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NOMAD UPDATE

A newsletter for the radiation control community.

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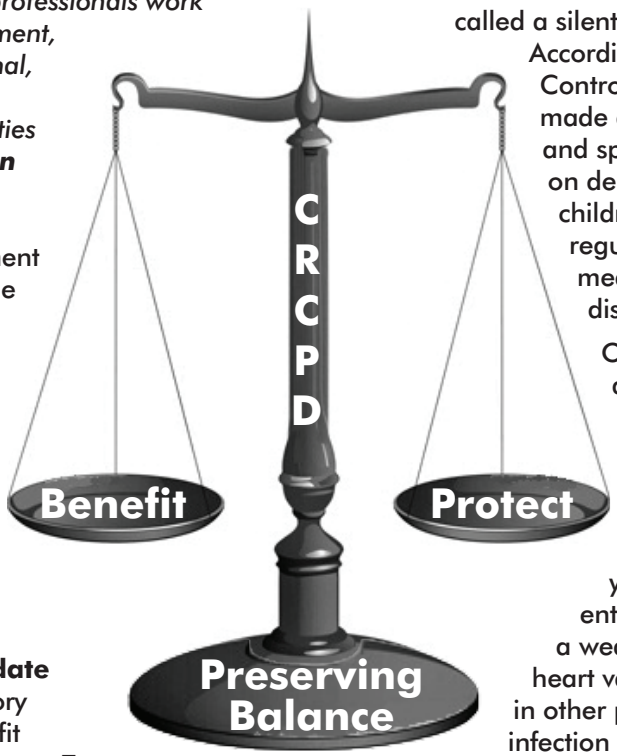
Benefit and Protect

In declaring November 2011 Radiation Safety Month, North Carolina Governor Beverly Eaves Perdue proclaimed, *"radiation protection professionals work throughout North Carolina government, industry, medical, dental, educational, research, law enforcement and emergency management communities* ***to bring the benefits of radiation to the people of our state while minimizing the hazards of radiation exposure****."* That sentiment is echoed in many states and by the Conference of Radiation Control Program Directors (CRCPD) whose published goal is, ***"To keep radiation exposure of the patient, worker, and general public to the lowest practical level, while not restricting the beneficial use of this valuable energy source****."*



In This Edition

In this edition of the **NOMAD Update** we will examine striking a regulatory balance between the goal to benefit patient and the goal to protect citizens. To do so we will briefly observe the consequences of neglecting oral health along with the significance of proper oral health care for overall health and look at how dental x-rays contribute to proper care. We will review some of the common challenges in access to care which includes the ability to obtain diagnostic radiographs. We will visit data that demonstrates how regulations, rules, and restrictions become a barrier to care and how reasonable those restrictions are when considering the intent of the ALARA principle.

Consequences of Neglecting Oral Health Care

According to the staff at the Mayo Clinic, oral health is a window to overall health. A human mouth is teeming with bacteria — most of them harmless. Normally the body's natural defenses and good oral health care, such as daily brushing and flossing, can keep these bacteria under control. However, harmful bacteria can sometimes grow out of control and cause oral infections, such as tooth decay and gum disease.

Cavities and other oral health problems have been called a silent epidemic in the United States. According to the Centers for Disease Control and Prevention, Americans made about 500 million dental visits and spent an estimated $102 billion on dental services in 2009. Yet many children and adults still go without regular dental services and other measures that can prevent oral diseases.

Oral health may affect, be affected by or contribute to various diseases and conditions, including:

- **Endocarditis**. Gum disease and dental procedures that cut your gums may allow bacteria to enter your bloodstream. If you have a weak immune system or a damaged heart valve, this can cause infection in other parts of the body — such as an infection of the inner lining of the heart (endocarditis).
- **Cardiovascular disease**. Some research suggests that heart disease, clogged arteries and stroke may be linked to oral bacteria, possibly due to chronic inflammation from periodontitis — a severe form of gum disease. Patients who have had hip and knee prosthesis are also at risk.
- **Pregnancy and birth**. Gum disease has been linked to premature birth and low birth weight.
- **Diabetes**. Diabetes reduces the body's resistance to infection — putting the gums at risk. In addition, people who have inadequate blood sugar control may develop more-frequent and severe infections of the gums and the bone that holds teeth in place, and they may lose more teeth than do people who have good blood sugar control.
- **HIV/AIDS**. Oral problems, such as painful mucosal lesions, are common in people who have HIV/AIDS.

- **Osteoporosis**. Osteoporosis—which causes bones to become weak and brittle —may be associated with periodontal bone loss and tooth loss.
- **Alzheimer's Disease**. Tooth loss before age 35 may be a risk factor for Alzheimer's disease.
- **Low self-esteem and unemployment**. Visible decay and tooth loss erode self-esteem and can make it difficult to obtain employment.
- **Death**. An untreated abscessed tooth can result in death.
- **Other conditions**. Other conditions that may be linked to oral health include Sjogren's syndrome—an immune system disorder—and eating disorders.

