

Chapter 246-224 WAC
RADIATION PROTECTION—RADIATION MACHINE ASSEMBLY AND REGISTRATION

Last Update: 2/19/19

WAC

246-224-0001	Purpose.
246-224-0010	Definitions, abbreviations, and acronyms.
246-224-0020	Radiation machine facility registration exceptions.
246-224-0040	Registering radiation machine facilities.
246-224-0050	Radiation machine facility registration process.
246-224-0060	Applicability.
246-224-0070	Reporting changes to a radiation machine facility registration.
246-224-0080	Radiation machine facility registration renewal requirements.
246-224-0090	Requirements for closing a radiation machine facility or removing a radiation machine from service.
246-224-0100	X-ray agent responsibilities.
246-224-0110	Temporary use of an out-of-state radiation machine in Washington state.

DISPOSITION OF SECTIONS FORMERLY CODIFIED IN THIS CHAPTER

246-224-001	Purpose and scope. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-001, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-001, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-210, filed 12/8/80; Order 1084, § 402-16-210, filed 1/14/76. Formerly WAC 402-16-010.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.
246-224-0030	Are there any radiation machines within Washington state that do not have to be registered? [Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0030, filed 6/27/02, effective 7/28/02.] Repealed by WSR 19-05-074, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080.
246-224-010	Exemptions. [Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-010, filed 12/27/90, effective 1/31/91; Order 1084, § 402-16-220, filed 1/14/76. Formerly WAC 402-16-100.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.
246-224-020	Application for registration of radiation machine facilities. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-020, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-020, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-16-230, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-230, filed 12/8/80; Order 1084, § 402-16-230, filed 1/14/76. Formerly WAC 402-16-020 and 402-16-040.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.
246-224-030	Issuance of certificate of registration. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-030, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-030, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-16-232, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-232, filed 12/8/80.] Repealed by WSR 94-01-073, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050.
246-224-040	Expiration of registration. [Statutory Authority: RCW 70.98.050. WSR 94-01-073, § 246-224-040, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-040, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-040, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-16-234, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-234, filed 12/8/80.] Repealed by WSR 97-20-101, filed 9/29/97, effective 10/30/97. Statutory Authority: RCW 43.70.040.
246-224-050	Renewal of registration. [Statutory Authority: RCW 70.98.050. WSR 94-01-073, § 246-224-050, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-050, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-050, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-16-238, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-238, filed 12/8/80.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.
246-224-060	Separate locations. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-060, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-060, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-16-240, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-240, filed 12/8/80; Order 1084, § 402-16-240, filed 1/14/76. Formerly WAC 402-16-050.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.
246-224-070	Report of changes. [Statutory Authority: RCW 70.98.050. WSR 94-01-073, § 246-224-070, filed 12/9/93, effective 1/9/94. Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-070, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-070, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order

2026), § 402-16-250, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-250, filed 12/8/80; Order 1084, § 402-16-250, filed 1/14/76. Formerly WAC 402-16-060.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.

- 246-224-080 Approval not implied. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-080, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-080, filed 12/27/90, effective 1/31/91; Order 1084, § 402-16-260, filed 1/14/76. Formerly WAC 402-16-070.] Repealed by WSR 97-20-101, filed 9/29/97, effective 10/30/97. Statutory Authority: RCW 43.70.040.
- 246-224-090 Repair person, assembler, or installer obligation. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-090, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-090, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.080. WSR 83-19-050 (Order 2026), § 402-16-270, filed 9/16/83. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-270, filed 12/8/80; Order 1084, § 402-16-270, filed 1/14/76. Formerly WAC 402-16-090.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.
- 246-224-0120 What happens if I do not register my radiation machine? [Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0120, filed 6/27/02, effective 7/28/02.] Repealed by WSR 19-05-074, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080.
- 246-224-100 Out-of-state radiation machines. [Statutory Authority: RCW 70.98.050 and 70.98.080. WSR 91-15-083 (Order 183), § 246-224-100, filed 7/23/91, effective 8/23/91. Statutory Authority: RCW 43.70.040. WSR 91-02-049 (Order 121), recodified as § 246-224-100, filed 12/27/90, effective 1/31/91. Statutory Authority: RCW 70.98.050. WSR 81-01-011 (Order 1570), § 402-16-280, filed 12/8/80; Order 1084, § 402-16-280, filed 1/14/76. Formerly WAC 402-16-110.] Repealed by WSR 02-14-050, filed 6/27/02, effective 7/28/02. Statutory Authority: RCW 70.98.050 and [70.98.]080.

WAC 246-224-0001 Purpose. The purpose of this chapter is to regulate sources of ionizing radiation as required by RCW 70.98.050 and 70.98.080. This chapter provides for the registration of all radiation machine facilities located in Washington state.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0001, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0001, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0010 Definitions, abbreviations, and acronyms. The definitions, abbreviations, and acronyms in this section and in WAC 246-220-010 apply throughout this chapter unless the context clearly indicates otherwise.

