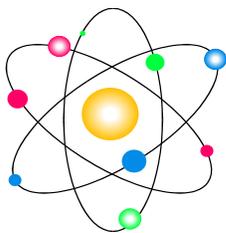

IOWA DEPARTMENT OF PUBLIC HEALTH

INDUSTRIAL & MEDICAL ONCOLOGY RADIATION MACHINE REGULATORY GUIDE



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**INDUSTRIAL AND MEDICAL ONCOLOGY RADIATION MACHINE REGULATORY
GUIDE**

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RADIATION EMITTING MACHINE REGULATORY GUIDE

1. INTRODUCTION

1.1 PURPOSE OF GUIDE

This regulatory guide is provided to describe the type and extent of information for registration to possess and use radiation emitting equipment in Iowa.

Registration of radiation emitting machines is required only for those machines that are operational and in use. Machines in storage or not operational are not required to be registered. Typically, the equipment is designed and manufactured for utilizing x-rays for examining a structure and/or composition of material or for medical therapeutic use. A radiation emitting machine must be labeled as such by the manufacturer, and must be used and maintained in accordance with the manufacturer's instructions.

You should carefully study this guide and other applicable rules in Iowa Administrative Code (IAC) 641, Chapters 38 through 41 and Chapter 45 and then complete the registration form. IDPH may request additional information to provide reasonable assurance that the applicant has established an adequate radiation protection program.

1.2 APPLICABLE REGULATIONS

Rules pertaining to this type of registration are found in the IAC 641, Chapters 38, 39, 40, 41 and 45 of the Radiation Machine and Radioactive Materials Rules. You may go to www.idph.state.ia.us and follow the links to the Bureau of Radiological Health.

1.3 AS LOW AS REASONABLY ACHIEVABLE (ALARA) PHILOSOPHY

Paragraph 641-40.1(3) states "...Every reasonable effort should be made to maintain radiation exposures as low as reasonably achievable (ALARA)." As a registrant, you should consider the ALARA philosophy in the development of work plans involving radiation emitting equipment.

The success of an ALARA program depends on the cooperation of each person who works at your facility. Management should make a formal policy commitment to the ALARA philosophy and implement that commitment with the use and maintenance of radiation emitting equipment. Management needs to designate one or more responsible persons who will oversee the day-to-day operations of the radiation safety program, including the mandatory annual audit of the radiation safety program.

2. REGISTRATION

IDPH registers radiation emitting equipment that is operational and in use.

Radiation emitting equipment may include but are not limited to: analytic x-ray, electron microscope, baggage x-ray, cabinet x-ray, medical and non-medical accelerators, industrial radiographic x-ray, x-ray fluorescent analyzer and portable or fixed gauges.

There are two types of registration -- initial registration and annual renewal of registration. Each type is handled somewhat differently.

2.1 INITIAL REGISTRATION

IDPH receives quarterly reports from companies that distribute radiation emitting equipment to facilities in Iowa. Upon receipt of these reports, IDPH verifies that all recipients have registered to possess and use radiation emitting equipment. Any companies that are not being registered are sent an application and are required to report all equipment to IDPH. Companies must verify that the information includes their current inventory of radiation emitting equipment. The registration fee, based per tube and upon the type of machine, must be sent with the application when it is submitted to IDPH. IDPH will send the registration certificate after the information on the invoice is processed.

2.2 REGISTRATION RENEWAL

IDPH sends out an annual invoice approximately two months prior to the expiration date of the certificate of registration. This invoice includes the registrant's name and address, contact person, and an inventory of all radiation emitting equipment on file with IDPH. It is the registrant's responsibility to update the information to include all corrections, additions and deletions. The contact person must then sign the form, list his or her telephone number, fax number, email and return the form to IDPH with the correct registration fee.

Please note that registrations are available for review by the public in IDPH offices. Do not submit proprietary information unless necessary. If submitting such information is necessary, please specify what the proprietary information involves. Failure to do so may result in unintended disclosure of propriety information. Also, do not submit personal information about your individual employees unless it is necessary. For example, the training and experience of individuals should be submitted to demonstrate their ability to manage radiation safety programs or to work safely with radiation emitting equipment. Home addresses and home telephone numbers should be submitted only if they are part of your emergency response plan. Dates of birth, social security numbers, and radiation dose information should be submitted only if specifically requested by IDPH.

3. CONTACT PERSON

The contact person should be an individual who knows your proposed radiation emitting machine program and can answer questions about the equipment. This individual -- usually the plant manager, safety officer, or a principal user of the equipment -- will serve as the point of contact during the registration and inspection process. The contact person may be the same individual as the responsible person.

4. RESPONSIBLE PERSON

The responsible person should have independent authority to stop operations that are considered unsafe. The responsible person should be allowed sufficient time and commitment from management to fulfill certain duties and responsibilities to ensure that radiation emitting equipment are used in a safe manner. Responsibilities should include training, or operational checks (if applicable), annual audits, and disposal of the equipment.

The responsible person may or may not be the same individual as the contact person. If two or more different individuals are designated, they may share the duties and responsibilities. This arrangement should be clearly documented.

5. INDIVIDUAL USERS - TRAINING AND EXPERIENCE

Individuals who use the equipment must follow the manufacturer's instructions for the proper operation, storage, and maintenance of the equipment. These instructions appear both in the operator's manuals and on the machine labels. Manufacturers often provide this training during installation or servicing of the equipment. The registrant should maintain records that document the individual users' training. Although it is not required, annual refresher training on proper operations checks of the machine and appropriate radiation safety procedures are valuable tools to maintain safety awareness and to ensure that personnel do not mishandle radiation emitting equipment.

