

Secretary of State

STATEMENT OF NEED AND FISCAL IMPACT

A Notice of Proposed Rulemaking Hearing or a Notice of Proposed Rulemaking accompanies this form.

Oregon Health Authority, Public Health Division

333

Agency and Division
Number

Administrative Rules Chapter

Update Radiation Protection Service's X-ray and radioactive materials program administrative rules

Rule Caption (Not more than 15 words that reasonably identifies the subject matter of the agency's intended action.)

In the Matter of: Amending, repealing and adopting rules in Oregon Administrative Rules chapter 333, divisions 102, 106, 116, 120, 121, and 122 pertaining to Radiation Protection Services (RPS).

Statutory Authority: ORS 453.605 – 453.807 and Oregon Laws 2013, chapter 411

Other Authority: Nuclear Regulatory Commission's (NRC) 10 CFR Parts 20, 30, 36, 39, 40, and 70

Stats. Implemented: ORS 453.605 – 453.807, Oregon Laws 2013, chapter 411

Need for the Rule(s):

The Oregon Health Authority, Public Health Division, Center for Health Protection is proposing to amend, adopt and repeal Oregon Administrative rules relating to the X-ray and radioactive materials programs within the Radiation Protection Services (RPS) section.

The Radioactive Materials Licensing (RML) program is proposing to adopt and amend rules for compatibility with the Nuclear Regulatory Commission's regulations 10 CFR parts 20, 30, 36, 39, 40, and 70 within divisions 102, 120, and 121. The amendments are in reference to updating decommissioning planning definitions and amend rules to comply with federal regulations pertaining to the transfer of a radioactive materials license and update criteria for license termination. Proposed rules will require no changes to the licensee's administrative or operational functions.

The X-ray program is proposing to amend and repeal rules in division 106 relating to the X-ray device operator training rules providing better clarity and eliminating potential conflicts with training requirements set forth by the Oregon Board of Medical Imaging and the Oregon Board of Dentistry. Proposed rules are being amended to better define the definition of supervision relating to the operation of an X-ray device. The amended definition will provide compatibility with the Oregon Board of Imaging's definitions. For persons who's training fall under RPS's authority, amended rules will provide specific requirements necessary for the safe operation of X-ray equipment and eliminate the generality requirements within the current rule. Rules relating to the use of fluoroscopic devices are being moved to be centralized with various fluoroscopic rules within division 106 and are not being amended or repealed.

The X-ray program is also proposing to amend OAR 333-106-0735, Dense Breast Notification directing mammography facilities to issue notifications to patients who have either extreme breast density or heterogeneous breast density tissue. The proposed amended notification statement is designed to provide the layperson with less specific information pertaining to additional screening and diagnostic modalities.

The Tanning program is proposing to amend various rules within division 119. Amended rules require the addition of the Fitzpatrick Skin Type Scale to the definitions and direct the tanning operator to use this process to establish the tanning client's skin type. The amended rules also directs the tanning operator to be responsible for verifying the age of the person using the tanning device and requires all users of tanning devices to present acceptable identification with date of birth to be recorded on the client's card during their initial visit. Additional rules direct the registrant to assure that the "Warning", "Notice to the Public" and "Persons Under Age 18" signs are not covered or obscured and are visible within a public space,

Documents Relied Upon, and where they are available:

Oregon Board of Dentistry:

Oregon Revised Statutes, Chapter 679 and 680. Oregon Administrative Rules Chapter 818.

https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2013ors679.html

https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2013ors680.html; and

http://arcweb.sos.state.or.us/pages/rules/oars_800/oar_818/818_tofc.html

Oregon Board of Medical Imaging:

Oregon Revised Statutes, Chapter 688 and Oregon Administrative Rules Chapter 337, Division 010.

https://www.oregonlegislature.gov/bills_laws/lawsstatutes/2013ors688.html

<http://www.oregon.gov/OBMI/pages/rules.aspx>

Nuclear Regulatory Commission:

10 CFR Parts 20, 30, 36, 39, 40, and 70

<http://www.nrc.gov/reading-rm/doc-collections/cfr/>

Fiscal and Economic Impact:

RPS does not anticipate any impacts to radioactive material licensees or X-ray device registrants by amending OARs for federal compatibility, or relating to X-ray device operator requirements and centrally locating the fluoroscopic rules.

OAR 333-106-0735 will require mammography facilities to distribute amended dense breast notifications to patients, but the rulemaking committee did not feel that a significant impact would occur.

RPS will experience no impact to administrative and operational functions within the licensing, registration and enforcement programs as a result of the proposed rules.

Amended tanning program rules will require that all tanning clients have their identification recorded on the client's information card upon their initial visit, and require tanning warnings to be displayed by the registrant in a conspicuous place with an unobstructed view.

Statement of Cost of Compliance:

1. Impact on state agencies, units of local government and the public (ORS 183.335(2)(b)(E)):

There is no cost of compliance to state agencies, units of local government or the public as a result of the proposed rule changes.

2. Cost of compliance effect on small business (ORS 183.336):

a. Estimate the number of small businesses and types of business and industries with small businesses subject to the rule:

Approximately 97 mammography facilities are subject to the proposed amendment of OAR 333-106-0735, Dense Breast Notification and 445 tanning facilities will be affected from various amendments within division 119.

RPS does not possess the data to determine how many small businesses providing X-ray services or radioactive material facilities will be subject to these rules.

b. Projected reporting, recordkeeping and other administrative activities required for compliance, including costs of professional services:

Mammography facilities will need to revise their dense breast notification forms, but it was determined by the rulemaking committee that the fiscal impact of this requirement would be insignificant.

There will be no additional administrative activities required of RPS's licensees. Tanning registrants shall have additional administrative responsibilities by requiring all tanning clients to present acceptable identification as age of proof and be recorded on the client's record as a result of these proposed rules.

c. Equipment, supplies, labor and increased administration required for compliance:

No additional supplies, labor or administrative oversight will be required for compliance with the proposed rules.

How were small businesses involved in the development of this rule?

The State of Oregon Radiation Advisory Committee and the Dense Breast Notification rulemaking committee have members representing various radioactive material and X-ray industries and effected stakeholders.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

Legacy Health Systems

Oregon State University Radiation Center

Kaiser Permanente

Oregon Health Science University

Oregon State University Radioactive Materials Program

Suns Up Tanning

Oregon Komen

Providence Medical Center

Signature

Printed name

Date

Administrative Rules Unit, Archives Division, Secretary of State, 800 Summer Street NE, Salem, Oregon 97310.