Watch for "**Dental Staff Doses With Handheld Dental Intraoral X-Ray Units**" by **Joel E. Gray**, **Edgar D. Bailey**, and **John B. Ludlow** in the February 2012 edition of the **Health Physics Society Journal**.

How Dental X-rays Contribute to Oral Health Care

Personal preventative oral health remains one of the most cost effective ways to ensure overall health via the practice of good oral hygiene. This is followed closely by a routine dental checkup, cleaning, and X-ray exam, all of which remain an integral part of a complete regular dental checkup.

Dental radiographs are among the most valuable tools a dentist has for keeping a mouth and teeth healthy. X-rays of the teeth, bones, and soft tissues around them help to identify and diagnose problems early, before any symptoms are present and to plan proper treatment of the teeth, mouth, and jaw. Without x-rays, certain dental conditions can and will be missed because they can't be seen solely by visual examination including:

- Tiny pits of tooth decay between the teeth (without X-rays, dentists may miss the early stages of decay between teeth).
- Problems inside a tooth or below the gum line.
- Decay that is developing underneath an existing restoration (filling).
- Cracks or other damage in an existing filling.
- Damage to the bones supporting the teeth and dental injuries.
- Infections in the bone.
- Developmental abnormalities such as the location of permanent teeth growing in the jaw in children who still have their primary (or baby) teeth. Teeth that are not in the right place or do not break through the gum properly, teeth that are too crowded to break through the gums (impacted), and poor tooth and root positions.
- Cancerous and non-cancerous tumors (cysts and solid growths), changes associated with metabolic and systemic diseases (such as Paget's disease and lymphoma), or abscesses
- Possible bone loss associated with periodontal (gum) disease
- Treatment of teeth that are not appropriately aligned (orthodontic treatment).
- Treatment for large or extensive cavities, root canal surgery, placement of dental implants, difficult tooth removals, dentures or other dental work
- Problems in the root canal (infection or death of the nerve)

Often, major problems can be prevented by catching small developing complications early and then making accommodations. Finding and treating dental problems that otherwise would not be seen at an early stage can save time, money and unnecessary discomfort which is why dental x-rays are an essential, preventative, diagnostic tool that provide valuable information not visible during a regular dental exam. Dental x-rays are a recognized standard of care for identifying problem areas which may go undetected during oral examinations.

Dental X-rays Challenges

Dental radiographs, despite being a recognized standard for care, are unfortunately not always possible for a number of reasons such as difficult subjects, cone drift, and patient movement. **Dr. Michelle L. D. Caldier**, DDS of Golden Age Dentistry of Kenmore, Washington shared this insight with Aribex: *"Most of my patients have had numerous health problems over the last few years, and have neglected their dental care during this time. On average, I am the first dentist they have seen in 5 years. Over these last years, their mouth has deteriorated considerably, and recent diagnostic radiographs are critical to determine the best plan of care. Unfortunately, their success rate on my patients was approximately 10% due to the cooperation level and uncontrolled head movements of my patients." However, Dr. Caldier reports that when she "utilized the Nomad hand-held x-ray system, I was able to achieve approximately an 85% success rate in obtaining films from my patients. I could position the film and expose the radiograph within one second, which is critical for my restless patient population. Without this system, I am unable to obtain current diagnostic films on most of my patients."*

Proper dental care for the underserved populations (children, sick, elderly, infirm, physically / mentally challenged, etc.) is particularly challenging because these populations are also the populations which often have multiple barriers to care such as transportation, education, insurance coverage, finances, etc.

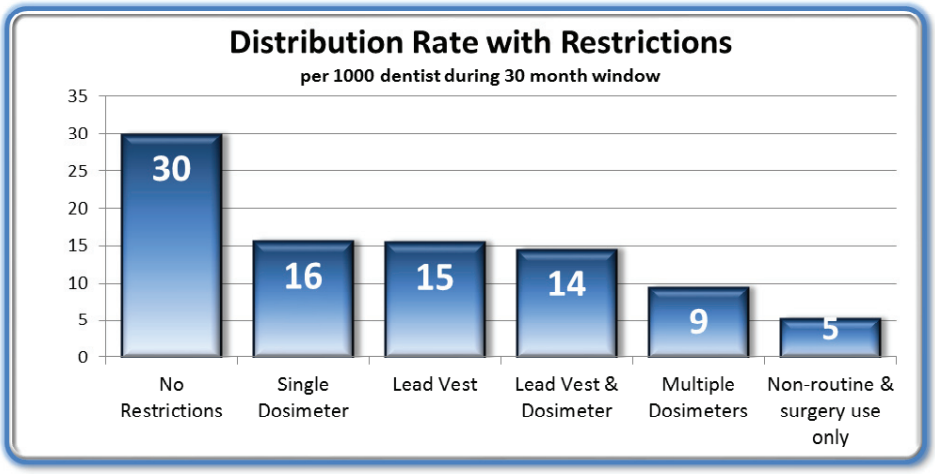
Overcoming those barriers to care is challenging and there is not an overall easy solution. It is particularly troubling when barriers to care are intensified by the severe application of originally well intentioned rules, regulations, and restrictions which have not kept pace with advances in technology and therefore become barriers to care in and of themselves.

