any change in the location of the accelerator within the treatment room
- After relocating the accelerator
- Before using the accelerator in a manner that could result in increased radiation levels in areas outside the treatment room
- After making a change in the occupancy of areas adjacent to the treatment room
- At least annually to check for unknown changes and malfunctioning equipment

The survey record shall include, but not limited to, the information listed in RH-10300.a.4.B.

<u>Dose to Members of the Public</u>

RH-1209 requires that licensees demonstrate, by measurement and calculation, compliance with the annual dose limit for members of the public. This assessment should demonstrate that the total effective dose equivalent to individual members of the public dose not exceed 0.1 rem (1 millisievert) in a year and 0.002 rem (0.02 millisievert) in any one hour.

If a survey indicates that an individual in an unrestricted area may be exposed to levels of radiation greater than those permitted by 1208.a. and RH-1208.b., before beginning the treatment program, the licensee shall ensure the following:

1. The unit is equipped with beam direction interlocks or additional radiation shielding is added to ensure compliance with the dose limits
2. The survey is performed again
3. The survey report generated includes the results of the initial survey, a description of the modification made in order to comply, and the results of the second survey
4. A license amendment is requested and received under RH-1208.d. that authorizes radiation levels in unrestricted areas greater than those permitted by RH-1208.a. and RH-1208.b.

APPENDIX I

OPERATING AND EMERGENCY PROCEDURES

The applicant must establish a set of operating and emergency procedures for particle accelerator operations, which address, at minimum, the items delineated in RH-5405, RH-5409, and RH-10302.s. Below is a list of items that must be addressed in the facility's operating and emergency procedures:

A. Operating Procedures

1. Procedures for securing the particle accelerator against unauthorized use when not in operation.
2. Only a button/switch on the accelerator control console shall be routinely used to turn the accelerator beam on and off. The safety interlock system shall not be used to turn off the accelerator beam except in an emergency or for testing the interlock.
3. All safety and warning devices, including interlocks, shall be checked for proper operability at intervals not to exceed three (3) months and shall be repaired as necessary. Results of these checks and records of repairs shall be maintained for five (5) years at the accelerator facility or inspection by the Department.
4. Electrical circuit diagrams of the accelerator and the associated safety, warning, and interlock systems shall be kept current and maintained for inspection by the Department. These diagrams shall also be available to the operator at each accelerator facility.
5. Safety procedures to be followed whenever an interlock has been tripped or intentionally bypassed. If intentionally bypassed, such action shall be:
    a. Authorized in writing by the Radiation Safety Committee or the Radiation Safety Officer
    b. Recorded in a permanent log and posted as a notice at the accelerator control console and at any affected interlock; and
    c. Terminated as soon as possible
6. In the event of a malfunction of a safety or warning device, the accelerator shall not be operated unless appropriate interim precautions are instituted to provide equivalent protection.
7. Records of maintenance and/or modifications performed on the accelerator shall be maintained, including the names of persons who performed the services. These records shall be maintained for five (5) years.
8. Procedures for ensuring that no individual except the patient is in the treatment room during treatment of a patient.
9. If other radiation-producing equipment (e.g., HDR unit) 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.

10. If a patient must be held in position during treatment, the use of mechanical supporting or restraining devices should be described.
11. When adjustable beam limiting devices are used, the position and shape of the radiation field shall be indicated by a light field.
12. Methods and occasions for conducting radiation surveys
13. Personnel monitoring and the use of personnel monitoring equipment
14. Preventative maintenance
15. Posting requirements

B. Emergency Procedures

1. Minimizing exposures to persons in the event of an accident
2. Reporting an actual or suspected exposure
3. Notifying proper persons in the event of an accident. This should include names and phone numbers of individuals to be contacted and the Arkansas Department of Health.
4. 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).

HOSPITAL/CLINIC NAME
LOCATION
PARTICLE ACCELERATOR LICENSE
ARK—
EXPIRATION DATE:

ANNUAL RADIATION SAFETY PROGRAM AUDIT FORM

DATE FROM _____ to _____

Date of This Audit _____ **Date of Last Annual Audit _____**

Next Audit Date _____

Auditor _____ **Date _____**
(Signature)

Management Review _____ **Date _____**
(Signature)

Audit History

A. Were previous audits conducted at least annually [RH-1004]?

B. Were records of previous audits maintained [RH-1500]?

C. Were any deficiencies identified during the previous audit?

D. Were corrective actions taken? (Look for repeated deficiencies).

Organization and Scope of Radiation Protection Program

A. Radiation Protection Program is in place [RH-1004]?

B. Radiation Safety Officer:

1. If the RSO was changed, was license amended? If no, explain.
2. Does new RSO meet Department training requirements? If no, explain.
3. Is RSO fulfilling all duties? If no, explain.
4. Is there a written agreement in place for the RSO [RH-8300]? If no, explain.

