PART B
REGISTRATION [LICENSURE] OF RADIATION MACHINE FACILITIES, [SERVICES]* AND ASSOCIATED HEALTHCARE PROFESSIONALS

Sec. B.1 - Purpose and Scope.

a. This Part provides for the registration [licensure] of ionizing radiation machine facilities, [persons providing radiation machine installation, servicing, and/or services] and healthcare professionals.

b. In addition to the requirements of this Part, all registrants [licensees] are subject to the applicable provisions of the General Provisions (Part A), Standards for Protection (Part D) and Notices, Instructions and Reports (Part J) of these regulations. In addition, some registrants [licensees] are subject to provisions of the regulations for Industrial Radiography (Part E), Healing Arts (Part F), Analytical Equipment (Part H), Particle Accelerators (Part I) of these regulations.

c. Registrants [licensees] utilizing healthcare professionals addressed in sections B.17 thru B.19 are subject to the provisions of Diagnostic X-Rays and Imaging Systems in the Healing Arts (Part F) and Radionuclides in the Healing Arts (Part G) of these regulations, as applicable.

Sec. B.2 - Definitions.

"Facility" means the location, building, vehicle, or complex under one administrative control, at which one or more radiation machines are installed, located and/or used.

"Storage" means a condition in which a device or source is not being used for an extended period of time, and has been made inoperable.

[Sec. B.3 - Prohibitions. All registrants [licensees] shall prohibit any person from furnishing radiation machine servicing or services as described in B.9d. to their radiation machine facility until such person provides evidence of registration [licensure] with the Agency as a provider of services in accordance with B.9.]

Sec. B.4 - Exemptions.

a. Electronic equipment that produces radiation incidental to its operation for other purposes is exempt from the registration [licensure] and notification requirements of this Part, provided that the dose equivalent rate averaged over an area of 10 cm² does not exceed 5 μSv (0.5 mrem) per hour at 5 cm from any accessible surface of such equipment.

---

* States should be aware that there may be a question of legal authority to register services as contrasted to radiation sources. If the State's enabling legislation does not provide such authority, the State should either amend the legislation to obtain the proper legal base or consider revising B.1a. and eliminating B.9 of these model regulations. Secondly, states may have authority for licensure versus registration. Therefore, optional language is bracketed.
equipment. The production, testing, or factory servicing of such equipment shall not be exempt.

b. Radiation machines in transit or in storage incident to transit are exempt from the requirements of this Part. This exemption does not apply to the providers of radiation machines for mobile services. Facilities that have placed all radiation machines in storage, including on-site storage, and have notified the Agency in writing, are exempt from the requirements of this Part. This exemption is void if any radiation machine is energized resulting in the production of radiation.

c. Domestic television receivers and video display terminals are exempt from the requirements of this Part.

d. Inoperable radiation machines are exempt from the requirements of this Part. For the purposes of this Part, an inoperable radiation machine means a radiation machine that cannot be energized when connected to a power supply without repair or modification.

e. Financial institutions that take possession of radiation machines as the result of foreclosure, bankruptcy, or other default of payment are exempt from the requirements in this part to the extent that they demonstrate that the unit is operable for the sole purpose of selling, leasing, or transferring.

**General Regulatory Provisions**

[Sec. B.5 - Shielding Plan Review]

a. Prior to construction, the floor plans, shielding specifications and equipment arrangement of all new installations, or modifications of existing installations, utilizing ionizing radiation machines shall be submitted to the Agency for review and approval. The required information is denoted in Appendices A and B of this Part.

b. The Agency may require the applicant to utilize the services of a qualified health physicist or a qualified medical physicist to determine the shielding requirements prior to the plan review and approval.

c. The approval of such plans shall not preclude the requirement of additional modifications should a subsequent analysis of operating conditions indicate the possibility of an individual receiving a dose in excess of the limits prescribed in D.1201, D.1206 thru 1208, D.1301 and D.1302 of these regulations.

d. After installation of a radiation machine, the registrant [licensee] shall maintain for inspection by the Agency:

i. The maximum rated technique factors of each machine;

ii. A scale drawing of the room in which a stationary radiation machine system is located with such drawing indicating the use of areas adjacent to the room and an
estimation of the extent of occupancy by an individual in such areas. In addition, the drawing shall include:

(1) The results of a survey for radiation levels present at the operator's position and at pertinent points outside the room at specified test conditions; or

(2) The type and thickness of materials, or lead equivalency, of each protective barrier.]

