



PUBLIC HEALTH DIVISION  
Radiation Protection Services

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Oregon  
**Health**  
Authority

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**INFORMATION BULLETIN 2011-03**

To: Dental X-Ray Machine Registrants

From: David M. Howe, Section Manager  
Radiation Protection Services

**IMPORTANT INFORMATION**

**HAND-HELD DENTAL X-RAY UNIT EXEMPTION  
FOR GENERAL DENTISTRY**

**and**

**DENTAL CARE AT LOCATIONS FOR UNDERSERVED POPULATIONS**

Oregon Administrative Rule (OAR) 333-100-0025(1) allows Radiation Protection Services (RPS) to grant exemptions from its rules as long as the exemption will not result in undue hazards to public health and safety.

**Effective immediately, RPS may grant an exemption to OAR 333-106-0325(9)(b), allowing dental practitioners to use RPS approved hand-held dental X-ray devices for general dentistry purposes, or at dental care locations providing care for underserved populations or in places lacking access to dental services, if the dental services are provided for greater than seven (7) days per year. If an exemption is granted it shall be subject to the "Exemption Conditions" listed below.**

**Dental practitioners are those who prescribe and/or take dental X-rays as permitted by Board of Dentistry Administrative Rule Chapters 679, 680 and 818.**

Background

Based upon "*promoting the health and safety of the people in Oregon by protecting them from unnecessary radiation exposure*" and applying As Low As Reasonably Achievable (ALARA) principals, RPS recently completed an evaluation of hand-held dental X-ray devices for possible broader use.

Current OAR 333-106-0325(9)(b) requires that hand-held dental X-ray devices only be used when it is impractical to transfer a patient to a stationary X-ray installation, per OAR 333-106-0045(3). As such, dental practitioners have only been able to use hand-held dental devices for specialized, non-general dentistry purposes or outreach efforts (less than one week in duration) for underserved patients.

Recently, RPS undertook an evaluation of hand-held dental X-ray devices that included: 1) completing a review, along with select members of the state Radiation Advisory Committee, of hand-held dental X-ray materials submitted by Aribex, a manufacturer of a hand-held dental X-ray device, 2) considering state Radiation Advisory Committee member, Oregon Board of Dentistry, Oregon Dental Association, Oregon Dental Hygienist Association, and manufacturer recommendations, 3) surveying other state regulations and practices, 4) conducting field observations of Oregon hand-held dental device users, 5) and reviewing Conference of Radiation Control Program Director (CRCPD) Suggested State Regulations and Oregon Board of Dentistry rules.

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As a result, RPS has determined that, subject to the conditions itemized below, it is appropriate for hand-held dental X-ray devices to be used for general dentistry purposes and dental care locations for underserved patients or those lacking access to dental services if the dental services are provided for greater than seven (7) days per year, by granting an exemption to OAR 333-106-0325(9)(b).

**Exemption Conditions:**

In order to qualify for the exemption, the following conditions must be met by the registrant:

1. Document that each hand-held device meets design requirements as outlined in OAR 333-106-0325.
2. Complete an RPS "Request for Hand-held Dental Device X-Ray Exemption" [OAR 333-106-0325(9)(b)] form.
3. Register the hand-held unit with RPS.
4. Comply with all dental and hand-held dental device OAR's, including Chapter 333, except those for which the exemption is granted. Note: Division 106 requires that operators shall wear a lead apron and thyroid collar.
5. Ensure each Operator wears dosimetry (whole body and ring) when using a hand-held device. Note: Dosimetry will be required for at least 24 months after receiving exemption approval and dosimetry records shall be provided to RPS staff upon request. If after a review of the data collected for the 24 month period the cumulative dose shows 10% or less than the annual occupational dose limit for each year then the registrant will be notified that dosimetry will not be required.

Current Hand-Held device registrants that have a need for an exemption must complete a "Request for hand-held Dental X-ray Exemption" form by September 1, 2011. **Enforcement of hand-held exemption conditions will begin October 1, 2011.**

Each exemption will be valid through September 30, 2013 which coincides with the next biennial X-ray Machine Validation renewal date. Any exemption must then be renewed at least 30 days before September 30, 2013.

After receipt of a "Request for Hand-held Dental X-ray Exemption" form, RPS shall inform each registrant, in writing, whether the registrant qualifies for the exemption. RPS will annually inspect facilities that use hand-held devices, per OAR 333-100-0060(4).