How Do Regulatory Restrictions Become A Barrier To Care?

Consider that it is highly unlikely that a general dentistry practice will purchase a NOMAD system (listed at between $6,495.00 and $7,495.00) if handheld use is restricted to a relatively small population such as special needs. This is illustrated by a recent State by State analysis of NOMAD sales to distributors during a 30 month window which found how regulatory restrictions affect the use of the NOMAD. States where there were no restrictions averaged a distribution rate of 30 NOMADs per 1000 dentists. However, where a restriction requiring the use of an operator dosimeter was imposed, the distribution rate was cut nearly in half (likely due to the recurring costs of dosimetry, the additional work associated, and the negative safety messaging of the requirement). Similarly, where protective apparel was required, distribution rates were half that realized in unrestricted States. When multiple dosimeters (whole body and ring) were required, distribution dropped to less than one third the rate of unrestricted States (<10 NOMADs per 1000 dentists). Finally, in the four States where use was restricted to special needs patients, distribution was merely 5 NOMADs per 1000 dentists (less than 17% of what it was realized in the unrestricted States).

Dentists inclined to provide outreach care are far less likely to do so without the proper diagnostic x-ray tools, there is just too much risk to the patient and liability for the caregiver when considering the potenial problems that could go undiagnosed. Each restriction, therefore, becomes an added barrier to care given the corresponding decline in distribution rates.

When dentists don't have access to the needed diagnostic tools (for fidgety children or elderly patients where radiographs are sometimes a challenge) it becomes difficult to provide proper care and it also becomes easier to see how regulatory restrictions can become a barrier to care.



Taxpayer And Patient Economic Benefits

The Nebraska Dental Association (NDA)is assisting on the formation of legislation relating to care within nursing homes in Nebraska. **Dr. Kenneth Hermsen, President of the NDA**, observed, *"If NOMADs were available in that environment, the screening and care of patients could be significantly improved. Traditional x-ray systems are expensive and represent a significant part of the cost of setting up a dental care facility. Here in Nebraska, dental sites have been set up (typically by Rural Health Department Districts) that are used by "traveling" dentists and hygienists that spend a day or two a week at a site. Currently, each site has its own dental x-ray(s) which makes equipping the sites expensive, thus wasting limited rural health department funds and limiting the number of sites [and patients served]. If NOMADs were available, the dentist could bring it with her/him to each site, eliminating the need for fixed x-ray units and significantly reducing the cost of equipping each site. The same could be applied to equipping small dental operatories in nursing homes."*

In The Fun With Numbers Category:

"If an individual worked 250 days/ year [5 days/wk X 50] the Nomad dose would be about 0.0005 mSv/day at 0.12 and 0.0012 mSv/day at 0.3. That is 0.5 - 1.5 µSv / day. Compare that number to daily background of 3 µSv to 8 µSv/day for background (the 8 µSv/day would include Radon exposure).

"Using the 5 mSv as the dose where an occupationally exposed person must wear a monitoring device, then 5 mSv/0.12 = 41.7X lower. At 5 mSv/0.3 = 16.6 X lower, and if you choose the Maximum Permissible Dose for Occupationally exposed persons at 50 mSv/ year then the numbers really pop at 417 to 166 X lower!"

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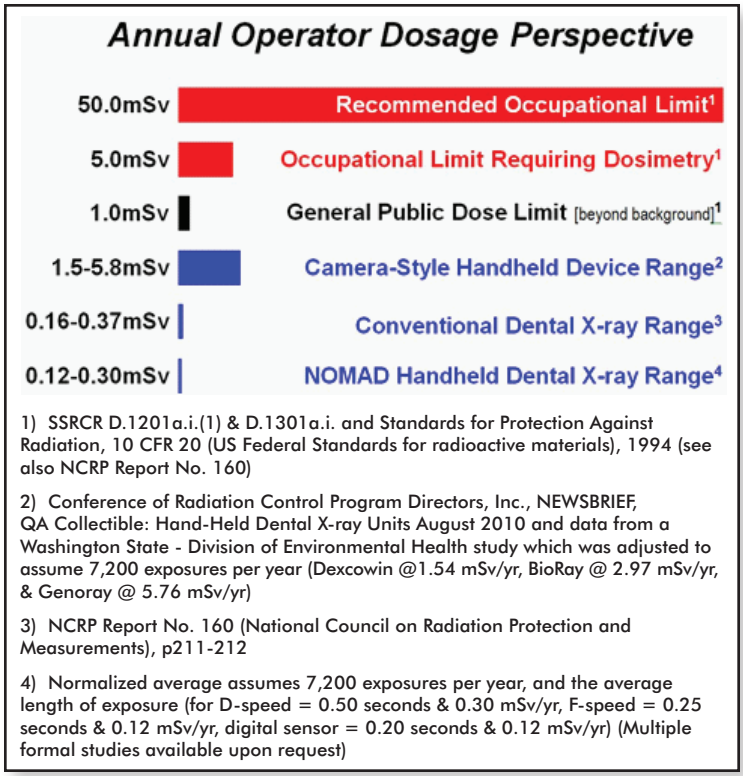
(See the ***Annual Operator Dose Perspective*** chart on page 4)



