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DEPARTMENT OF HEALTH AND HUMAN SERVICES

NEVADA DIVISION of PUBLIC and BEHAVIORAL HEALTH

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Administrator

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Chief Medical Officer

INFORMATIONAL NOTICE

DATE: July 24, 2023

TOPIC: Occupational Radiation Exposure at a Dental Facility Exceeds Legal Limit

CONTACT: John Follette, Manager, Radiation Control Program

TO: All Dental and Veterinary Registrants

The Nevada Radiation Control Program (RCP) is issuing this Informational Notice (IN) to alert addresses of an event where the operator of a handheld dental x-ray device received a whole-body radiation exposure in excess of the legal limit of 5 rem. The radiation overexposure appears to be a result of poor manufacturing and is not due to operator error or incorrect handling or wearing of dosimetry. Even though the event occurred in the State of Tennessee, these handled dental x-ray devices were sold over the internet and may be in use in other states. This event emphasizes the importance of operators wearing personnel monitoring devices and protective equipment when taking x-rays.

The handheld EvoCare X-Air device was purchased online by the registrant. Contact information for manufacturer is: 1309 Coffen Avenue, Suite 1200, Sheridan, WY 82801, phone: 509-517-7770, email: info@evocaredevices.com

After being contacted, evocaredevices.com removed the phone number from their website. A domain search for this website indicates that it's serviced/managed/owned by Domains by Proxy. This is a 3rd party group that will present themselves as the service and technical proprietor of a site to mask the information of the actual owner. Information about the actual owner is only released per legal requests. The website zirkey.com lists the exact same physical address as evocaredevices.com and was also set up by Domains by Proxy.

In February 2012, the RCP issued a related technical bulletin regarding illegal handheld dental and veterinary X-ray devices being sold on the internet. The technical bulletin provides guidance on how to ensure medical x-ray devices are approved by the Food and Drug Administration (FDA) and is available on our web site at: https://dpbh.nv.gov/Reg/RPM/dta/TechBulletin/Technical_Bulletins/

All FDA required labels/tags must be in the English language and permanently affixed or inscribed on each product so that they are legible and readily accessible when the X-ray unit is fully assembled for use.

The Certification Label should state: ***"This product complies with 21 CFR 1020.30 – 1020.31"***, ***"This product complies with 21 CFR Subchapter J"*** or other similar language.

The Warning Label must be on the x-ray panel of the unit and state these exact words: ***"This X-ray unit may be dangerous to patient and operator unless safe exposure factors, operating instructions and maintenance schedules***

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are observed." These requirements can be found on the FDA website at: Hand-held Dental X-ray Unit - USFDA Compliance.

Recipients are encouraged to review this IN for applicability to their operations and consider actions, as appropriate, to avoid similar problems. The IN contains no new requirements; therefore, no specific action or written response is required.

For more information, contact the RCP at (775) 687-7550 Monday through Friday between 8:00 AM and 5:00 PM; or email questions to radiationcontrolprogram@health.nv.gov.

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