

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

^{*/} 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.
- c. Medical physicists for mammography shall meet the requirements specified by the Mammography Quality Standards Act of 1992, Public Law 102-539, 42 U.S.C. 263b, and 21 C.F.R. Part 900.
- 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 m^2 (1 square foot);
 - (2) Regardless of size or shape, at least 0.09 m^2 (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.]

[APPENDIX C]**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.]

**2009
RATIONALE FOR REVISIONS**

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

Introduction

The option of licensure versus registration of radiation machine facilities and services has been added to reflect current authority in some states. Qualifications for health physicists, medical physicists, radiologic technologists, and nuclear medicine technologists have been added to Part B to facilitate recognition of professions related to diagnostic imaging as well as to fusion imaging. Additional appendices have been added to provide states with procedures relative to radiation safety officer (RSO) requirements, responsibilities of RSOs, minimum education and training for persons performing radiation machine assembly, installation or repair, and screening. In addition, the use of brackets indicates optional use by state radiation programs.

Specific Provisions

Title of Part B

The title has been changed to reflect the inclusion of associated healthcare professions in Part B.

Section B.1 – Purpose and Scope

This section was updated for the inclusion of associated healthcare professions.

Section B.3- Prohibitions

This new section was added to include language to prohibit use of unregistered or unlicensed services.

Section B.4 – Exemptions

This was previously Section B.3. Additional language was added to clarify radiation machines in transit or storage in the new Section B.4b.

B.4c. was updated to include video display terminals.

Section B.4d. and e. were added to include clarification on inoperable radiation machines and on financial institutions taking possession of radiation machines, respectively.

Section B.5 – Shielding Plan Review.

This was previously Section B.4. Health physics and medical physics services were added since they are an essential component of assurance in radiation protection.

Section B.6 – Registration [Licensure] of Radiation Machine Facilities.

This was previously Section B.5. This section was updated by adding the designation of a radiation safety officer and a practitioner on the registration or licensure application. The identification of these professionals and their qualifications has an impact on health and safety in radiation facilities.

Section B.7 – Registration [Licensure] of Mobile Service Operations.

This is a new section reflecting requirements for mobile service operations. This is included to place focus on the fact that mobile service operations must meet certain requirements in order to ensure appropriate assessment of services rendered. Mobile service operations today routinely cross over state borders. Components of mobile service operations can also be in different jurisdictions.

Section B.8 – Registration [Licensure] of Healing Arts Screening and Medical Research.

This is a new section reflecting requirements for healing arts screening and medical research. This has become increasingly important with the utilization of CTs for today's screening programs (e.g., lung cancer screening and whole body screening for cardiac pathology).

Section B.9 – Registration [Licensure] of Servicing and Services.

This was previously Section B.6. Section B.9c.v. was deleted since the information is not necessary on the application. Section B.9d.v. was added to include provider of the equipment.

Section B.10 – Issuance of Notice of Registration [Licensure]

This was previously Section B.7.

Section B.11 – Expiration of Notice of Registration [Licensure].

This was previously Section B.8.

Section B.12 – Renewal of Notice of Registration [Licensure].

This was previously Section B.9.

Section B.13 – Report of Changes.

This was previously Section B.10.

Section B.14 – Approval Not Implied.

This was previously Section B.11.

Section B.15 – Assembler and/or Transfer Obligation.

This was previously Section B.12.

Section B.16 – Reciprocal Recognition of Out-of-State Radiation Machines.

This was previously Section B.13.

Section B.17 – Qualification of Health Physicists and Medical Physicists for Registration [Licensure].

This is a new section in Part B recognizing and specifying the qualifications of health physicists and medical physicists. It is included to ensure that credentialing is specified in the physicist profession in the interest of health and safety for patients, providers, and the general public.

Section B.18 – Qualification of Radiologic Technologists and Nuclear Medicine Technologists.

This is a new section in Part B recognizing and specifying the qualifications of radiologic technologists and nuclear medicine technologists. It is included to ensure that educated and trained allied health professionals are performing their roles in various modalities in diagnostic imaging to include fusion imaging.

Section B.19 – Qualification of Dental Assistants, Dental Hygienists, Veterinary Assistants, and Chiropractic Assistants.

This is a new section in Part B recognizing and specifying the qualifications for dental assistants, dental hygienists, veterinary assistants, and chiropractic assistants. It is included to identify allied health professionals who have a role in the operation and safe utilization of radiation sources.

Appendix C – Radiation Safety Officer (RSO) Requirements

This is a new optional appendix specifying requirements for RSOs. It is included to place focus on the importance of having a knowledgeable person making appropriate decisions in the interest of health and safety of patients, providers, and the general public.