Sec. B.6 - Registration [Licensure] of Radiation Machine Facilities.

Each person having a radiation machine facility shall:

a. Apply for registration [licensure] of such facility with the Agency within 30 days following the effective date of these regulations or thereafter prior to the operation of a radiation machine facility. Application for registration [licensure] shall be completed on forms furnished by the Agency and shall contain all the information required by the form and accompanying instructions;**

b. A radiation safety officer (RSO) shall be designated on each application form. [The qualifications of that individual shall be submitted to the Agency with the application. The RSO shall meet the applicable requirements of Appendix C and carry out the responsibilities in Appendix D;]

c. 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 (for example, hospitals, large clinics, or multi-practitioner practices).

[Sec. B.7 - Registration [Licensure] of Mobile Service Operations. In addition to the requirements of Section B.6, the applicant shall submit the following information:

** The Agency may wish to require at least the following information on the Application for Registration of Radiation Machine Facilities form:

1. Name, address, and telephone number of the following:
   a. The radiation machine facility;
   b. The owner of the radiation machine facility;
   c. The individual responsible for the use of the facility, as designated under B.6c. for healing arts facilities;
   d. The individual designated under B.6b.;
   
2. The manufacturer, model number, serial number, and use/type of each radiation machine and tube located within the facility;

3. If the facility is mobile, the geographic areas within the State to be covered;

4. The signature of the individual designated under B.6b.;

5. Name of the radiation machine supplier, installer, and service agent;

6. The date of application and signature of the individual responsible for the use of the facility (individual designated under B.6c. for healing arts facilities.)
a. An established main location where the machine(s), records, etc. will be maintained for inspection. This shall be a street address, not a post office box number.

b. A sketch or description of the normal configuration of each radiation machine's use, including the operator's position and any ancillary personnel's location during exposures. If a mobile van is used with a fixed unit inside, furnish the floor plan indicating protective shielding and the operator's location; and

c. A current copy of the applicant's operating and safety procedures including radiological practices for protection of patients, operators, employees, and the general public.

[Sec.B.8 - Registration [Licensure] of Healing Arts Screening and Medical Research.

a. In addition to the requirements of B.6, each applicant shall apply for and receive authorization for healing arts screening before initiating a screening program. The information and evaluation in Appendix F shall be submitted with the application.

b. In addition to the requirements of B.6, any research using radiation machines on humans shall be approved by an Institutional Review Board (IRB) as required by Title 45, CFR, Part 46 and Title 21, CFR, Part 56. The IRB shall include at least one practitioner of the healing arts to direct any use of radiation in accordance with Part F]

[Sec. B.9 - Registration [Licensure] of Servicing and Services.]

[a. Each person who is engaged in the business of installing or offering to install radiation machines or is engaged in the business of furnishing or offering to furnish radiation machine servicing or services in this State shall apply for registration [licensure] of such services with the Agency within 30 days following the effective date of this regulation or thereafter prior to furnishing or offering to furnish any such services.]

[b. Application for registration [licensure] shall be completed on forms furnished by the Agency and shall contain all information required by the Agency as indicated on the forms and accompanying instructions.***]

[c. Each person applying for registration [licensure] under this Part shall specify:

i. That he/she has read and understands the requirements of this and other applicable Parts;

*** The Agency may wish to require at least the following information on the Application for Registration of Servicing and Services form:

1. Name, address, and telephone number of the following:
   a. The individual or the company to be registered;
   b. The owner(s) of the company;

2. The services which are to be provided;

3. The area of the State and other states to be covered;

4. A list of the individuals qualified to provide these services;

5. The date of application and signature of the individual responsible for the company, beneath a statement of the items specified in B.9.c.]
ii. The services for which he/she is applying for registration;

iii. The training and experience that qualify him/her to discharge the services for which he/she is applying for registration [licensure] in accordance with Appendix E;

iv. The type of measurement instruments to be used, frequency of calibration, and source of calibration; and

d. For the purpose of B.9, services may include but shall not be limited to:

i. Installation and/or servicing of radiation machines and associated radiation machine components;

ii. Calibration of radiation machines or radiation measurement instruments or devices;

iii. Radiation protection or health physics consultations or surveys;

iv. Personnel dosimetry services; and

v. Provider of equipment.]

e. No individual shall perform services that are not specifically stated for that individual on the notice of registration [license] issued by the Agency.]

