



Nevada State Health Division Technical Bulletin



Topic: Illegal Handheld Dental and Veterinary Use X-Ray Units May Present Hazard

Section/Program/Contact: Nevada State Radiation Control Program/Ed Sweeten

Date: February 2012

TO: Health Care Providers and Public/Medical Imaging Providers

It has come to the attention of the Nevada State Radiation Control Program that the U.S. Food and Drug Administration (FDA) is warning dental and veterinary professionals to not purchase or use certain potentially unsafe hand-held dental X-ray units. The X-ray units have been sold under several manufacturer names via the Internet and directly shipped to customers from Southeast Asia.

The FDA through regulations found in Title 21, Code of Federal Regulations (CFR), requires that X-ray producing machines undergo performance testing to make sure they are safe for use and do not cause unnecessary radiation exposure to both the operator and the patient. Approved testing is shown by a required placard visibly mounted on the X-ray unit indicating that 21 CFR requirements have been met.

The X-ray units sold from Southeast Asia directly to customers have not been reviewed by FDA and do not meet FDA radiation safety requirements and are not legal for sale in the United States. The FDA is currently investigating the extent of the problem.

All users of hand-held dental and veterinary X-ray units are asked to verify the presence of required FDA testing placards; ask vendors if the device has been reviewed by FDA and has met their requirements; or e-mail the FDA, Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at DSMICA@FDA.HHS.GOV or at 800-638-2041 or 301-796-7100.

Should you have any further questions, recommendations or suggestions please do not hesitate to contact Ed Sweeten, Supervising Radiation Physicist, at the Nevada State Health Division, Bureau of Health Care Quality and Compliance, Radiation Control Program at esweeten@health.nv.gov or at (702) 486.5280.

For further information on this event please refer to the following websites:

<http://www.infozine.com/news/stories/op/storiesView/sid/50694/>

<http://www.fda.gov/Radiation-EmittingProducts/RadiationSafety/AlertsandNotices/ucm291214.htm>

<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/default.htm>

Signed:

Date: February 15, 2012

A handwritten signature in blue ink that reads "Karen K. Beckley".

Karen K. Beckley, M.S., M.P.A.
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