

## SSRCR and the Hand-held X-ray

In this edition we will examine the new *Suggested State Regulations for the Control of Radiation (SSRCR)* for Hand-held x-ray equipment in light of this emerging technology, discussing how this Hand-held distinction for x-ray equipment differs from Mobile, Portable, and Stationary x-ray equipment.

### Hand-Held Recognition

The Conference of Radiation Control Program Directors (CRCPD) recognized the Hand-held class in the updated May 2009 release of SSRCR. This recognition followed a peer review by the: FDA, NRC, EPA, State Radiation Programs, American College of Radiology, American Association of Physicists in Medicine, and American College of Medical Physicists. This update is an acknowledgement that Hand-held x-ray equipment can be both safe and effective when appropriately designed and used.

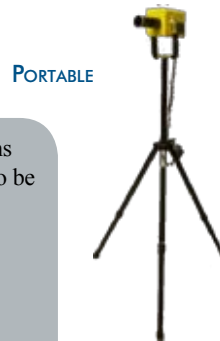
### Designed for All Dental Uses

THE NOMAD was designed to safely and effectively replace Stationary and Portable x-ray devices. Portable x-ray systems were never intended to replace Stationary x-ray systems or be hand-held during an exposure but were to be used when it was impractical to use a Stationary x-ray system.



HAND-HELD

MOBILE



PORTABLE

STATIONARY



*Hand-held x-ray equipment* means x-ray equipment that is designed to be hand-held during operation.

*Portable x-ray equipment* means x-ray equipment designed to be hand-carried.

*Mobile x-ray equipment* means x-ray equipment mounted on a permanent base with wheels and/or casters for moving while completely assembled.

*Stationary x-ray equipment* means x-ray equipment which is installed in a fixed location.

- SSRCR F.2

### Hand-carried Does Not Equate to Hand-held

When the NOMAD Hand-held x-ray device was introduced, existing rules and regulations had provisions for Stationary, Mobile, and Portable x-ray equipment classes. Portable seemed the closest fit for Hand-held since it referred to a "hand-carried"

device. As a result that grouping was often used to address the void presented by the Hand-held device class. While Portable x-ray equipment is designed to be "hand-carried", it is evident in the SSRCR, that Portable x-ray equipment is not intended to be operated in a Hand-held mode.

### Summary

The CRCPD's update of the SSRCR demonstrates recognition of the fact that Hand-held units are a unique x-ray device class, separate from Portable and Mobile. Most states have adopted this view and have welcomed the NOMAD as a way to benefit the public. The updated SSRCR no longer requires the preferential use of Stationary x-ray systems over Hand-held x-ray systems and no longer restrict Hand-held use to special needs populations.



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**PART F**

**F.2 *Hand-held x-ray equipment*** means x-ray equipment that is designed to be hand-held during operation.

**APPENDIX B**

**HAND-HELD INTRAORAL DENTAL  
RADIOGRAPHIC UNIT REQUIREMENTS FOR USE**

The Agency may specify any of, but not be limited to, the following requirements for intraoral dental radiographic units designed to be operated as a hand-held unit:

1. For all uses:

- a) Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.
- b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a lead apron and thyroid collar, unless otherwise authorized by the Agency or a qualified health or medical physicist.
- c) A hand-held intraoral dental radiographic unit shall be held without any motion during a patient examination. A tube stand may be utilized to immobilize a hand-held intraoral dental radiographic unit during patient examination.
- d) Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall be used with a secondary radiation block.
- e) The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held intraoral radiographic unit.

2. Additional requirements for operatories in permanent facilities:

- a) Hand-held intraoral dental radiographic units shall be used for patient examinations in dental operatories that meet the structural shielding requirements specified by the Agency or by a qualified health or medical physicist.
- b) Hand-held intraoral dental radiographic units shall not be used for patient examinations in hallways and waiting rooms.

## NOMAD is “for all uses”

As demonstrated by the SSRCR, the NOMAD Hand-held is intended “for all uses” (Appendix-B 1), across all general oral health care radiographic applications both in and out of the office, forensic uses, and veterinary dental use. Recognizing the benefits from these applications, many states accepted Hand-held use of the NOMAD before the May 2009 release of the SSRCR. Acceptance by these states has been validated by the release of these requirements.

Since rules are often slow to change, adopters used a provision similar to SSRCR A.3a. within their rules that authorizes the agency to take the initiative to grant an exemption, variance, or waiver from the regulations, recognizing that there will always be emerging technologies that the regulations have not yet addressed.



## Portable Restrictions Do Not Apply to NOMAD

### Does not apply to Hand-held X-ray:

Portable or mobile x-ray equipment shall be used only for examinations where it is impractical to transfer the patient(s) to a stationary x-ray installation.

- SSRCR F.3a.ix.(3)

Regulations that restrict the use of Portable and Mobile x-ray devices do not apply to an x-ray device designed to be Hand-held.

Portable and Mobile classes were designed to supplement Stationary x-ray installations in those cases where it was impractical to transport the patient to the x-ray (sedated

patients, emergency exams, etc.). These awkward machines presented their own set of challenges, including the possibility of operator exposure unless shielding or barriers were utilized. To minimize and avoid the issues unique to Portable and Mobile devices, many individual state’s regulations limit the use of Portable and Mobile x-ray equipment to those times where it is impractical to transfer the patient(s) to a Stationary x-ray installation. That requirement does not extend to the NOMAD because the NOMAD Hand-held dental x-ray systems were designed to safely and effectively replace Stationary, wall-mounted systems.