Appendix D – Responsibilities of Radiation Safety Officers (RSO)

This is a new optional appendix specifying the responsibilities of RSOs. This is included to ensure that an RSO recognizes and understands the scope of the area of responsibility when serving as an RSO.

Appendix E – Minimum Education and Training for Persons Performing Radiation Machine Assembly, Installation or Repair

This is a new optional appendix specifying the requisite education and training of persons performing radiation machine assembly, installation or repair. It is included to place focus on the importance of utilizing persons who are specifically trained on these activities. Untrained persons can increase the potential for inappropriate actions which may have consequences on the health and safety of patients, providers, and the general public.

**1995
RATIONALE FOR REVISIONS**

**PART B
REGISTRATION OF RADIATION MACHINE FACILITIES AND SERVICES**

Introduction

Plan review has moved here from Part F. Also the appendices have been given some attention.

Specific Provisions

Sec. B.2 - Definitions.

"Facility" has been modified so that it makes better sense.

A new definition has been added, "Storage." In B.3b. it is stated that machines while in storage are exempt from the requirements of Part B. This word has been subject to a different interpretation by agencies and facility personnel. The Committee agreed that an x-ray machine must be disabled (temporarily) in order to be exempt from registration; otherwise, it became too easy for some facilities to declare a seldom-used x-ray machine "in storage." A seldom-used machine could potentially cause unnecessary exposure to a few patients.

Sec. B.4 - Shielding Plan Review. This entire section has been moved from Part F into Part B and inserted here as B.4. The Committee decided that the administrative nature of this regulation more properly belonged in this Part since it dealt with matters not having to do with x-ray machine performance and use.

Related to plan review, and also inserted here as d., is the requirement for the facility to maintain certain documents and information. These items were moved from F.3 for the same reason.

The rationale for plan review is of course to ensure that adequate and proper shielding is installed before a facility is built. The documents required to be maintained would be necessary to have in order to demonstrate adequacy of such shielding. As the x-ray workload of a facility increases and/or a more powerful machine is installed, a re-evaluation of shielding may be desired.

Sec. B.5 through B.13. Every section was moved up one to account for the insertion of plan review as B.4.

Appendix A was updated. The plans should include the energy waveform of the x-ray equipment as well as the maximum techniques, make, and model. Energy waveform would influence the average energy of the radiation and thus the shielding specifications could be impacted.

Item 2 of Appendix A was changed so that the workload is specifically described in terms of mA-minutes per week, since those are the units that NCRP 49 uses in determining shielding.

The reference to a qualified expert was deleted from item 3 since the "basic assumptions" would be required no matter where the specifications came from.

Appendix B was also updated. Metric equivalents were rounded off to only 2 significant digits, and the English units were placed in parentheses.

In item 1(d) of Appendix B, the word "cassette" was deleted and replaced with a more encompassing phrase, and the word "position" replaced "station," since "position" is used throughout the regulations.

Item 3 of Appendix B was modified with the addition of the word "exposure" to "x-ray control," to match the definition change for that term in F.2. In 3.a, a problem was pointed out with the old requirement in that simply requiring 40 inches from the edge of the booth wall would be inadequate protection for an operator exposed to scatter (from a patient on the table or at a wall cassette holder) that came into the booth at an angle. Therefore, the language was changed to match the intent here: to place the exposure switch at a point 40 inches away from the scatter line. This may mean for certain booth and room layouts that the x-ray exposure switch must be fixed in place much more than 40 inches away from the open edge of the booth wall.

In item 4.(a)(2) of Appendix B, an option for placing a warning light outside the door was added. This in fact is common practice and interlocks are rarely seen in diagnostic x-ray room doors. The benefit of interlocks would be far outweighed by the cost.

In item 4.(b)(2) of Appendix B, the old 18 inch requirement between the edge of the booth wall and the distal edge of the viewing window was deleted and replaced by the new one. Many facilities have very large windows with control panels and exposure switches properly placed so that the operator can only make the exposure from the protected position. Technically, however, these facilities did not comply with the old 18 inch standard since the window extended all the way to the edge of the booth. Clearly, this problem had to be resolved. Currently, all that is necessary is that at least part of the window (1 sq ft) be in the specified position. Indeed, if one wants to install only the minimal size window (1 sq ft), then that small window must be placed as specified to ensure that the operator can use it properly from the protected area. Otherwise, the facility is free to install a large window as is sometimes done with lead impregnated plastic in computed tomography facilities, and compliance is still achieved.

