

Secretary of State
STATEMENT OF NEED AND FISCAL IMPACT
A Notice of Proposed Rulemaking Hearing accompanies this form.

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ARCHIVES DIVISION
SECRETARY OF STATE

Oregon Health Authority, Public Health Division
Agency and Division

333
Administrative Rules Chapter Number

Update Radiation Protection Service's X-ray, tanning 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 and adopting rules in Oregon Administrative Rules chapter 333, divisions 102, 106, 116, 119, 120, 121, and 122 pertaining to Radiation Protection Services (RPS).

Statutory Authority:

ORS 413.042, 431.925 - 431.955 & 453.605 - 453.807 & Oregon Laws 2013, chapter 411

Other Authority:

Nuclear Regulatory Commission's (NRC) 10 CFR Parts 20, 30, 36, 39, 40, & 70

Statutes Implemented:

ORS 431.655, 431.925 - 431.955 & 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 and adopt Oregon Administrative rules relating to the X-ray, tanning 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, 121, and 122. The proposed amendments will update decommissioning planning definitions, 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 adopt rules in division 106 relating to the X-ray device operator training rules to provide better clarity and eliminate potential conflicts with training requirements set forth by the Oregon Board of Medical Imaging and the Oregon Board of Dentistry. Proposed amendments will 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 whose 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 in OAR 333-106-0045, Use of Best Procedures and Equipment, are being moved to OAR 333-106-0205, Activation of Fluoroscopic Tube. These rules are being consolidated within division 106 with other rules relating to fluoroscopic operations.

OAR 333-106-0210 through 333-106-0245, which relates to fluoroscopic operations, will have the term "fluoroscopic" added to each rule title for clarity.

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 direct 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 ensure 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 business and types of businesses 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 radioactive materials 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, tanning and X-ray industries and effected stakeholders.

Administrative Rule Advisory Committee consulted?: Yes

If not, why?:

11-24-2014 5:00 p.m.	Brittany Sande	brittany.a.sande@state.or.us
Last Day (m/d/yyyy) and Time for public comment	Printed Name	Email Address