Individuals who will be operating a therapeutic radiation machine for medical use are required to be instructed in safe operating procedures and hold a current permit to practice in radiation therapy.

Individuals who may be considered as users include but are not limited to contact persons, line workers, lead shift workers, maintenance workers, researchers, or others who work in the area where a piece of equipment is installed.

6. INSPECTION AND MAINTENANCE

Each registrant will need to develop, document, and implement a radiation protection program in compliance with IAC 641-40.10(1). Inspections of industrial radiography x-ray equipment should consist of:

1. Change in the general operating characteristics of the unit;
2. Wear of electrical cables and connectors;
3. Proper labeling of console;
4. Proper console with machine, as appropriate;
5. Proper operation of locking mechanism;
6. Timer run-down cutoff;
7. Damage to tube head housing that might result in excessive radiation levels.

Medical oncology radiation emitting equipment must follow regulations in IAC 641-41.3(136C).

7. ANNUAL AUDITS OF THE RADIATION SAFETY PROGRAM

An annual audit is required by IAC 641-40.10(3). It is essential that once problems are identified; they are corrected. IDPH will review a registrant's audit program and determine if corrective actions are thorough, timely, and sufficient to prevent recurrence. IDPH encourages registrants to regulate their own compliance. Normally self identified violations that have been corrected by the registrant will not be cited.

Audits should include personnel training, inventory, operational checks (if appropriate), actual observations of machine use, identification of any problems, and resolution of those problems. Any equipment failure must be reported immediately to IDPH. A copy of a model audit checklist is included as Appendix A. However, this model may need to be modified for your specific operations.

8. POSTINGS AND SIGNS

All machine labels must be clean and legible, and caution individuals that radiation is produced when energized. IDPH recognizes that in a manufacturing setting it may not be possible to maintain these conditions. However, it is appropriate to clean labels and check them for legibility any time the equipment is inventoried, or checked for operation.

IDPH "Notice to Workers," must be posted to allow individuals to observe it on the way to or from the area where equipment is used or stored. This can be posted on a bulletin board in the employee lounge, on the door to the area where the equipment is located, or on a notification bulletin board where other official documents (for example, Occupational Safety and Health Administration or the US Environmental Protection Agency information) are posted.

Also, postings must either include: (1) the certificate of registration, inspection reports, other documents pertaining to the equipment; or (2) information where these documents can be located.

9. TRANSFER OR DISPOSAL

When transferring or disposing of radiation equipment, you should notify IDPH in writing about equipment that has been disposed of and where it was sent. This notification may also be done during the registration renewal period. In either case, a copy of the receipt of transfer must be sent to IDPH.

10. REGISTRATION FEES

An annual registration fee must be paid in full as required by IAC 641-38.8(1) for all equipment. Fees for processed registrations are not refundable. Make the check or money order payable to the Iowa Department of Public Health.

Late fees of \$25 a month are assessed starting 30 days after the due date.

11. REGISTRATION CORRECTIONS OR UPDATES

A registration can be corrected or updated by providing the correct information to IDPH. There is no fee to make these changes. Items about which IDPH should be informed include receiving or transferring a new device and changes in contact person, responsible person, name of the firm, address, or telephone number.

APPENDIX A

MODEL ANNUAL AUDIT CHECKLIST

AUDITS

- A. Were previous audits conducted at intervals not to exceed 12 months? [40.10(3)] N/A Yes No
- B. Were records of previous audits maintained? [40.81(136C)] N/A Yes No

ORGANIZATIONAL STRUCTURE

- A. If the mailing address or places of use changed, was IDPH notified? N/A Yes No
- B. If ownership changed or bankruptcy filed, was IDPH notified? N/A Yes No
- C. Responsible Person N/A Yes No
 - 1. Is the Responsible Person fulfilling his or her duties? N/A Yes No
 - 2. If the designated Responsible Person changed, was IDPH notified? N/A Yes No
- D. If the designated Contact Person changed, was IDPH notified? N/A Yes No
- E. Radiation Emitting Equipment N/A Yes No
 - 1. Have manufacturers or distributor's manuals for operation and maintenance? N/A Yes No
 - 2. Are the actual uses of equipment consistent with the authorized uses? N/A Yes No

TRAINING AND INSTRUCTION TO WORKERS

- A. Did all workers receive training in accordance to the manufacturer's recommendations? N/A Yes No
 - 1. Has refresher training provided? N/A Yes No
 - 2. Are records maintained? N/A Yes No
- B. Did individuals who perform non-routine operations receive training before performing the operations? N/A Yes No
- C. Do users know the emergency procedures? N/A Yes No

MAINTENANCE

- A. Are manufacturer or distributor's procedures followed? N/A Yes No
- B. Was each on-off mechanism tested for proper operation every six (6) months or at other prescribed intervals? N/A Yes No
- C. Are repair and maintenance of components related to the radiological safety of the machine performed by the manufacturer, distributor? N/A Yes No
- D. Are labels, signs, and postings identifying radiation emitting equipment and lockout procedures/warnings clean and legible? N/A Yes No

POSTINGS

- A. Is IDPH "Notice to Employees" posted? N/A Yes No
- B. Are IDPH regulations and license documents posted, or is a notice posted indicating their location? N/A Yes No

SIGN OFF

- A. Is the date of audit noted? N/A Yes No
- B. Are the dates the audit is covering noted? N/A Yes No
- C. Has the auditor signed audit? N/A Yes No

SUMMARY OF REVISIONS

<u>REVISION</u>	<u>SECTION</u>	<u>DESCRIPTION</u>
03/23/2009	All	New regulatory guide