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INFORMATIONAL BULLETIN 2015-03

To: X-ray Device Facilities and Sales and Service Vendors

From: David M. Howe, Program Director   
Radiation Protection Services (RPS)

Subject: Sales and Service Vendors, Providing X-ray Device Registration Services

The Oregon Health Authority, Public Health Division, Center for Health Protection, Radiation Protection Services (RPS) is committed to protecting the public and workers from unnecessary exposure to ionizing radiation generated from devices and materials. RPS inspects facilities to ensure compliance with Oregon Administrative Rules (OARs).

RPS inspection staff have seen an increase in the number of unregistered X-ray devices being operated in facilities. Selected X-ray device installation vendors are offering to register devices with the State of Oregon as part of their service. This is problematic in that vendors do not have signature authority for the facility and that some vendors do not actually submit the registration application. This puts the facility Registrant in violation of OAR 333-101-0005 and, therefore, subject to possible civil penalty sanctions.

Please be advised that the Registrant (facility owner), versus the vendor, is responsible for completing and submitting a registration application for each X-ray device installed, per OAR 333-101-0005. This does not prohibit vendors from assisting in the registration process, but places the burden with the Registrant to ensure that each X-ray device is registered by completing the application provided by RPS. The Registrant, or appropriate representative of the facility, must sign and date the application to attest that the information on the application is true. The vendor's signature is not valid.

The Registrant is also required to ensure that the vendor providing services is licensed with RPS [per OAR 333-101-0005(5)]. As such, the registration application requires the applicant to furnish the vendor's license number. The X-ray facility should verify the license number prior to the purchase, installation, or servicing of X-ray equipment.

In addition, OAR 333-101-0060 directs the vendor installing the X-ray device to notify RPS by submitting the Report of Assembly, FDA form 2579 (industrial vendors submit notification on their letterhead). This report serves to notify RPS that an installation of an X-ray device occurred.

Use [www.healthoregon.org/rps](http://www.healthoregon.org/rps) to obtain a Registration form. Select the "Forms and Applications" link on the left side of the page, then "X-ray program", followed by "X-ray Machine Registration Request". Please contact Judy Smith, 971-673-0507 or email [Judith.a.smith@state.or.us](mailto:Judith.a.smith@state.or.us) for additional assistance.