

**SECTION 1.
REGISTRATION OF SOURCES OF RADIATION**

Due to public comment (RH-21. and RH-26.)

RH-21. Initial Registration.

~~Every person who possesses a reportable source of radiation on January 1, 1963 shall register with the Department prior to April 1, 1963. Every person not already registered who acquires possession of a reportable source of radiation subsequent to January 1, 1963 shall register with the Department within thirty (30) days of the date of acquisition.~~

- a. ~~Each person (registrant) having physical possession or control of a radiation machine capable of producing radiation in the state of Arkansas shall apply for registration of such machine with the Department prior to the operation of the machine within thirty (30) days of the date of acquisition. Application for registration shall be completed on forms furnished by the Department and shall contain all the information required by the forms. The Department may request additional information as part of the registration process.~~
- b. ~~Notwithstanding RH-21.a., each applicant for the following uses shall apply for and receive authorization from the Department prior to operation of the machine: healing arts screening; therapeutic radiation machine use pursuant to RH-10301., RH-10307., or RH-10308.; and use of radiation therapy simulation systems.~~
- ~~b c.~~ A Radiation Safety Officer shall be designated on each application form. The qualifications of this individual shall be submitted for Department approval with the application.
- ~~c d.~~ A practitioner, licensed by the respective state board of examiners (i.e., state medical board, state dental board, state chiropractic board, state podiatric board), responsible for directing the operation of radiation machines shall be designated on each healing arts application. The signature of the administrator, president, or chief executive officer will be accepted in lieu of a licensed practitioner's signature if the facility has more than one licensed practitioner who may direct the operation of radiation machines. Each application shall be signed by the applicant or registrant or other individual duly authorized to act for and on his behalf.
- ~~d e.~~ A prospective Authorized User physician responsible for directing the operation of therapeutic radiation machines subject to RH-10301., RH-

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10307., or RH- 10308., as applicable, shall be designated on each therapeutic radiation machine application. ~~The signature of the administrator, president, or chief executive officer will be accepted in lieu of a prospective Authorized User physician signature if the facility has more than one prospective Authorized User physician.~~

Portion of RH-21.a. moved to RH-23.

RH-23. Registration Form.

Registration and renewal shall be made on forms furnished by the Department. The registration or renewal of registration shall set forth all applicable information called for by the form. The Department may request additional information as part of the registration process.

RH-26. Report of Changes.

~~Within ten (10) days of change, the registrant shall report in writing to the Department any~~ The registrant shall notify the Department in writing before making of any changes that would render the information contained in the application for registration no longer accurate, including, but not limited to, the following changes: change in the name or mailing address of the registrant; or location of the installation or an additional use location; designation of the Radiation Safety Officer; and the receipt, sale, or disposal of any reportable source of radiation. In the case of disposition of the machine, such notification should specify the recipient of the machine. Notification of the Department is required within ten (10) days of a change, unless the change involves a machine use listed in RH-21.b. Changes regarding RH-21.b. uses must be reported in writing to the Department prior to the change being made.

SECTION 6. **LICENSES AND RADIATION SAFETY REQUIREMENTS** **FOR PARTICLE ACCELERATORS**

To match RH-10300.a.4.B. (which had been written reflective of NCRP recommendations) - cleanup

RH-5407. Radiation Area Monitoring and Survey Requirements. ...

h. The survey report shall include, but not be limited to, the following:

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1. The date of the measurements;
2. The reason the survey is required;
3. A description of the accelerator including the manufacturer's name, model number and serial number, beam type, and beam energy;
4. A diagram of the facility that details building structures; areas surrounding an irradiation or treatment room, if applicable, that were surveyed; and the position of the accelerator, control panel, and associated equipment;
5. A description of the instrumentation used to determine radiation measurements, including the date of the most recent calibration and who performed the calibration for each instrument used;
6. The conditions under which radiation measurements were taken;
7. Survey data including:
 - A. The measured dose rate at several points in each area expressed in millirems (microsieverts) per hour;
 - B. The projected maximum "in-any-one-hour" dose equivalent in each unrestricted area adjacent to the accelerator;
 - ~~B-C.~~ The projected **maximum** annual total effective dose equivalent (TEDE) in **each restricted and unrestricted** areas adjacent to the accelerator; and
 - ~~C-D.~~ A description of workload, use, and occupancy factors employed in determining the projected annual TEDE; and
8. The signature of the individual responsible for conducting the survey.

To be commensurate with the keeping of full calibration records for 5 years (internal comment)

...

- p. Radiation measurements shall be performed with a calibrated dosimetry system. The dosimetry system calibration shall be traceable to a national standard. The calibration shall have been performed within the previous twenty-four (24) months and after any servicing that may have affected system calibration. Records of dosimetry system calibrations shall be maintained **until termination of the license for five (5) years.**

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Same revision for the same requirement in Section 11

SECTION 11. **THERAPEUTIC RADIATION MACHINES**

RH-10300. General Technical Requirements for Facilities Using Therapeutic Radiation Machines. ...

c. Dosimetry equipment.

3. The licensee or registrant shall maintain a record of each dosimetry system calibration and comparison ~~for the duration of the license/registration for five (5) years.~~ For each calibration or comparison, the record shall include the following: the date of the calibration or comparison; the manufacturer's name, model numbers, and serial numbers of the instruments that were calibrated or compared as required by RH-10300.c.1. and RH-10300.c.2.; the correction factors that were determined; the names of the individuals who performed the calibration or comparison; and evidence that the comparison was performed by, or under the direct supervision and in the physical presence of, a Qualified Medical Physicist.

"Licensee/registrant" clean-up

RH-10304. Calibration of Survey Instruments. ...

- c. To satisfy the requirements of RH-10304.b., the licensee ~~or registrant~~ shall:
 1. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 10 percent (10%); and
 2. Consider a point as calibrated if the indicated dose rate differs from the calculated dose rate by not more than 20 percent (20%) if a correction factor or graph is conspicuously attached to the instrument and is used to interpret readings to within 10 percent (10%).

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RH-10307. Electronic Brachytherapy. ...

b. An electronic brachytherapy device shall only be utilized for human use applications specifically approved by the U.S. Food and Drug Administration (FDA) unless participating in a research study approved by the **licensee's registrant's** Institutional Review Board (IRB).

...

g. Qualified Medical Physicist support.

...

2. If the Qualified Medical Physicist is not a full-time employee of the **licensee registrant**, the operating procedures required by RH-10307.h. 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.

...

i. Safety precautions for electronic brachytherapy devices.

1. In accordance with RH-1302., "Conditions Requiring Individual Monitoring of External and Internal Occupational Dose," each **licensee registrant** shall monitor exposures to radiation at levels sufficient to demonstrate compliance with the occupational dose limits of Section 3, "Standards for Protection Against Radiation."

RH-10308. Other Use of Electronically-Produced Radiation to Deliver Therapeutic Radiation Dosage.

A person shall not utilize any device which is designed to electrically generate a source of ionizing radiation to deliver therapeutic radiation dosage, and which is not appropriately regulated under any existing category of therapeutic radiation machine, until:

a. The applicant or **licensee**/registrant has, at a minimum, provided the Department with: ...