A RADIATION SAFETY ANALYSIS OF THE MaxRay DX-3000

by

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INTRODUCTION

The use of X-ray in dental diagnosis has been around a long time. Historically, X-ray emission devices were mounted to the wall and thus permanently installed in any given room of a dental office. In the past decade or so, hand-held X-ray emission units have been made available and are used in many dental practices throughout the world. These X-ray units are essentially no different that the wall-mounted version, except that they are portable. This portability has given rise to questions of safety for both the patient and the device operator. As with any radiation emission source, if the product is used in a manner that is contrary to that which is intended, dangerous levels of radiation exposure can occur.

From the patient's perspective, little has changed. The wall-mounted and hand-held X-ray units are technologically identical and essentially emit the same array of X-ray photons, with slight variation between units. For the patient, the procedural risk/benefit is the same regardless of X-ray emission technique.

The technologist/operator, however, can be affected in different ways by both units. Regardless of source, an operator who does not take advantage of shielding material (e.g., leaded apron, leaded walls) will experience higher occupational radiation dose. Likewise, an operator who purposefully stands in an area known to have high radiation fields exposes themselves needlessly. The greatest difference between the wall-mounted and hand-held X-ray emission devices is that the operator can leave the room while using the wall-mounted unit, but, by definition, must hold the hand-held emission device during radiography.

Even though the hand-held devices have been engineered for safety, product testing is important for peace of mind and to ensure that levels of radiation exposure are well below those deemed safe for the industry. In this report, we explain the testing that was conducted at Oregon State University on the MaxRay DX-3000 to validate its level of safety for dental radiography.

OBJECTIVES

Two major objectives were embarked upon at the outset of this work. Both objectives focus on the health and safety of the operator, and include:

(1) to measure the radiation exposure around the DX-3000 from leakage radiation;

and

(2) to conduct a detailed analysis of the exposure from scatter radiation, demonstrating the effectiveness of the integrated backscatter shield.

EXPERIMENTAL STUDIES

Our study involved the use of three major instruments: (1) the Radcal Accu-Dose¹ system; (2) the MaxRay DX-3000²; and (3) the NOMAD Pro³. An 8 m² (86 sq. ft.) concrete-block storage room in the Radiation

¹ Radcal Corporation. 426 West Duarte Road. Monrovia, CA 91016

² Iridium Dental. 6824 19th Street. University Place, WA 98466.

³ Aribex, Inc. 11729 Fruehauf Drive. Charlotte, NC 28273.

Center on the Corvallis campus of Oregon State University was used for all measurements. The room is on the small side of a dental exam room. Because of the potential for increased scatter in a small room, we took precautions against wall-scattered radiation during all measurements.

Radcal Accu-Dose exposure instrumentation. To measure the radiation exposure caused by the handheld X-ray units, we used a Radcal Accu-Dose control unit with a 10x6-180 Ion Chamber Sensor. This sensor allowed for high-sensitivity measurements of exposure rate as low as hundredths of micro-Roentgen (μ R) per second. The Radcal had been calibrated four months prior to our use. The 10x6-180 is a 100 cm² parallel plate ion chamber and is ideal for leakage and low-level measurements. The Radcal ion chamber is unsealed and automatic temperature/pressure corrections, as well as background corrections, are made by the control unit. The overall accuracy is reported as +/- 5%.

All measurements were conducted for exposure times of 1 second, and results from the Radcal were provided in terms of either mR/sec or μ R/sec, with the units automatically adjusted depending on rate of exposure. The Radcal provides a lowest single-measurement exposure rate of 0.05 μ R/sec, with smallest increments of 0.05 μ R/sec. Therefore, for very small exposure rates (on the order of 0.05 μ R/sec for some of our leakage measurements), the relative standard deviation of 10 measurements ("uncertainty") could be in excess of 100%. However, once exposure rates were on the order of ~1 μ R/sec, uncertainties drop to less than 5%.

Exposure-to-Dose Calculation. All ionization chamber measurements provide results as exposure or exposure rate, not radiation dose. Exposure is measured in air and radiation dose is typically of importance for human tissue. The two parameters of exposure and tissue dose are closely related, but there is a fundamental difference. In order to estimate tissue dose from exposure, one should multiply the exposure value by 0.95 and then convert units (mR to mrem). For example, an exposure of 1 mR is equal to a tissue dose of 0.95 mrem. Because of this close similarity in numerical value, many times we see the (incorrect) conversion from mR to mrem as one-to-one.

Exposure factors used throughout. For this work, we analyzed two hand-held dental X-ray devices: the MaxRay DX-3000; and the NOMAD Pro. As with the majority of hand-held units, the X-ray tube potential and tube current are fixed and not adjustable by the operator. Both units have a tube potential of 60 kV. The MaxRay has a tube current of 2.0 mA, while the NOMAD has a tube current of 2.5 mA. A simple adjustment of exposure time (e.g., 0.25 seconds for the MaxRay and 0.20 seconds for the NOMAD) results in the same production of X-rays from both units. As stated above, throughout this work, all raw exposure measurements were made for exposure times of 1 second. Any comparisons made thereafter were carried out by scaling of exposure time.

Determination of Significance of Detector Orientation. Before beginning any of our leakage or scatter measurements, we first wanted to check the response of the ion chamber. In order to determine what influence was introduced by chamber orientation to the primary X-ray beam (be it direct or scatter), the following set of experiments were conducted. As seen in the photographs below (Figs 1a-1c), the ion chamber was positioned at a distance of 1 meter from the MaxRay, in the primary X-ray beam. Ten measurements were taken for each of three orientations: perpendicular (Fig 1a); 45 degree (Fig 1b); and parallel (Fig 1c).



Figure 1a. Perpendicular orientation



Figure 1b. 45 degree orientation



Figure 1c. Parallel orientation

Using the perpendicular orientation (Fig 1a) as the standard, experiments showed that the average exposure rate at 1 meter from the MaxRay was 7.27 + -0.012 mR/sec, the variability of 10 measurements being less than 0.2%. An identical result (7.27 + -0.011 mR/sec) was obtained for the 45 degree orientation (Fig 1b). With the X-ray beam striking the ion chamber parallel to its plates (Fig 1c), the exposure rate measurement dropped by 16.5% to 6.07 +/- 0.009 mR/sec.

As expected, the studies indicate that orientation is important, but its influence is only significant past an angle of about 45 degrees, and its greatest significance is shown to result in a reduction of only 16.5%, within the uncertainty of many of the lower-level exposure measurements. Except where space was limited, all studies were conducted with the ion chamber in the perpendicular orientation to the primary source of X-rays.

Testing of wall scatter effects. Two additional experiments were conducted prior to leakage/scatter testing to determine the influence of X-ray room wall scatter. First, a "head-on" approach was assumed in which the ion chamber was placed directly in the X-ray beam, 5 cm from the end of the cone. This configuration was maintained while moving the X-ray unit and detector closer to the wall from 100 cm to 10 cm, in 10 cm increments. The study confirmed (Fig 2a) that the exposure rate in the direct beam is so high (hundreds of mR/sec) that any exposure contribution from wall scatter is insignificant, resulting in a flat line response regardless of distance from the wall.

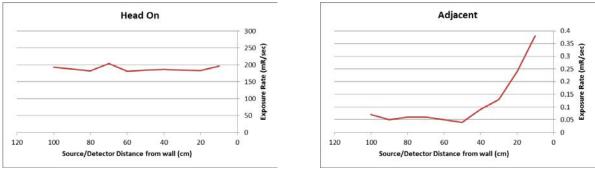


Figure 2. (a) Head on, and (2) adjacent

Second, we again held the source and detector in a constant configuration, but this time the two were directly adjacent to each other both facing the significant scatter wall. The two together were moved closer to the wall from 100 cm to 10 cm, in 10 cm increments. This study suggests (Fig 2b) that the contribution of indirect wall-scatter (tenths of mR/sec) becomes significant once the source and detector are within about 40 cm of the wall surface. We conclude therefore that all experiments should be conducted with at least 40 cm of clearance; our work maintained no less than 1 meter clearance from any wall.

Linearity. As stated above, the exposure factor parameter that is adjustable by the operator is exposure time. This being the case, a simple experiment was conducted on each hand-held unit to determine whether the X-ray output was indeed linear with time. For example, increasing and decreasing exposure time by a factor of 2 should also increase and decrease total exposure by a factor of 2, respectively. In order to test this, we first determine the total exposure (mR) at a given location for an exposure time of 1 second for each X-ray device. All other measurements are then normalized to this exposure. Figures 3a and 3b provide indications of linearity for both devices.

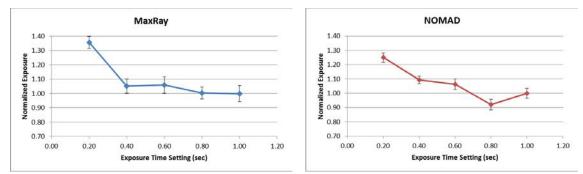


Figure 3. (a) MaxRay, and (b) NOMAD. Error bars show one standard deviation in the collected data.

If the device is completely linear in time, we would expect to see all measurements fall on a normalized exposure of 1.00. Our results show that the MaxRay is quite linear (within +5%) for exposure times from 0.4 to 1.0 seconds, with about a 35% increase in exposure during very short time intervals. The NOMAD is less stable in its linearity, but with variations ranging from about -8% to +25%. The only scaling that is conducted in this work occurs by collected data from the NOMAD with 1 second exposures and then scaling to 0.8 seconds. The potential impact of this scaling appears only when the MaxRay and NOMAD devices are compared for leakage radiation, resulting in a difference of roughly 8%.

LEAKAGE AND SCATTER STUDIES

Presentation of Data. The data that follow are presented as cumulative exposure (mR) in 1 beam hour. One beam hour is considered appropriate for providing a conservative estimate of beam exposure time if a typical exposure is 0.2 seconds and an operator takes 18,000 exposures over the course of the working year. Therefore, the raw exposure measurement (M), collected as exposure during 1 second of beam time (μ R/sec), is converted to an estimate of annual occupational exposure (E), by the following calculation:

$$E\left[\frac{mR}{yr}\right] = \frac{M\left[\frac{\mu R}{sec}\right] * 0.2 \left[\frac{sec}{ex}\right] * 18,000 \left[\frac{ex}{yr}\right]}{1000 \left[\frac{\mu R}{mR}\right]}$$

For example, a measured exposure rate of 2 μ R/sec in the laboratory results in an annual total exposure to the operator of 7.2 mR. It is the value of 7.2 mR that is then presented in the data below. If desired, the annual exposure could then be converted to annual dose by multiplying by 0.95, i.e., 6.8 mrem (in this example).

Leakage Radiation Measurements. Exposure to leakage radiation, the X-rays that escape through the housing and its shielding, is an important safety concern for the operator of any hand-held device. Prior to using similar devices, it is paramount to determine how much leakage radiation exists and if there is potential for significant radiation dose simply by being near the unit as it generates X rays. Our experiments were conducted on the MaxRay DX-3000 to ensure its operational safety, and on the NOMAD Pro, for comparison. We collected ten measurements at thirty different locations around the MaxRay in order to map its leakage radiation exposure field. All measurements were conducted in a way that reduced any potential wall scatter; the judicious use of external lead shielding (Fig 4) ensured that we measured only leakage from the unit.



Figure 4. Experimental arrangement for leakage measurements

As stated above, raw measurements of exposure rate (μ R/sec) were converted to annual occupational exposure estimates (mR) and are presented below in all three dimensions (Figs 5a – 5c) for the MaxRay DX-3000. The representation of exposure is plotted as a bubble (sphere) with its diameter linearly proportional to its numerical value. For all leakage radiation plots, bubbles are drawn relative in size to diameter, e.g., a bubble that is twice the diameter of another bubble represents a leakage exposure that is twice its value. All bubbles have been put on the same scale so that they are comparable.

In an initial examination of all three plots (Figs 5a-5c), we see that the greatest exposure rate for an entire working year is 4.97 mR (i.e., 4.72 mrem to the fingertips of the right hand). This dose is extremely small and is 10,000 times lower than the dose to extremities allowed by the federal government⁴. Looking at Figure 5a, we see that generally exposures are higher above the device and to the right side, and at a distance of 20 cm from the X-ray focal spot, exposures have diminished to less than half a milliRoentgen. Figure 5b indicates similar results, and Figure 5c shows higher leakage toward the front of the device, as expected.

⁴ 10CFR20.1201

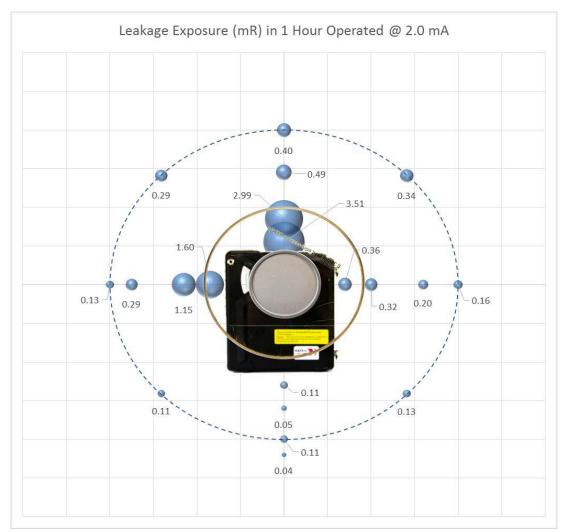


Figure 5a. Front view where the primary beam of X-rays is coming out of the page. Bubbles indicate the magnitude of exposure relative to their diameter.

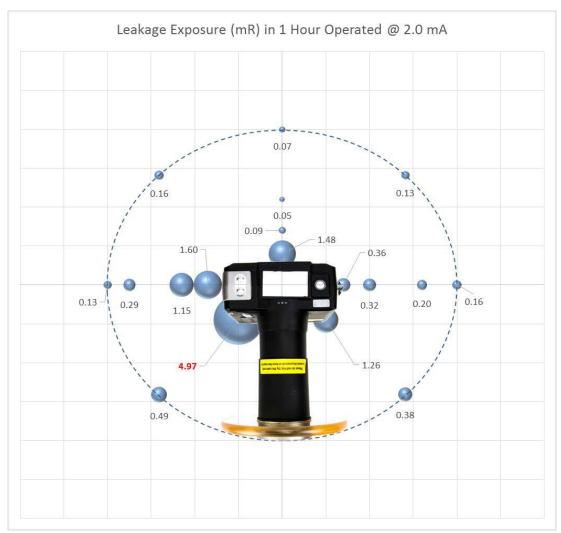


Figure 5b. Top view. Bubbles indicate the magnitude of exposure relative to their diameter.

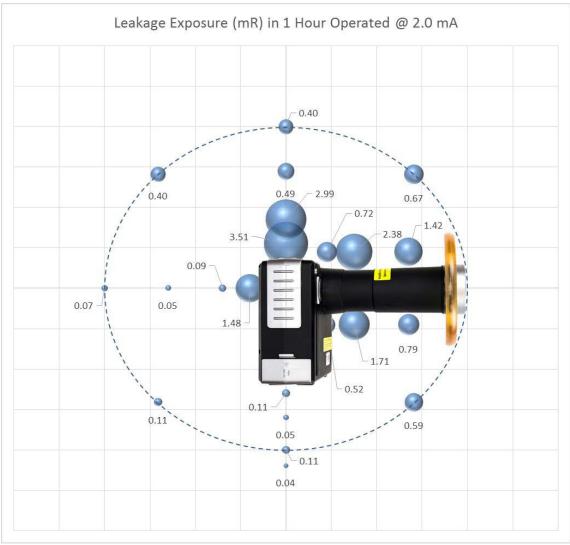
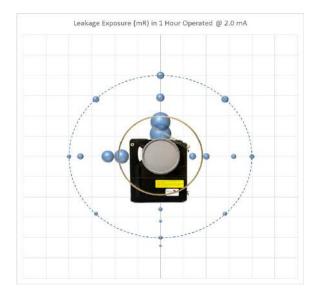
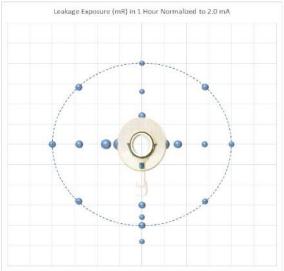


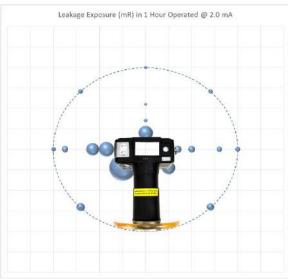
Figure 5c. Side view. Bubbles indicate the magnitude of exposure relative to their diameter.

The set of plots on the next page provides a comparison of the leakage data obtained from the MaxRay DX-3000 and the NOMAD Pro. The bubbles in all plots are sized relative to each other so that a quick examination is possible to determine comparative exposure rates and total annual exposure. Data for the NOMAD indicates general uniformity of leakage all around the device, with some slight tendency to higher exposures along the X-ray emission cone. For the NOMAD, the maximum exposure (3.87 mR) appears along the right side of the cone, in roughly the same location as that found with the MaxRay.

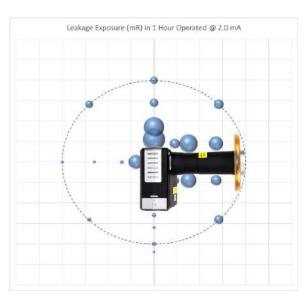
In terms of comparison, there is no difference between annual leakage radiation exposures from operation of the MaxRay and the NOMAD.

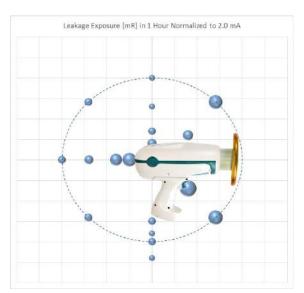












Scatter Radiation Measurements. In terms of dose to the operator, radiation leakage from the device is quite small compared to the amount of radiation scattered off the skull of the patient. This scatter radiation is called "backscatter" in that it is scattered back toward the operator. The MaxRay DX-3000 contains a backscatter shield designed to provide a cone of protection in which the operator stands for maximum radiation shielding. As part of this safety analysis, we collected hundreds of measurements in and around the backscatter shielding zone to assess the effectiveness of the safety design.

In any study where scatter radiation is the central factor, the material from which scatter is assessed is of utmost importance. For example, we are interested in the X-ray field scattering off the skull of a human while obtaining dental radiographs. The most accurate assessment of scatter will be obtained by tests on humans. This obviously isn't possible in the laboratory, therefore we look for the next nearest surrogate. We have chosen to use an alpaca skull (Fig 7a) in water to simulate the human skull with its surface tissue. The modified skull (Fig 7b) was placed inside a plastic bag filled with water and shaped so that about 5 mm of water covered the surface of the bone (approximate cheek thickness).



Figure 7. (a) Original alpaca skull, and (b) the modified skull

The X-ray emission cone from the MaxRay was aimed directly at the alpaca teeth, in one experiment nearly touching the plastic bag, and then 10 cm from the bag surface. The ion chamber was placed at various locations around the backscatter shield to provide an exposure map and delineate the operator's backscatter protection zone. The results are provided in Figures 8 and 9.

Exposure values are again presented as bubbles (spheres) of difference size, but this time the bubbles are relative in size by surface area. Plotting relative to area (proportional by the power of 2) gives the ability to show a greater range of data values on the same plot.

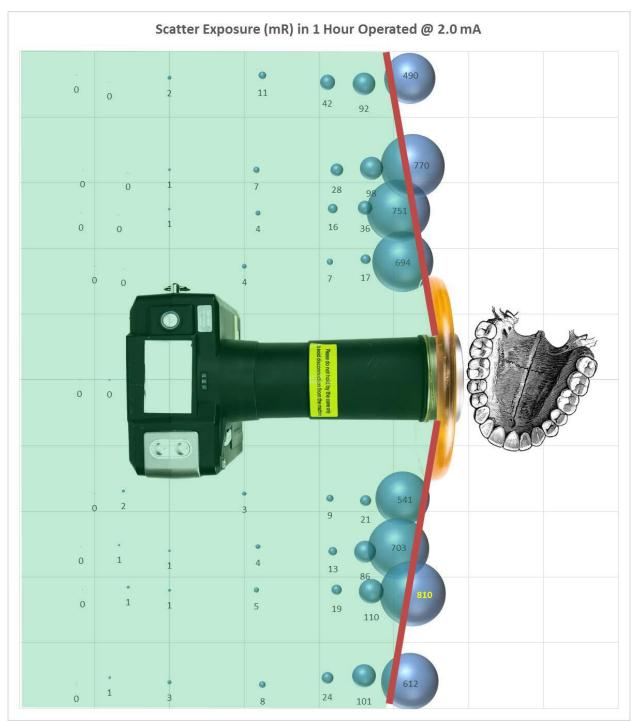


Figure 8a. Top view. Bubbles indicate the magnitude of exposure relative to their surface area.

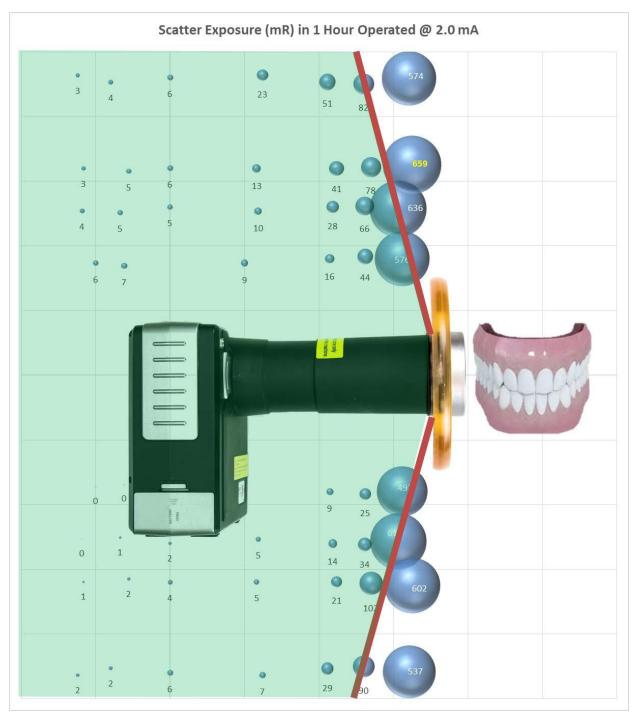


Figure 8b. Side view. Bubbles indicate the magnitude of exposure relative to their surface area.

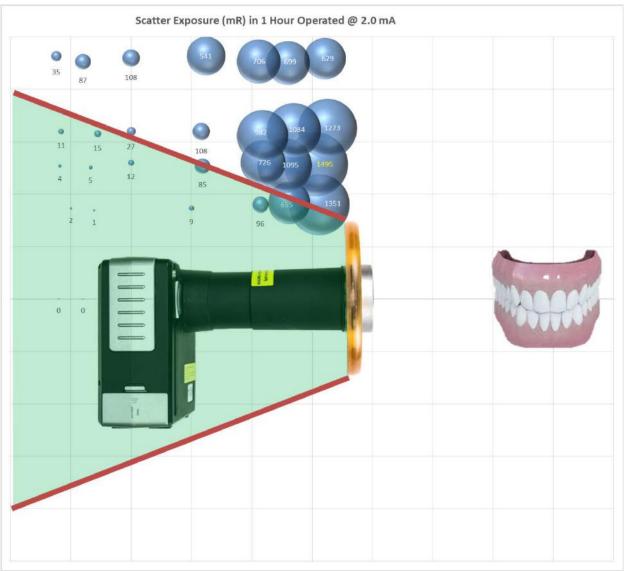


Figure 9. Bubbles indicate the magnitude of exposure relative to their surface area.

Figures 8a (top view) and 8b (side view) show the backscatter field present when the operator places the X-ray cone very close to the patient's face. The backscatter shield does an excellent job of keeping high radiation fields off the operator. The plots show that the annual exposure values are in the hundreds of mR outside the backscatter zone, but that the shielding is quite effective at keeping total annual exposures within the backscatter zone to about 10 mR or less (i.e., < 10 mrem). The federal government maintains an occupational dose limit of 5,000 mrem⁵ to the whole body.

Figure 9 shows what can happen to the backscatter zone when the X-ray cone is moved away from the image receptor. As the gap between the end of the X-ray cone and the patient's face is increased, the backscatter safety zone decreases. Annual exposures in the safety zone are still less than 10 mR, but the zone is smaller, meaning that the operator's head or lower body could be exposed to higher radiation

⁵ 10CFR20.1201

levels. This shows the importance of keeping the Xray cone very close to the patient's face during radiography so as to ensure image quality while maintaining a safe work zone for the operator.

CONCLUSIONS

A safety analysis of the MaxRay DX-3000 has been conducted. The data confirm that the MaxRay is a safe device, is comparable to otherhand-held X-ray units, and has design features that protect the operator keeping their occupational radiation dose to values hundreds of times lower than those stipulated in federal law. Within our current state of knowledge, the unit is deemed safe for the operator when used as intended.

