



PUBLIC HEALTH DIVISION
Radiation Protection Services

John A. Kitzhaber, MD, Governor

Oregon
Health
Authority

800 NE Oregon Street, Suite 640
Portland, OR 97232
Voice 971-673-0490
FAX 971-673-0553
TTY 971-673-0372

September 17, 2013

Dear Registrant;

You have been using an Aribex handheld dental x-ray unit(s) under an exemption from Oregon Radiation Protection Services (RPS) rule OAR 333-106-0045(3) that prohibits use of such devices except in certain circumstances. The exemption, which allows you to use the Aribex unit for general dental use, is now due for renewal.

You have three renewal options which include:

- 1) Apply for an exemption to ultimately allow operators to use the Aribex unit without personal dosimetry and a lead apron with thyroid collar. Conditions: An annual inspection will be conducted until your facility can demonstrate that all operators can use the Aribex unit properly. Inspectors will make sure that each operator is wearing a lead apron with thyroid collar, has documented Aribex training on file, and that dosimetry records show that no operator is exceeding 10% of their annual dose (500 mrem). Once the facility can successfully pass an annual inspection, operators will be exempt from wearing a lead apron with thyroid shield and personal dosimetry. A second annual inspection will be conducted to confirm proper technique is still being used.
- 2) Request, in writing, a variance to OAR 333-106-0325(9) (b) which will allow you to operate the Aribex unit more than 7 days in a year. Conditions: All staff using the Aribex will be required to wear a lead apron with a thyroid collar each time the machine is used. Documented Aribex training for all operators must be current and available. Inspections will be conducted at the current Dental Facility inspection frequency of 3 years.
- 3) No exemption or variance needed because you will limit the use of the Aribex unit to off-site activities for underserved populations or emergency situations totaling seven or fewer days per year. Conditions: All staff using the Aribex will be required to wear a lead apron and a thyroid collar each time the machine is used. Documented Aribex training for all operators must be current and available. Inspections will be conducted at the current Dental Facility inspection frequency of 3 years.

Please indicate on the accompanying "Aribex Exemption 2013" form which option you choose. Return the completed Aribex Exemption 2013 form with your registration payment.

RPS inspection staff will inspect according to your selection of the above options.

For your review, see the attached Information Bulletin 2012-04, dated May 1, 2012 which provides an explanation of the Exemption Conditions for the Aribex-manufactured dental X-ray unit.

Sincerely,

for Richard A. Wendt BS, RTR, FABC
Operations/Emergency Response Manager
(971)-673-0505

Aribex Exemption 2013

Please indicate by checking the appropriate response below which option you elect:

(CHECK ONE)

- 1) Apply for an exemption to ultimately allow operators to use the Aribex unit without personal dosimetry and a lead apron with thyroid collar. Conditions: An annual inspection will be conducted until your facility can demonstrate that all operators can use the Aribex unit properly. Inspectors will make sure that each operator is wearing a lead apron with thyroid collar, has documented Aribex training on file, and that dosimetry records show that no operator is exceeding 10% of their annual dose (500 mrem). Once the facility can successfully pass an annual inspection, operators will be exempt from wearing a lead apron with thyroid shield and personal dosimetry. A second annual inspection will be conducted to confirm proper technique is still being used.
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- 3) No exemption or variance needed because you will limit the use of the Aribex unit to off-site activities for underserved populations, or emergency situations totaling seven or fewer days per year. Condition: All staff using the Aribex will be required to wear a lead apron and a thyroid collar each time the machine is used. Documented Aribex training for all operators must be current and available. Inspections will be conducted at the current Dental Facility inspection frequency of 3 years.

Facility Name: _____

Facility Registration Number: _____

Printed Name of Authorized Agent: _____

Signature of Authorized Agent: _____

Date: _____

BE SURE TO COMPLETE THIS FORM AND RETURN IT WITH YOUR REGISTRATION PAYMENT.

IF YOU FAIL TO MAKE A SELECTION, THE DEFAULT WILL BE THAT YOU ARE OPERATING THE ARIBEX DEVICE UNDER THE TERMS OF THE ORIGINAL EXEMPTION. RPS STAFF WILL INSPECT TO THE TERMS OF THE EXEMPTION.