Sec. B.10 - Issuance of Notice of Registration [License].

a. Upon a determination that an applicant meets the requirements of the regulations, the Agency shall issue a notice of registration [license].

b. The Agency may incorporate in the notice of registration [license] at the time of issuance or thereafter by appropriate rule, regulation, or order, such additional requirements and conditions with respect to the registrant's receipt, possession, use, and transfer of radiation machines as it deems appropriate or necessary.

Sec. B.11 - Expiration of Notice of Registration [License]. Except as provided by B.12b., each notice of registration [license] shall expire at the end of the specified day in the month and year stated therein.

Sec. B.12 - Renewal of Notice of Registration [License].

a. Application for renewal of registration [license] shall be filed in accordance with B.6 [or B.9].

b. In any case in which a registrant [licensee] not less than 30 days prior to the expiration of his/her existing notice of registration has filed an application in proper form for renewal,
such existing notice of registration [license] shall not expire until the application status has been finally determined by the Agency.

Sec. B.13 - Report of Changes. The registrant [licensee] shall notify the Agency in writing before making any change that would render the information contained in the application for registration and/or the notice of registration no longer accurate.

Sec. B.14 - Approval Not Implied. No person, in any advertisement, shall refer to the fact that their facility is registered [licensed] with the Agency pursuant to the provisions of B.6 [or B.9], and no person shall state or imply that any activity under such registration has been approved by the Agency.

Sec. B.15 - Assembler and/or Transfer Obligation. ****

a. Any person who sells, leases, transfers, lends, disposes, assembles, or installs radiation machines in this State shall notify the Agency within 15 days of:

i. The name and address of persons who have received these machines;

ii. The manufacturer, model, and serial number of each radiation machine transferred; and

iii. The date of transfer of each radiation machine.

b. No person shall make, sell, lease, transfer, lend, assemble, or install radiation machines or the supplies used in connection with such machines unless such supplies and equipment when properly placed in operation and used shall meet the requirements of these regulations.

Sec. B.16 - Reciprocal Recognition of Out-of-State Radiation Machines.

a. Whenever any radiation machine is to be brought into the State, for any temporary use, the person proposing to bring such machine into the State shall give written notice to the Agency [at least 2 working days] before such machine is to be used in the State. The notice shall include:

i. The type of radiation machine;

ii. The nature, duration, and scope of use;

iii. The exact location(s) where the radiation machine is to be used; and

**** Note: Some states may wish to include a provision regarding assembler's reports, similar to the following: "In the case of diagnostic x-ray systems which contain certified components, a copy of the assembler’s report prepared in compliance with requirements of the Federal diagnostic x-ray standard (21 CFR 1020.30(d)) shall be submitted to the Agency within 15 days following completion of the assembly. Such report shall suffice in lieu of any other report by the assembler."
iv. States in which this machine is registered.

b. If, for a specific case, the [2 working-day] period would impose an undue hardship on the person, upon application to the Agency, permission to proceed sooner may be granted.

c. The person referred to in B.16a. shall:

i. Comply with all applicable regulations of the Agency;

ii. Supply the Agency with such other information as the Agency may reasonably request; and

iii. Not operate within the State on a temporary basis in excess of 180 calendar days per year.