Be advised that failure to follow the above conditions and OARs may result in revocation of the exemption and/or civil penalties, per Oregon Revised Statutes 453.761 and 453.771. RPS will take enforcement action if a situation presents an imminent threat to patient and/or operator safety.

If you have any questions or concerns, please contact Todd Carpenter, RPS Licensing Manager, at 971-673-0500 or [Todd.S.Carpenter@state.or.us](mailto:Todd.S.Carpenter@state.or.us), or go to [www.oregonhealth.org](http://www.oregonhealth.org)



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**Request for Hand-held Dental X-ray Exemption**  
Oregon Administrative Rule 333-106-0325(9)(b)

Submit this form to: Oregon Health Authority (OHA) – Radiation Protection Services (RPS),  
800 NE Oregon Street, Suite 640, Portland, OR 97232

This “Request for Hand-Held Dental X-ray Exemption” form must be submitted if a hand-held device is to be used for general dentistry purposes or for temporary dental care locations that will be in operation for greater than seven (7) days per year. This form must be completed and approved by RPS, and the hand-held device registered with RPS **before** being used on patients.

**REGISTRANT INFORMATION (Please print clearly):**

Owner’s Name: \_\_\_\_\_

Facility Name: \_\_\_\_\_

Physical Address of Facility: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip: \_\_\_\_\_

Phone Number @ Physical Location: \_\_\_\_\_

Fax Number @ Physical Location: \_\_\_\_\_

Owner’s E-mail Address: \_\_\_\_\_

Do you currently have any X-ray control panels registered with RPS?    Yes            No  
If yes, what is your current Facility ID number? (4 digits found on the validation certificate, upper left corner)

Hours of Operation: \_\_\_\_\_

Device Manufacturer Name/Model/Serial Number of hand-held unit(s) planned to be used:

\_\_\_\_\_  
(Please be advised that not all hand-held dental units are approved for use in Oregon.)

This is a request for an exemption to OAR 333-106-0325(9)(b) which provides, in part, that “Hand-held dental X-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary X-ray installation.” Even if a registrant qualifies for an exemption, the registrant is required to meet all other appropriate Oregon Administrative Rules of Chapter 333. The following is a partial list of the rules that must be met:

1. The unit shall be operated by authorized personnel who have been trained in the operation of the device. (Training documentation must be kept on site and available upon inspection.)
2. The operator of the hand-held unit must wear a protective apron and thyroid collar of 0.25 mm lead equivalent when using the unit.

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3. Only the operator of the hand-held unit and the patient can be in the room during the X-ray exposure.
4. The unit will only be operated in an enclosed room when possible. The unit will not be used for patient examinations in hallways and waiting rooms.
5. Only E/F, F or digitally acquired imaging receptors may be used.
6. Registrants must provide for security and safe storage while the unit is not in use.
7. Each operator shall wear dosimetry (whole body and ring) when using a hand-held device.

Dosimetry will be required for at least 24 months after receiving the exemption approval and dosimetry records shall be provided to RPS staff upon request.

\* RPS will annually inspect facilities that use hand-held devices, per OAR 333-100-0060(4).

Where will the hand-held unit be primarily used (i.e. dental office, temporary clinic, or mobile dental services)?  
 Note: For RPS inspection purposes, indicate the estimated length of time that any temporary clinic or mobile dental service program will be in operation.

\_\_\_\_\_

Where will the hand-held unit(s) be securely stored when not in use?

\_\_\_\_\_  
 \_\_\_\_\_

I have read the rules regarding hand-held dental units and understand that failure to follow the above conditions and OARs may result in actions by RPS including revocation of this exemption and/or civil penalties. Enforcement of hand-held exemption conditions/rules will take effect October 1, 2011. If approved, this exemption will be valid through September 30, 2013 which coincides with the next biennial X-ray Machine Validation renewal date. This exemption must be renewed at least 30 days before September 30, 2013.

\_\_\_\_\_  
 Name (facility owner)

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Signature

**Oregon Health Authority  
 Radiation Protection Services ACTION  
 (for Agency use only)**

After due consideration, the above requested exemption from OAR 333-106-0325(9)(b) is hereby:

Approved     Denied    Reviewer's Signature \_\_\_\_\_    Review Date \_\_\_\_\_

This approval expires on \_\_\_\_\_  
 Date

Reason for denial: \_\_\_\_\_

\_\_\_\_\_  
 Radiation Protection Services Manager

\_\_\_\_\_  
 Date