- (1) "Agent" means a person, company, or dealer that sells, leases, transfers, lends, disposes of, assembles, repairs, replaces, or installs radiation machines or components in Washington state.
- (2) "Application" means, for the purpose of this chapter, the business license application or business license renewal application and appropriate addenda used by the BLS of the department of revenue.
- (3) "BLS" means the department of revenue's business licensing service.
- (4) "Department" means the department of health.
- (5) "FDA" means the United States Food and Drug Administration.
- (6) "Radiation" means, for the purposes of this chapter, ionizing radiation, including X-ray, electron beam, and other machine produced particulate radiation.
- (7) "Radiation machine facility" means each separate building, structure, and operation or buildings, structures, and operations designated by one physical address that connect through a walkway or share a common wall, where there is at least one radiation machine installed, manufactured, tested, or used. A vehicle that has one or more radiation machines installed, manufactured, tested, or used is considered a radiation machine facility.

(8) "Registrant" means the owner or controller of the radiation machine who is responsible for the safe operation of the radiation machine.

(9) "Storage" means the status of a radiation machine that is approved by the department as being unable to produce radiation without substantial effort at set-up, reassembly, or reinstallation. A radiation machine is considered in storage if a registrant locks out or disables the radiation machine.

(10) "X-ray system" means an assemblage of components for the controlled production of X-rays. It includes minimally an X-ray high-voltage generator, an X-ray control, a tube housing assembly, a beam-limiting device, and the necessary supporting structures. Additional components which function with the X-ray system are considered integral parts of the system.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0010, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050, 70.98.080 and chapter 19.02 RCW. WSR 13-17-040, § 246-224-0010, filed 8/13/13, effective 9/13/13. Statutory Authority: RCW 19.02.050, 43.20B.020, 43.70.110, 70.98.050, and 70.98.080. WSR 08-09-079, § 246-224-0010, filed 4/16/08, effective 5/17/08. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0010, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0020 Radiation machine facility registration exceptions. A registrant shall register each radiation machine facility with the department. A registrant shall include each radiation machine they own or control in a radiation machine facility registration except if:

(1) The radiation machine produces incidental X-rays with an equivalent dose rate that does not exceed 5 µSv/hr (0.5 mrem/hr) at 5 cm from any accessible equipment surface averaged over an area of 10 square centimeters;

(2) The radiation machine is in transit;

(3) The radiation machine is held for sale or lease by X-ray agents; or

(4) The department allows an exemption in accordance with WAC 246-220-050(1).

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0020, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0020, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0040 Registering radiation machine facilities. (1) A registrant shall register each radiation machine facility even if these facilities are under one administrative control, for example, several satellite clinics operated by one health care institution.

(2) Each radiation machine facility must have a designated contact person.

(3) If a radiation machine is routinely moved between or among separate radiation machine facilities, the registrant shall notify BLS prior to moving the radiation machine, or notify the department at the time shielding plans are submitted for review.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0040, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 19.02.050, 43.20B.020, 43.70.110, 70.98.050, and 70.98.080. WSR 08-09-079, § 246-224-0040, filed 4/16/08, effective 5/17/08. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0040, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0050 Radiation machine facility registration process. (1) A registrant shall register a radiation machine facility with the department through submission of a business license application and appropriate addendum used by BLS no later than fifteen calendar days after initial use unless a shielding plan review is required.

(2) When a radiation machine facility requires a shielding plan review, the registrant shall register with BLS and submit plans to the department for review prior to construction or installation of radiation machines according to WAC 246-225-030 General requirements—Plan review.

(3) Registration is valid for one year from the department approval date, or any other date as may be determined by BLS.

(4) A registrant shall submit registration information and applicable fees identified in WAC 246-254-053 Radiation machine facility fees to BLS in accordance with BLS instructions.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0050, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050, 70.98.080 and chapter 19.02 RCW. WSR 13-17-040, § 246-224-0050, filed 8/13/13, effective 9/13/13. Statutory Authority: RCW 19.02.050, 43.20B.020, 43.70.110, 70.98.050, and 70.98.080. WSR 08-09-079, § 246-224-0050, filed 4/16/08, effective 5/17/08. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0050, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0060 Applicability. A registrant shall:

(1) Comply with this chapter and the requirements under:

- (a) Chapter 246-225 WAC;
- (b) Chapter 246-225A WAC;
- (c) Chapter 246-226 WAC;
- (d) Chapter 246-227 WAC;
- (e) Chapter 246-228 WAC; and
- (f) Chapter 246-229 WAC.