Sec. B.17 - Qualification of Health Physicists and Medical Physicists for Registration [Licensure].

a. All persons registered [licensed] to provide health physics services shall be certified by the American Board of Health Physics in the appropriate fields or specialties in which services are provided; or

i. Hold a masters or doctorate degree in physics, medical physics, other physical science, engineering, or applied mathematics from an accredited college or university, and

ii. Have forty (40) hours practical training and/or supervised experience in x-ray physics.

b. All persons registered [licensed] to provide medical physics services shall be certified by at least one of the following organizations in the appropriate fields or specialties in which services are provided:

i. The American Board of Medical Physics;

ii. The American Board of Radiology;

iii. The American Board of Science in Nuclear Medicine; or

iv. The Canadian College of Physicists in Medicine.


d. Health physicists and medical physicists licensed by individual states shall meet the requirements for registration [licensure] specified by that state.
e. Medical physicists involved with facilities using radioactive materials on humans shall meet the requirements of Part G of these regulations for registration [licensure].

f. All surveys, audits, reports, or other work performed by a health physicist or medical physicist as required by these regulations shall be reviewed and signed by a health physicist or medical physicist holding registration or [licensure] specified by this Part.

Sec. B.18 - Qualification of Radiologic Technologists and Nuclear Medicine Technologists.

a. All persons practicing radiography on human patients shall be:
   i. Registered by the American Registry of Radiologic Technologists in radiography and/or
   ii. Meet the requirements for certification, training, and/or examination as specified by the individual states.

b. All persons practicing nuclear medicine technology on human patients shall be:
   i. Registered by the American Registry of Radiologic Technologists in nuclear medicine technology, or certified by the Nuclear Medicine Technology Certification Board; and/or
   ii. Meet the requirements of certification, training, and/or examination as specified by the individual states.

c. All persons practicing radiologic technology involving fusion imaging shall meet one or more of the requirements specified in B.18a. or b.

[Sec B.19 — Qualification of Dental Assistants, Dental Hygienists, Veterinary Assistants, and Chiropractic Assistants.

a. All dental assistants and dental hygienists operating dental x-ray units shall meet the requirements for certification, training, and/or examination as specified by the individual states.

b. All veterinary assistants operating veterinary x-ray units shall meet the requirements for certification, training, and/or examination as specified by the individual states.

c. All chiropractic assistants operating chiropractic x-ray units shall meet the requirements for certification, training, and/or examination as specified by the individual states.]
PART B

APPENDIX A

INFORMATION ON RADIATION SHIELDING REQUIRED FOR PLAN REVIEWS

[In order for the Agency to provide an evaluation, technical advice, and official approval on shielding requirements for a radiation installation, the following information must be submitted.]

1. The plans showing, as a minimum, the following:
   (a) The normal location of the system's radiation port; the port's travel and traverse limits; general direction(s) of the useful beam; locations of any windows and doors or other openings; the location of the operator's booth; and the location of the control panel;
   (b) The structural composition and thickness or lead equivalence of all walls, doors, partitions, floor, and ceiling of the room(s) concerned;
   (c) The dimensions of the room(s) concerned;
   (d) The type of occupancy of all adjacent areas inclusive of space above and below the room(s) concerned. If there is an exterior wall, show distance to the closest area(s) where it is likely that individuals may be present;
   (e) The make and model of the equipment, the maximum technique factors, and the energy waveform (single phase, three phase, etc.);
   (f) The type of examination(s) or treatment(s) which will be performed with the equipment.

2. Information on the anticipated workload of the system(s) in mA-minutes per week.

3. A report showing all basic assumptions used in the development of the shielding specifications.]
PART B

APPENDIX B

DESIGN REQUIREMENTS FOR AN OPERATOR'S BOOTH

[1. Space Requirements:

(a) The operator shall be allotted not less than 0.70 m² (7.5 square feet) of unobstructed floor space in the booth;

(b) The operator's booth may be any geometric configuration with no dimension of less than 0.6 m (2 feet);

(c) The space shall be allotted excluding any encumbrance by the x-ray control panel, such as overhang, cables, or other similar encroachments;

(d) The booth shall be located or constructed such that unattenuated direct scatter radiation originating on the examination table or at the wall-mounted image receptor will not reach the operator's position in the booth.

2. Structural Requirements:

(a) The booth walls shall be permanently fixed barriers of at least 2 m (7 feet) high;

(b) When a door or movable panel is used as an integral part of the booth structure, it must have an interlock which will prevent an exposure when the door or panel is not closed;

(c) Shielding shall be provided to meet the requirements of Part D of these regulations.