Item 4.(b)(3) was updated to allow for a very common situation where a facility installed the proper amount of shielding for the viewing window, but happened to have over-shielding in the booth wall itself. Therefore, the facility was non-compliant because the window was less than the wall, although both were adequate. The regulation now requires simply that the window be at least of the same lead equivalence.

Matters for Future Consideration

At this time there are no Matters for Future Consideration.

**1988
Rationale for Revisions**

**Part B
Registration of Radiation Machine Facilities [and Services]**

Introduction

There are no amendments to Part B for this edition of Volume I (Ionizing Radiation) of the Suggested State Regulations for Control of Radiation (SSRCR). However, it is suggested that high priority be given to a thorough re-examination of Part B for the next revision of the SSRCR.

The Part B Working Group sent a request to the state radiation control programs for comments on and suggested changes to Part B, and received a number of responses. The comments and suggested changes received were considered by the Working Group and selected comments were further evaluated by the SSRCR Technical Review Committee (TRC). For those selected comments that were presented to the TRC, an Analysis of Comments document has been prepared or they are included below in the Matters for Future Consideration (MFC). Other proposals discussed by the TRC are also included in the MFC.

Matters for Future Consideration

1. A recommendation was made to add a Section B.13 on Inspection of Radiation Machines and Facilities.
2. A recommendation was made to exempt inoperable radiation machines with definitive criteria for such exemption.
3. The SSRCR TRC recommends that the issue of preregistration (registration prior to acquisition of the machine) be considered for the next edition of the SSRCR.
4. It was suggested that the 2 working days notice in Section B.12 for out-of-state radiation machines be changed to 3 working days for consistency with NARM in Paragraph C.90(b).

**1982
Rationale for Revisions**

**Part B
Registration of Radiation Machine Facilities [and Services]**

Specific Provisions

B.3(a) Exemptions. The SI unit of microsievert is added. This is self-explanatory and does not change the dose rate.

B.5(c)(4) and (5) Application for Registration of Servicing and Services. Subparagraph B.5(c)(4) and (5) are added: (4) the type of measurement instrument to be used, frequency of calibration, and source of calibration; and (5) the type of personnel dosimeters supplied, frequency of reading, and replacement or exchange schedule. This addition requires the registrant of services to provide more technical information and that properly calibrated instruments and personnel dosimeters are used.

B.7 Expiration of Notice of Registration. The term "on the date" has been changed to read "in the month and year" to clarify the date.

B.12(a)(4) Out-of-State Radiation Machines. A new subparagraph (4) is added, "States in which this machine is registered." This will assure the State that a machine is registered with some regulatory authority. It can also eliminate extra work if another State has already evaluated the health and safety program of the x-ray user.

Matters for Future Consideration

1. A recommendation was made to add a new section on "Quarterly Reports" between the sections on "Issuance of Notice of Registration" and "Expiration of Notice of Registration" to read as follows:

"Each person registered with the Agency as a supplier of services shall file a report with the Agency within 15 days of the end of each calendar quarter. This report shall contain the following information for the preceding quarter.

- a. Names of licensees or registrants to whom a service was supplied.
- b. Location and date of service.
- c. Nature of service.

1982 Rationale for Part B

- d. If more than one individual is listed on the notice of registration, the name of the individual supplying the service shall be stated for each service supplied."

The proposed section was not included in Part B of the 1982 Edition, but it will be considered by the Part B Working Group during the next revision of the SSRCR.

1978 Rationale for Revisions

Part B Registration of Radiation Machine Facilities [and Services]

Introduction

As Part B of the Suggested State Regulations for Control of Radiation (SSRCR) was thoroughly revised for the 1974 SSRCR, the changes made in this revision were based on comments received plus editorial, format, and other changes made by the Technical Review Committee for clarification and consistency with other Parts of the SSRCR. The general and specific changes from Part B of the 1974 SSRCR and their rationale are as indicated below.

General

The word "person" was changed to "individual" for this revision of Part B in the asterisked footnote to Paragraph B.4(a) in items 1c, 1d, 4 and 6 and in the asterisked footnote to Paragraph B.5(b) in items 4 and 5. The rationale for these changes is based on the definitions for "person" and "individual" in Part A. "Person" is defined in Section A.2 as follows: "means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof, and any legal successor, representative, agent or agency of the foregoing." "Individual" is defined in Section A.2 as follows: "means any human being." Therefore, in the footnote items referred to above, the use of the word "person" gave a much broader meaning than was intended and use of the word "individual" is more accurate terminology.