C. Multiple places of use? If yes, list locations.

D. Are all locations listed on license? If no, explain.

D. Were periodic (at least annually) reviews of the radiation protection program content and implementation done at each location? If no, explain.

E. Describe scope of the program (staff size, number of procedures performed, etc.).

1. Staff size- Radiation Safety Officer
   Medical Physicist/Qualified Experts ___ FTE,

Radiation Oncologist (Authorized Users) ____,
Dosimetrists ___ FTE,
Radiation Therapists ___ FTE,
and Radiation Safety Committee of ___ members.

2. Number of particle accelerators:
3. Number of patients started during the year:
4. Training is provided to staff on an annual basis.
5. Radiation Safety Committee meets semiannually. Describe RSO reports given:

F. Licensed Material:

G. If places of use changed, was the license amended? If no, explain.

H. If control of license was transferred or bankruptcy filed, was Department prior consent obtained or notification made, respectively [RH-5205.b and RH-5205.d]?

Radiation Safety Program

A. Minor changes to program [RH-8301]?

B. Records of changes maintained for 5 years [RH-8701]?

C. Content and implementation reviewed at least annually by the licensee [RH-1004]?

D. Records of reviews maintained [RH-1500]?

Use by Authorized Individuals

Compliance is established by meeting at least one criterion under each category.

A. Authorized User [RH-10000.c, 10200.c]:

_____ 1. Certified by specialty board specified
_____ 2. Identified on Department, NRC or Agreement State license
_____ 3. Identified on permit issued by broad scope or master materials licensee
_____ 4. Listed on facility license

B. Qualified Medical Physicist [RH-10200.d]:

_____ 1. Certified by specialty board
_____ 2. Identified on Department, NRC or Agreement State license
_____ 3. Identified on permit issued by broad scope or master materials licensee
_____ 4. Listed on facility license

Amendments Since Last Audit

A. Any Amendments since last audit?

Notifications (of State) Since Last Audit

A. Any Notifications since last audit [RH-8020]?

B. Appropriate documentation provided to Department for review and approval by Department prior to physician acting as an authorized user for any therapeutic radiation machine [RH-10200.c.1.B.2]?

C. Department notified within 30 days after: authorized user, qualified medical physicist, or RSO stops work or changes name; license's mailing address changes; licensee's name changes without a transfer of control of the license?

D. Survey due to licensee making any changes in the treatment room shielding, location or use that would result in an increase in radiation levels in unrestricted areas per RH-10300.a.2 submitted to the Department?

Training, Retraining, and Instructions to Workers

A. Have workers been provided with required instructions [RH-2803, RH-8633]?

B. Is the individual's understanding of current procedures and regulations adequate?

C. Training program implemented?

1. Operating procedures [RH-5401, RH-5410]?
2. Emergency procedures [RH-5401]?
3. Periodic training required and implemented [RH-5401]?
4. Were all workers provided annual refresher training, as needed [RH-5401]?
5. Was each supervised user instructed in the licensee's written radiation protection procedures and administration of written directives, as appropriate [RH-10201]?
6. Are initial and periodic training records maintained for each individual [RH-5401]?
7. Briefly describe training program:

D. Section 3 - Workers cognizant of requirements for:

1. Radiation Protection Program [RH-1004]?
2. Annual dose limits [RH-1200, RH-1208, RH-1209]?
3. Department Forms :

   a. RC Form 110 Occupational Dose Record for a Monitoring Period (formerly Form Y)

   b. RC Form 111 Cumulative Occupational Dose History (formerly Form Z)
4. 10% monitoring threshold [RH-1302]?
5. Dose limits to embryo/fetus and declared pregnant worker [RH-1207]?
6. Grave Danger Posting [RH-1303]?

Facilities

A. Facilities as described in license application?

B. Therapy device facilities provided with electrical interlock system, viewing and intercom systems, radiation monitor, and beam on lights?