3. Radiation Exposure Control Placement:

The radiation exposure control for the system shall be fixed within the booth and:

(a) Shall be at least 1.0 m (40 inches) from any point subject to direct scatter, leakage or primary beam radiation;

(b) Shall allow the operator to use the majority of the available viewing windows.

4. Viewing System Requirements:

(a) Each booth shall have at least one viewing device which will:

(1) Be so placed that the operator can view the patient during any exposure; and
(2) Be so placed that the operator can have full view of any occupant of the room and should be so placed that the operator can view any entry into the room. If any door which allows access to the room cannot be seen from the booth, then outside that door there shall be an "x-ray on" warning sign that will be lighted anytime the rotor of the x-ray tube is activated. Alternatively, an interlock shall be present such that exposures are prevented unless the door is closed.

(b) When the viewing system is a window, the following requirements also apply:

(1) The window shall have a viewing area of at least 0.09 m² (1 square foot);

(2) Regardless of size or shape, at least 0.09 m² (1 square foot) of the window area must be centered no less than 0.6 m (2 feet) from the open edge of the booth and no less than 1.5 m (5.0 feet) from the floor;

(3) The window shall have at least the same lead equivalence as that required in the booth's wall in which it is mounted.

(c) When the viewing system is by mirrors, the mirror(s) shall be so located as to accomplish the general requirements of Appendix B4.(a).

(d) When the viewing system is by electronic means:

(1) The camera shall be so located as to accomplish the general requirements of Appendix B4.(a); and

(2) There shall be an alternate viewing system as a backup for the primary system.]
RADIATION SAFETY OFFICER (RSO) REQUIREMENTS

1. All RSOs shall meet the following general requirements in addition to requirements in specific categories, except for industrial radiography RSOs:

(a) Knowledge of potential radiation hazards and emergency precautions; and

(b) Completed educational courses related to ionizing radiation safety or a radiation safety officer course; or

(c) Experience in the use and familiarity of the type of equipment used.

2. Specific requirements for RSOs by facility are as follows.

(a) Healing arts facilities shall have:

(1) Licensed practitioner RSOs with documentation of licensing board number; or

(2) Non-practitioner RSOs with the following:

(A) Evidence of a state license in medical radiologic technology and at least two years of supervised use of radiation machines;

(B) Evidence of registry by the American Registry of Radiologic Technologists (ARRT) and at least two years of supervised use of radiation machines;

(C) Evidence of associate degree in radiologic technology, health physics, or nuclear technology, and at least two years of supervised use of radiation machines;

(D) Evidence of registration with the Board of Nurse Examiners as a Registered Nurse or a Registered Nurse with an extended scope of practice (Nurse Practitioner) performing radiologic procedures, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(E) Evidence of registration with the State Board of Physician Assistant Examiners, and at least two years of supervised use of radiation machines in the respective practitioners' specialty;

(F) Evidence of:
(-a-) License/registration with the State Board of Medical Examiners performing radiologic procedures under a physician's instruction and direction;

(-b-) License/registration with the State Board of Chiropractic Examiners performing radiologic procedures under a chiropractor's instruction and direction; or

(-c-) License/registration with the State Board of Podiatry Examiners performing radiologic procedures under a podiatrist's instruction and direction;

(-d-) License/registration with the State Board of Dental Examiners performing radiologic procedures under a dentist's instruction and direction; and

(-e-) At least four years of supervised use of radiation machines in the respective practitioners' specialty;

(-f-) Evidence of bachelor's (or higher) degree in a natural or physical science, health physics, radiological science, nuclear medicine, or nuclear engineering; or

(-g-) For radiotherapy facilities, evidence of a current state license in medical physics or board certification in health or medical physics and in accordance with Part G or X, as applicable;

(b) Academic institutions and/or research and development facilities shall have RSOs who are faculty or staff members in radiation protection, radiation engineering, or related disciplines. (This individual may also serve as the RSO over the healing arts section of the facility.)]
[APPENDIX D]

RESPONSIBILITIES OF RADIATION SAFETY OFFICERS (RSO)