(2) Comply with general radiation protection rules and standards in accordance with:

- (a) Chapter 246-220 WAC;
- (b) Chapter 246-221 WAC; and
- (c) Chapter 246-222 WAC.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0060, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0060, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0070 Reporting changes to a radiation machine facility registration. A registrant shall submit any change to the registration information to BLS and the department within thirty days.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0070, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050, 70.98.080 and chapter 19.02 RCW. WSR 13-17-040, § 246-224-0070, filed 8/13/13, effective 9/13/13. Statutory Authority: RCW 19.02.050, 43.20B.020, 43.70.110, 70.98.050, and 70.98.080. WSR 08-09-079, § 246-224-0070, filed 4/16/08, effective 5/17/08. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0070, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0080 Radiation machine facility registration renewal requirements. (1) A registrant shall renew their registration annually by submitting renewal information and the applicable fees to BLS.

(2) If a registrant does not receive a renewal notice, the registrant shall contact BLS.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0080, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050, 70.98.080 and chapter 19.02 RCW. WSR 13-17-040, § 246-224-0080, filed 8/13/13, effective 9/13/13. Statutory Authority: RCW 19.02.050, 43.20B.020, 43.70.110, 70.98.050, and 70.98.080. WSR 08-09-079, § 246-224-0080, filed 4/16/08, effective 5/17/08. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0080, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0090 Requirements for closing a radiation machine facility or removing a radiation machine from service. (1) A registrant that closes a radiation machine facility or removes a radiation machine from service shall notify the department and BLS within thirty days.

(2) If a radiation machine is disposed of or transferred within Washington state, the registrant shall provide the department the following:

- (a) The name and contact information of the recipient;
- (b) The address of the recipient; and
- (c) The date of the disposal or transfer.

(3) If the radiation machine is to be placed in storage and retained, the registrant shall obtain approval from the department.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0090, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050, 70.98.080 and chapter 19.02 RCW. WSR 13-17-040, § 246-224-0090, filed 8/13/13, effective 9/13/13. Statutory Authority: RCW 19.02.050, 43.20B.020, 43.70.110, 70.98.050, and 70.98.080. WSR 08-09-079, § 246-224-0090, filed 4/16/08, effective 5/17/08. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0090, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0100 X-ray agent responsibilities. (1) Within fifteen calendar days, any agent who sells, leases, transfers, lends, disposes of, assembles, repairs, replaces, or installs radiation machines or components in Washington state shall notify the department of the:

- (a) Recipient's name and radiation machine facility address;
- (b) Manufacturer, model, and serial number of each radiation machine master control; and
- (c) Date of transfer of the radiation machine.

(2) An agent may use the FDA form 2579 or equivalent to meet the notification requirements of subsection (1) of this section.

(3) An agent who installs X-ray systems, controls, or components shall ensure that the radiation machines, accessories, or components, including exposure switch placement, meet the applicable requirements of:

- (a) Chapter 246-225 WAC;
- (b) Chapter 246-225A WAC;
- (c) Chapter 246-226 WAC;
- (d) Chapter 246-227 WAC;
- (e) Chapter 246-228 WAC; and
- (f) Chapter 246-229 WAC.

(4) An agent shall not install or transfer a radiation machine if the registrant does not submit:

- (a) A required plan review according to chapter 246-225, 246-226, or 246-227 WAC; or
- (b) Shielding plan or radiation machine facility design, or both if required.

(5) An agent shall assemble certified X-ray systems according to 21 C.F.R., Sec. 1000 through 1050 (2018) so that manufacturer's specifications and intended performance designs are met.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0100, filed 2/19/19, effective 3/22/19. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR 02-14-050, § 246-224-0100, filed 6/27/02, effective 7/28/02.]

WAC 246-224-0110 Temporary use of an out-of-state radiation machine in Washington state. (1) A registrant shall notify the department at least three business days prior to in-state use when bringing a radiation machine into the state for any temporary use. The department may waive the time requirement upon a hardship request by the owner. Notification to the department includes, at a minimum, the:

- (a) Type of radiation machine;
- (b) Nature, duration, and scope of use; and
- (c) Exact location where the radiation machine is to be used.

(2) All radiation machines and assemblies must comply with all applicable regulations.

(3) Any medical or dental use radiation machines within the state must register with the department according to WAC 246-224-0020.

(4) For radiation machines not intended for patient diagnosis and treatment, a registrant shall register the radiation machine if it is used for more than sixty calendar days. Registration is waived if the radiation machine is used for sixty or fewer calendar days per year.

[Statutory Authority: RCW 43.20B.020, 43.70.110, 43.70.250, and 70.98.080. WSR 19-05-074, § 246-224-0110, filed 2/19/19, effective

3/22/19. Statutory Authority: RCW 70.98.050 and [70.98.]080. WSR
02-14-050, § 246-224-0110, filed 6/27/02, effective 7/28/02.]