C. Radiation Machines Registered in timely manner [RH-22]?

Radiation Survey Instruments

A. Survey instruments used to show compliance with Section 3 [STANDARDS FOR PROTECTION AGAINST RADIATION] and RH-10300.a.;

1. Appropriate operable survey instruments possessed or available [Section 3]?
2. Calibrations [RH-5412]:
    a. Before first use, annually and after repairs?
    b. Within 20% on each scale or decade of interest?
3. Records maintained [RH-5412.d]?

B. Radiation surveys performed in accordance with the licensee's procedures and the regulatory requirements [RH-10300.a.]?

Dosimetry Equipment

A. Calibrated Dosimetry equipment available for use [RH-10300.c]?

B. Record of each dosimetry system calibration and comparison kept for 5 years and available [RH-10300.c.]?

Public Dose

A. Is dose to the public in unrestricted areas kept below 100 mrem (1mSv) in a year [RH-1208. Dose Limits for Individual Members of the Public]?

B. Has a survey or evaluation been performed [RH-5407.f]?

C. Have there been any additions or changes to the storage, security, or use of surrounding areas that would necessitate a new survey or evaluation?

D. Do unrestricted area radiation levels exceed 2 mrem (0.02 mSv) in any one hour [RH-1208]?

E. Records maintained [RH-5407.g]?

Equipment Quality checks

A. Full Calibration of Particle Accelerators [RH-10302.t] ?
B. Quality Periodic assurance checks [RH-10302.u]?
C. QA for IMRT done [RH-10302.v]?
D. QA for Simulation System [RH-10306]?

Personnel Radiation Protection

A. Exposure evaluation performed [RH-1300]?

B. ALARA program implemented [RH-1004)]?

C. External Dosimetry:

1. Monitors workers per [RH-1302)]?
2. External exposures account for contributions from airborne activity [RH-1202]?
3. Supplier _____ Frequency _____

4. Supplier is NVLAP-approved [RH-1300)]?
5. Dosimeters exchanged at required frequency?

E. Review of Records and Reports

1. Reviewed by: _____ Frequency _____
2. Auditor reviewed personnel monitoring records for period mm/dd/yyyy, to mm/dd/yyyy.
3. Prior dose determined for individuals likely to receive doses [RH-1500]?
4. Maximum exposures TEDE _____ Other _____
5. Maximum CDEs _____ Organs _____
6. Maximum CEDE _____
7. Internal and external summed [RH-1201]?
8. Were occupational limits met [RH-1200]?
9. Department forms or equivalent [RH-1500.d, RH-1500.f]?
10. If a worker declared her pregnancy during the audit period, then was the dose in compliance [RH-1207] and were the records maintained [RH-1500]?

F. Who performed any planned special exposures at this facility (number of people involved and doses received) [RH-1205, RH-1500, RH-1504]?

G. Records of exposures, surveys, monitoring, and evaluations maintained [RH-1500]?

Confirmatory Measurements

Detail location and results of confirmatory measurements.

Area monitoring done: of shielding (see above). Annual protection survey of the environs around the particle accelerator rooms was done on mm/dd/yyyy. Results listed below:

Insert test results for each particle accelerator survey here

Medical Events

If any misadministrations [RH-10201.b] have occurred since the last audit, evaluate the incident(s) and procedures for implementing and administering written directives using the existing guidance.

1. Event date _____ Information Source _____
2. Notifications

   Department Notification?

   Referring Physician?

   Patient?

   Method of Notification Telephone _____ Written _____

   If notification did not occur, why not?
3. Written Reports [RH-8800]:

   Submitted to the Department within 15 days?

Notification and Reports

A. In compliance with RH-1505, RH-1502(reports to individuals, public and occupational, monitored to show compliance with Section 3-Dose limits)?
B. In compliance with RH-1502(incidents)?
C. In compliance with RH-1504, RH-1502 (overexposures and high radiation levels)?
D. Aware of Department's 24-hour Telephone number phone number?

Posting and Labeling

A. Department Form RH-11, "Notice to Employees" is posted [RH-2802]?

B. Other posting and labeling per RH-1303 and not exempted by RH-1304, RH-1303?

Letter and Information Notices

A. Department Letters, Information Notices, and other correspondence received?

B. Appropriate action in response to Letters, Information Notices, etc.?

Special License Conditions or Issues

A. Special license conditions or issues to be reviewed:

B. Evaluation:

Audits and Findings

A. Audit Reports to RSC

B. TLD measurements on Linear Accelerators

C. Survey and Dosimetry System Equipment Calibrations

D. Summary of Findings:

E. Corrective and Preventive Actions: