

**Arkansas Department Of Health
Medical Particle Accelerator
Licensing Guide Part One: 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, 20 CAR Pt. 3 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, 20 CAR Pt. 3

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.

Complete and submit license package as described below.

1. Application for Medical Particle Accelerator License Form
2. Medical Accelerator Licensing Guide Part Two.
 - a. Complete Part Two by filling in the page number next to each item listed.
3. Supporting Documentation.
 - a. After gathering ALL documentation number each page at the bottom starting with number 1.