Specific Provisions

B.2 Definitions. The definition of "facility," as used in Part B, was transferred from paragraph (b) of Section B.1 to a new Section B.2 as more appropriate organization for this provision. As a result of this change, Paragraph B.1(c) of the 1974 SSRCR was recodified as Paragraph B.1(b) in this revision and Sections B.2 - B.11 were recodified to Sections B.3 - B.12.

B.5(a) Application for Registration of Servicing and Services. In paragraph (a) of Section B.5, the term "to an Agency licensee or registrant" was deleted and the term "these regulations" was changed to "Part B" to now read as follows: "[(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 service in this State shall apply for registration of such services with the Agency within 30 days following the effective date of Part B or thereafter prior to furnishing or offering to furnish any such services.]"

The rationale for the one change is to help clarify that the requirement to apply for registration to provide

services is not limited to those services offered to an Agency licensee or registrant (e.g., certain electronic equipment is exempt from registration but the servicing of this equipment should not necessarily be exempted from registration). The change from "these regulations" to "Part B" is intended to provide for those cases where the registration requirements of this Part may be revised but not the entire regulations.

B.5(c)(2) Application for Registration of Servicing and Services. A new subparagraph (2) was included in paragraph (c) of Section B.5 in this revision to read as follows: "(2) the services for which he is applying for registration; and". The rationale for this change is that an individual should be registered to supply specific services. As a result of this addition, subparagraph (2) of this paragraph was renumbered as subparagraph (3) in this revision.

B.5(e) Application for Registration of Servicing and Services. A new paragraph (e) was included in Section B.5 in this revision to read as follows: "[e] No individual shall perform services which are not specifically stated for that individual on the notice of registration issued by the Agency.]" The rationale for this added paragraph is to further clarify the intent of Section B.5, including the new Subparagraph B.5(c)(2), and to help assure that the registered individual is limited to providing those services for which he is qualified.

B.12(a) Out-of-State Radiation Machines. The format of this paragraph was changed by dividing it into two subparagraphs and by including indented subdivisions in subparagraph (1) for greater ease of reading.

B.12(b) Out-of-State Radiation Machines. The first line of this paragraph was changed from "In addition, the out-of-state person shall" to "The person referred to in Paragraph B.12(a) shall" in order to be more specific and for greater clarity.

Matters for Future Consideration

1. In Subparagraph B.5(d)(2), "calibration of radiation machines or radiation measurement instruments or devices," is included as one of the services for which an application for registration is required. Reference is made to the suggestion for the working groups of Part A and Part I to consider defining the term "calibration" for inclusion in the next revision of the Suggested State Regulations for Control of Radiation (See Matters for Future Consideration in the rationale of Part A and Part I).
2. A recommendation was made to add a new section on Quarterly Reports between the sections on "Issuance of Notice of Registration" and "Expiration of Notice of Registration" to read as follows:

"Each person registered with the Agency as a supplier of services shall file a report with the Agency within 15 days of the end of each calendar quarter. This report shall contain the following information for the preceding quarter."
 - a. Names of licensees or registrants to whom a service was supplied.

- b. Location and date of service.
- c. Nature of service.
- d. If more than one individual is listed on the notice of registration, the name of the individual supplying the service shall be stated for each service supplied."

The proposed section was not included in this Part B, but it was suggested that it be considered by the Part B Working Group during the next revision of the SSRCR.

**1974
Rationale for Revisions**

**Part B
Registration of Radiation Machine Facilities [and Services]***

General Approach

The main features of the revised draft of Part B include the following:

1. Registration is provided for facilities rather than individual tubes in keeping with current practice of many States.
2. Registration is also provided for persons in the business of servicing or offering services relating to x-ray equipment and other radiation-producing equipment. These services include installation and/or servicing, calibration of radiation machines or radiation measurement instruments or devices, radiation protection or health physics surveys or consultations, and personnel dosimetry services.*
3. There is no longer included a grace period for registration of facilities or services after the fact. In other words, 30 days after the regulations are in effect, individuals must register their x-ray facilities or services prior to engaging in their use. This is contrasted with the 15-, 30-, or 60-day grace periods which currently exist in many State regulations. While this goal is optimistic, a number of States may wish to reinstitute a grace period.
4. The registration process in this revised version consists of an applicant submitting a form called "Application for Registration" and the State Agency in turn issuing a "Notice of Registration" if the application is in order. This additional step not contained in previous Council of State Governments Suggested State Regulations for Control of Radiation (SSRCR) is in fact what many States do; however, it has not been spelled out in detail in previous versions.

Specific Provisions

B.1 Purpose and Scope. This Section was revised to reflect the approach of registering radiation machine facilities and services.* The meaning of "facility" is specified here as used in this Part, rather than with the Part A definitions, as "facility" or "facilities" may be used somewhat differently in other Parts of the model regulations. Paragraph (c) was revised to indicate that registrants are subject to applicable provisions of other Parts rather than specifying the Parts in order to allow for flexibility in use of the model regulations by the States.

B.2 Exemptions

- (a) An exemption is provided for the registration and notification requirements for electronic equipment that produces radiation incidental to its operation for other purposes, provided it meets the dose equivalent rate limits specified.
- (b) and (c) Radiation machines while in transit or storage and domestic television receivers are exempted from the requirements of Part B.

B.3 Application for Registration of Radiation Machine Facilities

- (a) This paragraph allows 30 days following the effective date of these regulations for applying for registration, but after this date it is required prior to operation of a radiation machine facility. Information that the State Agency may wish to include on the application form for the facility is included in a footnote.
- (b) An individual to be responsible for radiation protection shall be designated on the application form, but the specific requirements for the individual are not included in the regulations.
- (c) This paragraph places a requirement on the radiation machine facility registrant to allow only registered service persons to install equipment or service his facility.*

B.4 Application for Registration of Servicing and Services*

- (a) The time requirement in paragraph (a) for making application for registration of services is similar to the registration application requirement for the radiation machine facility in Paragraph B.3(a).
- (b) Information that the State Agency may wish to include on the application form for the service person is included in a footnote to this paragraph.
- (c) The person applying for registration under this Part shall specify the training and experience that qualify him to discharge the services rather than just specifying that he is qualified.
- (d) The types of services to which this Section applies are provided in this paragraph, but need not be limited to those listed.

B.5 Issuance of Notice of Registration. This Section is included in order that the registrant will receive an official notification that action has been taken on his application. This also presents a means for issuing instructions to help assure safe radiation protection practices or to impose additional conditions or requirements, at the time of issuance of the Notice of Registration or later, that are deemed appropriate or necessary to minimize danger to public health and safety or property, as provided by Section A.7.

B.6 Expiration of Notice of Registration. This Section states the specific time that a Notice of Registration will expire, but leaves the period of time that a Notice of Registration will be in effect up to the State Agency.

B.7 Renewal of Notice of Registration

- (a) The procedure for filing an application for renewal of the Notice of Registration is the same as that given in Section B.3 or B.4.
- (b) This paragraph provides a means whereby the registrant may keep the existing Notice of Registration in effect until the Agency has taken action on the application for renewal.

B.8 Report of Changes. This Section is intended to provide the Agency with current information on the registrants' facilities or services in order to conduct a timely and effective radiation control program.

B.9 Approval Not Implied. This Section is similar to that in the 1970 SSRCC, and is meant, in part, to prevent the registration process from being used, by implication or otherwise, as an approval of a radiation machine facility or service by the Agency.

B.10 Assembler and/or Transfer Obligation

- (a) This paragraph is aimed at keeping the State Agency informed of any installation, assembly, transfer, sale, lease, loan, or disposal of radiation machines. The relatively short period of time (15 days) for notification is intended to assist the State Agency in keeping its records current so as to provide any necessary follow-ups by the State radiation control personnel. This time period is also consistent with the assembler's reporting requirements of the Federal Diagnostic X-Ray Standard (21 CFR 1020.30(d)). The footnote to this Section suggests a provision whereby the State could use the assembler's report required by 21 CFR 1020.30(d) in place of any other report by the assembler.
- (b) This provision is designed to assure that the manufacture, sale, lease, transfer, loan, assembly or installation of radiation machines or supplies will result in operational equipment that meets the requirements of these regulations.

B.11 Out-of-State Radiation Machines

- (a) This requirement is intended to provide information essential to the Agency for the proper surveillance and control of radiation machines that operate within the State, but are from outside of the State. Written notice is to be given a selected period of time before such machine "is to be used in the State," rather than "before such machine enters the State." The amount of advance notice required before using the machine in the State, on any temporary basis, is left up to the option of the Agency, as indicated by the brackets. Provision is made for obtaining permission to proceed sooner, if the situation warrants.
- (b) The out-of-state radiation machines are limited to 180 calendar days per year of operation within the State on a temporary basis and must comply with the applicable regulations of the Agency.

*It has been suggested that there might be a legal question regarding the registration of persons providing services, unless those persons actually possess the radioactive material or sources of radiation involved. Therefore, an asterisk has been included at the title to Part B with a footnote at the bottom of the page to alert the States to that possibility. If the State's enabling legislation does not provide such authority or the State does not wish to register services, Section B.4 and B.3(c) should be deleted and Paragraph B.1(a) should be revised accordingly.