METHOD TO DETERMINE A REGIONAL DIAGNOSTIC REFERENCE LEVEL FOR INTRAORAL RADIOGRAPHS IN THE STATE OF SANTA CATARINA, BRAZIL

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Abstract—**This study aimed to describe a method for the determination of a Regional Diagnostic Reference Level (RDRL) for intraoral radiographs in the State of Santa Catarina, Brazil. The incident air kerma at the exit of the X-ray tube was measured from 990 intraoral radiographic devices, and Entrance Skin Dose (ESD) was estimated. Bootstrap resampling was applied, with a population mean of 2.87 mGy, producing a sample mean of 2.86 mGy. The RDRL for the incident air kerma rate at the exit of the X-ray tube is approximately 9.9% lower than the value recommended by the current Brazilian legislation. From a general perspective, approximately 89.09% of the equipment analyzed are below 3.5 mGy and only 10.91% are above that. Two RDRLs were established for incident air kerma at the exit of the X-ray tube and another for ESD.**

Keywords— **Regional Diagnostic Reference Level, Kerma, Intraoral Radiograph, Entrance Skin Dose, Dentistry.**

I. INTRODUCTION

Radiographs are a crucial tool for dentists for the diagnosis, planning, follow-up or treatment of lesions. However, no exposure to ionizing radiation can be considered completely risk-free, being the dentist the one responsible for the safety of patients, the public and other professionals involved in the process (1).

ICRP Publication 60 (ICRP, 1991) has issued recommendations for the optimization of medical exposure by adopting values called dose constraints and reference levels (2). In ICRP 73 (ICRP, 1996), the term Diagnostic Reference Levels (DRLs) was introduced, revealing the agency's objective of having a dose value that could reflect a level of reference to identify unjustified exposures (3).

DRLs do not provide a dividing line between good or bad practice, so it is inappropriate to use them as dose limits or restrictions because they are applied only in medical practices and therefore are unsuitable for public and occupational exposures. DRLs are adopted by agencies for good practice recommendations and radiological protection in dental radiology (4).

In DRL determination, values can be derived from national, regional or local data using the third quartile, given that the remaining 25% are derived from exceptional cases that may underestimate dose distributions to estimate DRLs (5). In Brazil, there is neither a national nor a regional DRL in the field of intraoral radiology. As Brazil is a country with a large territorial extension, the determination of a regional level is an excellent practice to aid in dose optimization. In view of that, the present paper aimed to describe in detail the method used to determine a Regional Diagnostic Reference Level (RDRL) for intraoral radiographs in the State of Santa Catarina, Brazil.

II. METHOD

According to the International Atomic Energy Agency (6), DRL estimations should draw on data from a specific type of examination (e.g. for adults or children) or procedure. For example, in the case of chest X-ray examinations for a typical adult patient, the first step is to verify how many tests were performed within a certain time interval and avoid months with atypical movements in order to estimate the sample size. The second step is to verify the technical parameters adopted in the clinical routine – if the work is done by more than one person, the research should be individualized and consider mean values to obtain the data.

In the present case, the sample needs to be representative of the intraoral radiographic procedures practiced in the State of Santa Catarina, Brazil. Therefore, it is necessary to know how many machines are available in the State. In such cases, official sources must be consulted.

Brazil has the National Register of Healthcare Facilities (CNES), which to date counts 2,520 machines available, but only 2,439 in use.

Once the population is known, it is possible to estimate the sample size (n) (7) by adopting the following ratio (1):

$$n = \frac{N \cdot n_0}{N + n_0}, where \quad (1)$$

N is the population size and n_0 is the first approximation of the sample size given by ratio (2):

$$n_0 = \frac{1}{E_0^2}, where \quad (2)$$

E_0 is the tolerable error of the sample.

There is no optimal or recommeded value for E0, therefore it was considered to be the percentage variation

between the existing machines and those in use, according to the CNES database:

$$E_0 = \frac{(2{,}520 - 2{,}439)}{2{,}520} .100$$

$$E_0 = 3.2\ \%$$

Substituting this value into Equation 2:

$$n_0 = \frac{1}{(0.032)^2}$$

$$n_0 = 976.56$$

Finally, Equation 1 was used to calculate the sample:

$$n = \frac{(2{,}439 \times 976.56)}{(2{,}439 + 976.56)}$$

$$n = 697$$

Therefore, the sample estimated for RDRL determination should be at least 697.

The decision of using a specific procedure and examination should be based on clinical and practical criteria. It is necessary to ask the team (physicians, technicians, technologists and biomedical professionals) for information and tips about procedures that need to be evaluated and optimized. It is worth mentioning that keeping the team committed will contribute to greater adherence to the project. One can choose to compare one's results with other reference levels previously established or with provisions of the local legislation.