## Meeting the ALARA Expectation

A significant and growing number of studies and evaluations all harmonize in support of the fact that the NOMAD Hand-held x-ray systems are both safe and effective. The F.3a. ix.(3) restriction is not included in SSRCR Appendix B because there is no need for a Stationary preeminence requirement with the NOMAD, the restriction application would become a needless barrier to care without increasing protection. When traditional operators’ dose readings (acquired by the NCRP) are compared to NOMAD operator dose readings and charted against regulatory dose limits, it places NOMAD operator dose into graphic perspective.

### Operator Dosage Perspective



1) SSRCR D.1201a.i.(1) & D.1301a.i. and Standards for Protection Against Radiation, 10 CFR 20 (US Federal Standards for radioactive materials), 1994 (see also NCRP Report No. 116)

2) Conference of Radiation Control Program Directors, Inc., NEWSBRIEF, QA Collectible: Hand-Held Dental X-ray Units August 2010 and preliminary data from a Washington State - Division of Environmental Health study which was adjusted to assume 7,200 exposures per year (Dexcowin @ 1.54 mSv/yr, BioRay @ 2.97 mSv/yr, & Genoray @ 5.76 mSv/yr)

3) NCRP Report No. 160 (National Council on Radiation Protection and Measurements), p211-212

4) Normalized average assumes 7,200 exposures per year, and the average length of exposure for (D-speed = 0.50 seconds & 0.30 mSv/yr, F-speed = 0.25 seconds & 0.12 mSv/yr, digital sensor = 0.20 seconds & 0.12 mSv/yr)

Commenting recently on the NOMAD systems, one state Director of Radiation Control observed: **“There is just no scientific reason not to approve it.”**

## How does the NOMAD stack up to SSRCR?

APPENDIX B	The NOMAD:
<p>1. For all uses: a) Operators of hand-held intraoral dental radiographic units shall be specifically trained to operate such equipment.</p>	<p><i>“The operator’s manual and training documentation including Operator Training CD were reviewed and found to be complete. Positioning instructions, X-ray protection information, operator warnings and qualifying exam were complete.”</i> <b>Evaluation &amp; testing of Nomad Pro Hand-held Intraoral X-ray System – April 2010</b> University of Toronto, Mammographic Physics Consulting Group., G.E. Mawdsley, FCCPM, P. Phys., and M.J. Yaffe, Ph.D., FAAPM</p> <p><i>“Aribex provides an Operator Training compact disc (CD) with every NOMAD Pro™. Considering the outstanding quality of this instructional material, DECS highly encourages the use of this CD and the accompanying exam/certificate to document training within our Air Force clinics.”</i> <b>NOMAD Pro™ Hand-held X-ray System (Project 08-19) – October 2009</b> USAF Dental Evaluation and Consultation Service</p> <p>Contact Aribex regulatory staff to request a copy of this acclaimed training for yourself.</p>
<p>b) When operating a hand-held intraoral dental radiographic unit, operators shall wear a lead apron and thyroid collar, unless otherwise authorized by the Agency or a qualified health or medical physicist.</p>	<p>Unlike conventional x-ray systems, the NOMAD was designed to be handheld without the need for protective apparel. Both agencies and qualified medical and health physicists have confirmed this.</p> <p><i>“Review of the data supplied indicates that shielding of the x-ray tube combined with use of the backscatter shield results in exposure to operators that does not exceed regulatory limits. Since shielding of the NOMAD as designed satisfies section 21.11(e)(2), no variance, protective apron, or 2 meter operator separation is required provided the unit is used and positioned as designed.”</i> <b>Approval letter, Pennsylvania Dept. of Environmental Protection – December 2005</b> - Louis Ray Urciuolo, Chief, Division of Radiation Control</p> <p><i>“...there is little risk of operators receiving a dose above that allowed to the general public, and there is no requirement to wear a protective garment.”</i> <b>Evaluation &amp; Testing of Nomad Pro Hand-held Intraoral X-ray System – April 2010</b> – University of Toronto, Mammographic Physics Consulting Group., G.E. Mawdsley, FCCPM, P. Phys., and M.J. Yaffe, Ph.D., FAAPM</p>
<p>c) A hand-held intraoral dental radiographic unit shall be held steady during a patient examination.</p>	<p><i>“Interestingly, it was difficult to produce a “blurry” image due to movement, suggesting that the Nomad is easy to keep stable, even at 0.5 sec exposures.”</i> <b>Gammasonics Institute for Medical Research - April 2006</b> – Bruce Waters, Senior Radiographer, Westmead Centre for Oral Health, Westmead Hospital, NSW Australia</p> <p><i>“Produced sharp images, even with intentional shaking or moving in CRA tests.”</i> <b>Clinical Research Associates (CRA) Foundation - October, 2006</b> – Clinical Research Associates (CRA) Foundation</p> <p>The NOMAD 0.4mm focal spot and 2.5mA ensures a high quality image.</p>
<p>d) Unless otherwise authorized by the Agency, a hand-held intraoral dental radiographic unit shall only be used with a backscatter radiation shield in place.</p>	<p>Each NOMAD device incorporates a permanently affixed 0.50 mm leaded acrylic backscatter shield. When the device is held next to the patient, the backscatter shield is designed to capture the backscatter radiation, affording the operator with a “Significant Zone of Occupancy” directly behind the device and adjacent to the patient.</p>
<p>e) The operator shall ensure there are no bystanders within a radius of at least six feet from the patient being examined with a hand-held intraoral radiographic unit.</p>	<p>These requirements are consistent with NOMAD training materials and instructions for use.</p>

