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AMENDED EXEMPTION TO CALIFORNIA CODE OF REGULATIONS (CCR)

Title 17 (17CCR), Sections 30311(b)(4), 30314(a)(5) and 30314(b)(1)

The California Department of Public Health, Radiologic Health Branch (Department), is issuing this exemption to address the use of Portable Hand-Held X-Ray Systems used in dental and veterinary settings. This exemption supersedes Radiation Safety Advisory 06-01, issued February 24, 2006, and the exemptions issued on August 17, 2010, March 13, 2013 and January 26, 2016. Pursuant to Title 17, California Code of Regulations, §30104, the Department may grant exemptions from the applicable requirements of Title 17 as it determines are authorized by law and will not result in any undue hazard to health, life, or property.

California dentists and the trained staff operating under the supervision of a dentist are hereby granted an exemption from the prohibition listed in 17 CCR 30311(b)(4), which states “Neither the tube housing nor the position indicating device (cone cylinder) shall be hand-held during exposure.” Veterinarians and the trained staff operating under the supervision of a veterinarian are hereby granted an exemption from the prohibitions listed in 17 CCR 30314(a)(5), which states “A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least 6 feet from the animal during all X-ray exposures” and in 17 CCR 30314(b)(1), which states, in part, “The tube housing shall not be held by the operator.” These individuals (dentists, veterinarians, and their trained staff) may operate portable hand-held x-ray systems while this exemption remains in effect.

Compliance with the provisions listed below will be evaluated during inspections conducted by Departmental personnel. This exemption remains in effect provided the following conditions are met:

1. The portable dental X-ray system being used has received FDA approval and is being used in a manner consistent with that approval;
2. A backscatter shield provided by the manufacturer, which provides not less than 0.25 mm lead equivalent, must be permanently affixed in place at all times; the X-ray system may not be used if this component becomes broken or dislodged;

3. Personnel monitoring devices must be worn by all individuals operating portable dental X-ray systems. The personnel monitoring must be evaluated on a monthly basis, and records must be available for review by the Department;
4. All personnel must receive training in the safe use of these X-ray systems; records of training must be available for review by the Department.

Further exemption is made for users of the Dexcowin DX3000, KaVo Nomad Pro2, Aribex Nomad, Aribex Nomad Pro, Nomad Pro2, Aribex Nomad eXaminer, and Nomad 75kV, based on ten years of exposure data from the same or substantially similar Aribex Nomad devices. Users of these portable hand-held X-ray systems are not required to comply with the personnel monitoring requirements found in condition 3. The personnel monitoring requirements may be reevaluated for other units after sufficient historical exposure data has been obtained and submitted, by the manufacturer, to the Department for review.

As with other radiation-producing devices subject to regulation, users must adhere to the Standards for Protection Against Radiation, as specified in 17 CCR 30253. This exemption is subject to review and may be revoked if the registrant does not adhere to the conditions of the exemption. This exemption is valid until rescinded, or until amendments are made to 17 CCR 30311(b)(4), 30314(a)(5), and/or 30314(b)(1).

For the Department of Public Health:

Signature on file

Gonzalo L. Perez, Chief
Radiologic Health Branch