

IOWA DEPARTMENT OF PUBLIC HEALTH
Bureau of Radiological Health (BRH)
Lucas State Office Building, 5th Floor
321 East 12th Street, Des Moines, IA 50319

July, 2007

IDPH INFORMATION NOTICE 07-x02: Update and review of rules for the operation of therapeutic radiation machines

ADDRESSEES: Facilities operating therapeutic radiation machines in Iowa

PURPOSE:

The Iowa Department of Public Health (BRH) is issuing this information notice to notify Iowa facilities of updated rules. This notice also requests that facilities review current rules for compliance. No written response to this notice is required. All individuals operating or servicing therapeutic radiation machines should read this notice and adjust their practices if needed.

DISCUSSION:

The following is a summary of the rule changes. Please review these and the complete copy of 41.3 attached.

New or amended rules:

41.3(5)g. A physician shall not act as an authorized user for any therapeutic radiation machine until such time as said physician's training has been reviewed and approved by the registrant (the facility).

41.3(8). Written safety procedures and rules shall be developed by a radiation therapy physicist and shall be available in the control area of a therapeutic radiation machine, including any restrictions required for the safe operation of the particular therapeutic radiation machine. The operator shall be able to demonstrate familiarity with these rules. All individuals associated with the operation of a therapeutic radiation machine shall be instructed in and shall comply with procedures for maintaining written directives.

41.3(10). Records for visiting authorized users. Notwithstanding the provisions of 41.3(5), a registrant may permit any physician to act as a visiting authorized user for up to 60 days per calendar year under the following conditions:

- a. The visiting authorized user has prior written permission of the registrant's management, and, if the use occurs on behalf of an institution, the institution's radiation safety committee, and
- b. The visiting authorized user meets the requirements of 41.3(5), and

c. The registrant maintains copies of all records specified in 41.3(5) for five years from the date of the last visit.

41.3(11). Information and maintenance record and associated information. The registrant shall maintain the following information in a separate file or package for each therapeutic radiation machine for inspection by the agency.

41.3(16), in part, a radiation protection survey shall also be performed prior to any subsequent medical use and

...After making any change in the location within the treatment room...

...After relocating the machine...

41.3(18)a(15)4. For equipment manufactured after July 9, 1997, the selection of energy shall be in compliance with International Electrotechnical Commission (IEC) Document 60601-2-1.

All testing shall be performed in accordance with "AAPM Code of Practice for Radiotherapy Accelerators: AAPM Report No. 47," prepared by Radiation Therapy Task Group 45 and the manufacturer's contractual specifications.

41.3(18)f(5)2, 3, and 7.

2. If all quality assurance check parameters appear to be within their acceptable range, the quality assurance check shall be reviewed and signed by either the authorized user or radiation therapy physicist within 3 treatment days.

3. The radiation therapy physicist shall review and sign the results of each radiation output quality assurance check at intervals not to exceed one month.

7. At least one emergency power cutoff switch. If more than one emergency power cutoff switch is installed and not all switches are tested at once, each switch shall be tested on a rotating basis. Safety quality assurance checks of the emergency power cutoff switches may be conducted at the end of the treatment day in order to minimize possible stability problems with the therapeutic radiation machine.

Please review the requirements of 41.3(20) for calibration of survey instruments. The rules can be found at: www.legis.state.ia.us. Click on Iowa Administrative Code (under Popular Publications), PDF format. Page down approximately seven pages to 641 Public Health, and click on Chapter 41. Please review the rules carefully and make adjustments in operation of the therapeutic radiation machine as needed.

If you have any questions regarding this notice or the therapeutic radiation machines rules, please contact Randy Dahlin (515/281-0419) or Nancy Farrington (515/281-0422).

Melanie Rasmusson, Chief

Date