Specific duties of the RSO include, but are not limited to, the following:

1. Establishing and overseeing operating and safety procedures that maintain radiation exposures as low as reasonably achievable (ALARA), and to review them regularly to ensure that the procedures are current and conform with this chapter;

2. Ensuring that individual monitoring devices are properly used by occupationally-exposed personnel, that records are kept of the monitoring results, and that timely notifications are made as required by Part D;

3. Investigating and reporting to the agency each known or suspected case of radiation exposure to an individual or radiation level detected in excess of limits established by this chapter and each theft or loss of source(s) of radiation, determining the cause, and taking steps to prevent its recurrence;

4. Having a thorough knowledge of management policies and administrative procedures of the registrant and keeping management informed on a periodic basis of the performance of the registrant's radiation protection program, if applicable;

5. Assuming control and having the authority to institute corrective actions including shut-down of operations when necessary in emergency situations or unsafe conditions;

6. Maintaining records as required by this chapter; and

7. Ensuring that personnel are adequately trained and complying with this chapter, the conditions of the certificate of registration, and the operating and safety procedures of the registrant.
[APPENDIX E

MINIMUM EDUCATION AND TRAINING FOR PERSONS PERFORMING RADIATION MACHINE ASSEMBLY, INSTALLATION OR REPAIR

All persons performing radiation machine assembly, installation or repair shall meet the general requirements in subparagraph 1. of this paragraph and one or more of the specialized requirements in subparagraph 2. of this paragraph.

1. General requirements include:

   (a) Experience or education providing familiarity with the type(s) of equipment to be serviced, to include radiation safety;

   (b) Knowledge of protective measures to reduce potentially hazardous conditions; and

   (c) Six months of supervised assembly and repair of the type(s) of equipment to be serviced.

2. Specialized requirements include:

   (a) One year of formal training (may be satisfied by factory school, military technical training school, or other courses in radiation machine assembly, installation or repair techniques) or an associate's degree in biomedical equipment repair;

   (b) A bachelor's degree in electrical engineering with specialized training in radiation producing devices; or

   (c) A combination of training and experience equal to clause (a) of this subparagraph.]
[APPENDIX F

SCREENING

Information to be submitted by persons proposing to conduct healing arts screening. Persons requesting that the agency approve a healing arts screening program shall submit the following information and evaluation.

1. Administrative controls to include the following:

   (a) The name and address of the applicant and, where applicable, the names and addresses of agents within the state;

   (b) The diseases or conditions for which the x-ray examinations are to be used in diagnoses;

   (c) A detailed description of the x-ray examinations proposed in the screening program;

   (d) A description of the population to be examined in the screening program, for example, age, sex, physical condition, and other appropriate information;

   (e) An evaluation of any known alternate methods not involving ionizing radiation that could achieve the goals of the screening program and why these methods are not used instead of the x-ray examination; and

   (f) For mobile screening operations, location(s) where radiation machines are used and maintained.

2. Operating procedures for all x-ray systems (except bone densitometers) to include the following:

   (a) An evaluation of the x-ray systems to be used in the screening program. The evaluation shall be performed by a licensed medical physicist with a specialty in diagnostic radiological physics. The evaluation shall show that such systems do satisfy all requirements of this section;

   (b) A description of the diagnostic imaging quality control program; and

   (c) A copy of the technique chart for the x-ray examination procedures to be used.

3. Operating procedures for bone densitometers to include the manufacturer's evaluation of the system to be used in the screening program. The evaluation shall show that such systems satisfy all requirements of this section.

4. Training data to include the following:

   (a) The qualifications of each individual who will be operating the x-ray systems;
(b) The qualifications of the individual who will be supervising the operators of the x-ray systems. The extent of supervision and the method of work performance evaluation shall be specified; and

(c) The name and address of the practitioner licensed in the state who will interpret the radiographs.

5. Records to include the following:

(a) A description of the procedures to be used in advising the individuals screened, and their private practitioners of the healing arts, of the results of the screening procedure and any further medical needs indicated; and

(b) A description of the procedures for the retention or disposition of the radiographs and other records pertaining to the x-ray examinations.]