THE FACILITY WILL BE RESPONSIBLE TO ASSURE THAT STAFF MEETS ALL CONDITIONS SET FORTH IN THE ORIGINAL EXEMPTION.



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May 1, 2012

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INFORMATION BULLETIN 2012-04

To: Dental X-Ray Machine Registrants

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



IMPORTANT INFORMATION

**ARIBEX-Manufactured
HAND-HELD DENTAL X-RAY UNIT**

**REVISED EXEMPTION
FOR GENERAL DENTISTRY
&**

DENTAL CARE AT LOCATIONS FOR UNDERSERVED POPULATIONS

Effective immediately, Radiation Protection Services (RPS) will begin granting new exemption conditions for dental practitioners (e.g. those who prescribe and/or take dental X-rays as permitted by Board of Dentistry Oregon Revised Statute Chapters 679 and 680, and Administrative Rule Chapter 818) who use the Aribex-manufactured hand-held dental X-ray device. By meeting the "Revised Exemption Conditions" listed below, registrant operators will ultimately not be required to wear personal dosimetry and will be exempt from wearing a protective whole body apron and thyroid collar when using the Aribex Hand-held Dental X-Ray Device.

Background

Oregon Administrative Rule (OAR) 333-106-0325(9)(b) requires that hand-held dental X-ray devices only be used (by dental practitioners) when it is impractical to transfer a patient to a stationary X-ray installation per OAR 333-106-0045(3). Dental practitioners are those who prescribe and/or take dental X-rays as permitted by Board of Dentistry Oregon Revised Statute Chapters 679 and 680, and Administrative Rule Chapter 818.

However, as a result of completing a formal evaluation, RPS began granting individual exemptions on July 29, 2011 to allow 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 (7) days per year. Presently, the Aribex hand-held dental X-ray device is the only RPS-approved unit for use in Oregon.

Based upon a more recent RPS review, the July 29, 2011 Aribex exemption conditions have been modified. By adhering to the Revised Exemption Conditions listed below, registrant operators will ultimately not be required to wear personal dosimetry and will be exempt from wearing a protective whole body apron and thyroid collar when using the Aribex Hand-Held Dental X-Ray unit.

Revised Exemption Conditions for Aribex-manufactured hand-held dental X-ray unit:

In order to qualify for the revised exemption, the following conditions must be met by the registrant, including registering the unit with RPS and completing an RPS "Request for Hand-held Dental Device X-Ray Exemption" [OAR 333-106-0325(9)(b)] form. See the Request for Exemption form for a more detailed list.

1. Comply with all dental and hand-held dental device Oregon Administrative Rules (OARs), including Chapter 333, except those for which the exemption is granted.
2. For the first 12 months from the date of first use after the exemption is granted, each operator shall wear a whole body apron and thyroid collar of .25 mm lead equivalent, and personal dosimetry (whole body and ring). [Note: Registrants will receive credit for any time earned from their original exemption toward the 12-month requirement of these Revised Exemption Conditions].
3. RPS shall conduct an annual inspection to confirm proper use of dosimetry and proper use of device by operators. If all operator dosimeter levels are 10% or less than the yearly allowed occupational dose limit [per OAR 333-120-0210(1)(a)], then dosimetry may be discontinued and the operators will be exempted from wearing the whole body apron and thyroid collar.
4. After successfully completing the first annual inspection, the registrant will not be required to renew the exemption, but will be required to post a safety worker safety notice (provided by RPS) regarding proper use of the hand-held device.
5. If, during a second annual inspection, all operators can demonstrate proper use of the device, inspections will revert to RPS' routine inspection cycle (currently once every three years).
6. If, during the second annual inspection, an operator is not demonstrating proper use of the device, the registrant shall be required to have all operators wear dosimetry (whole body and ring) and a whole body apron and thyroid collar as appropriate, and the registrant will be inspected annually until all operators demonstrate proper use of the device.

After receipt of a "Request for Hand-held Dental X-ray Exemption" form (see attached), RPS shall inform each registrant, in writing, whether the registrant qualifies for the exemption.

Be advised that failure to follow the exemption 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, or go to www.healthoregon.org/rps