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. 160)

2) Conference of Radiation Control Program Directors, Inc., NEWSBRIEF, QA Collectible: Hand-Held Dental X-ray Units August 2010 and 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) (Multiple formal studies available upon request)

The ALARA Principle

The ALARA principle is intended to guide protection without denying the diagnostic benefits. This is accomplished by ensuring that the exposure levels remain as low as achievable, while also ensuring that restrictions or requirements remain reasonable and do not become a barrier to the beneficial radiation use. ALARA is not intended as a regulation; consider the following statements from NRCP Report No. 107, Appendix 3.10.

- *"Modern radiation protection practice requires that exposures be kept to levels which are as low as reasonable achievable (ALARA), economic and social factors being taken into account."* P.1
- *"Difficulties arise in attempting to define precisely what is meant by 'low', 'reasonably achievable', and 'optimal'. To facilitate practical implementation, it is necessary to discuss the intentions and meaning of the ALARA recommendation. It is also necessary to avoid inflexible and imperative definitions. Without flexibility, an ALARA recommendation is subtly transformed into a specific limitation which, although possibly easier to regulate, may ultimately defeat the underlying intent of the recommendation."* P.2

"Low" does not mean "0.0 mSv" and is not "reasonably achievable" with any x-ray system. Contrary to what one might expect, even operators using conventional wall-mount x-ray systems can still receive a small amount of radiation exposure. In reporting average annual exposure levels NCRP Report No. 160 P. 211-212 related that from 2003-2006, 9% of dental workers showed recordable doses ranging from 0.16 mSv to 0.37 mSv. While this exposure level is not zero, it is well below regulatory limits, only one-third of the dose limit for the general public, and may realistically be considered as "low" under ALARA.

While initial NOMAD caution by the regulatory community was understandable, it is important to note that over the past six years more than 8,000 units have been place into service with no negative consequences reported. Like the State radiation professionals, Aribex has worked extensively to reduce patient dose and operator exposure as substantiated by *Image Quality and Radiation Dose for Intraoral Radiography: Hand-Held (Nomad), Battery Powered vs. Wall-Mount X-ray Systems*[1]. This study found that the absorbed radiation dose to the NOMAD patient is lower than for the conventional system, and the "*occupational doses are lower with the NOMAD than with conventional intraoral x-ray systems*." That report is amplified by an emerging University of North Carolina, Chapel Hill, School of Dentistry study (*Comparative dosimetry of Nomad Pro handheld and wall-mounted x-ray sources*[2]). This study concludes that the **NOMAD *"patient dose was reduced by 63%"*** when using the NOMAD and ***"operator dose was indistinguishable from background dose."***

When "reasonable" is properly considered there is no scientific foundation for imposing restrictions requiring the dosimetry, protective apparel, or special needs for NOMAD use. Each restriction becomes a barrier to care. The data from all formal studies has demonstrated repeatedly that such restrictions are not necessary and are therefore not "reasonable". In reality, where studies demonstrate a significantly lower patient dose and an operator does that is "*indistinguishable from background dose*" one is almost forced to ask, "*Why aren't NOMADs universally accepted for handheld use as a way to benefit patients and operators?*" NOMAD systems have been well received by dental professionals worldwide in helping *to bring the benefits of radiation to the people … while minimizing the hazards of radiation exposure*.

Reed W. Best
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Quality and Regulatory Manager

1 (Edgar Bailey, M.S.E.H.E., C.H.P., Joel Gray, Ph.D., DIQUAD, LLC, & John Ludlow, D.D.S., School of Dentistry, University of North Carolina, Chapel Hill) presented at the 41st Annual Conference on Radiation Control CRCPD (May 2009)

2 (Phillips BJ, Ludlow JB, Platin E, Mauriello SM)) This study has been accepted for oral presentation by the American Association for Dental Research during their March 2012 annual meeting.