To adjust the machine to the desired radiographic technique, it is recommended to personally consult the operator in charge, who preferably shall select it on the control panel. One should avoid using lists of techniques attached near the machines, as each technician may have their own particularities, and using online forms or email is not a good option, as one cannot guarantee the origin of the answers, or the provision of further information. If there is automatic exposure control (AEC), then the clinical routine should be followed in order to map the values.

In the present case, a reference value was chosen for an incidence in an upper molar of a typical adult patient. This choice was based on three facts:

- ✓ There are other established reference levels.
- ✓ It is the most usual incidence.
- ✓ In the Brazilian state where this study was carried out, there is a dose limit stipulated by the current legislation.

A peculiarity of intraoral radiography machines is that they have only a fixed voltage value, so in order to obtain the radiograph the operator has to select only the exposure time. There are some machine models with fixed exposure menus, that is, the dentist selects the type of incidence based on the patient's biotype and the equipment suggests the exposure time. In the present study, when the machine had selectable exposure times, the dentist was asked about the value that he/she had selected. In machines with preset menus, the interviewed dentist was asked to indicate which option they used, since the commands do not discriminate the type of incidents, as shown in Figure 1.

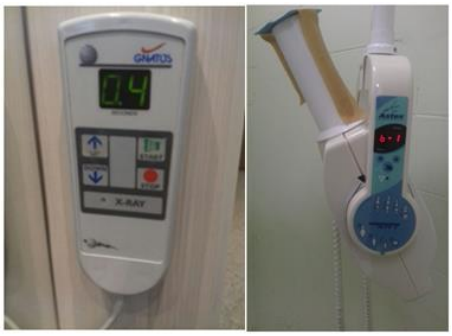

Figure 1: On the left, a Gnatus machine with selectable times. On the right, an Astex machine with a preset menu

Data collection requires that validated standards be followed and that the same experimental arrangement be maintained. For example, if the object of study is mammographic dosimetry, and if the guidelines in the literature indicate that measurements should be taken at 6 cm from the chest wall, at 4.5 cm high from the Buck, and using a compression plate, one should attempt to keep such architecture. The present study adopted the method of the International Atomic Energy Agency (IAEA), described in document TRS 457 (8). This document recommends that kerma values be collected at the exit of the focusing cup. This way, regardless of the machine analyzed, the experimental arrangement adopted was the one shown in Figure 2.

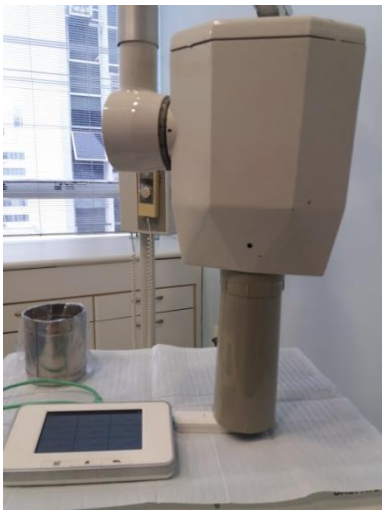

Fig. 2 Experimental arrangement adopted. Solid-state detector positioned at the exit of the X-ray tube.

The readings were taken using these six radiation detectors: Radcal Corporation 9096 with 10X6-6 Ion Chamber sensor; Radcal Corporation Accu Gold with AGMS-D+ sensor; RaySafe X2 with R/F sensor; Electronic Control Concepts, Model 890, Dose Meter; Unfors 407L; and RTI Electronics Piranha. It is of the utmost importance that the machines used for dosimetry be certified with valid calibration.

After the readings in the detector, Equation 2 was adopted to estimate the incident air kerma at the exit of the tube:

$$K_i = \bar{M} N_{K,Q_o} K_Q K_{TP} \pm u_{c,} \text{, where} \qquad (2)$$

$\bar{M}$ is the mean of the readings obtained with the radiation detector, N_{K,Q_o} is the calibration coefficient of the dosimeter, [1]K_{TP} is the correction factor for temperature and pressure and the term u_c is the expanded uncertainty for a confidence interval (K = 2) obtained by Equation 2.

Without this method, there is no way to quantify the reliability of the measured results. In an experiment, there are numerous factors of error, so it is up to the researcher to identify and quantify them. In the present case, data were collected in a real environment and during clinical routine, which made it impossible to control and quantify all the sources, therefore two inevitable errors were considered. One of them is associated with the radiation detector - Type B[2], and the other is associated with fluctuation in the measured values - Type A[3], as shown in Equation 3.

$$u_c = \sqrt{(u_A^2 + u_B^2)} \qquad (3)$$

where u_A is the standard deviation of the mean of the readings from the detector, and u_B is the uncertainty provided in the calibration certificate for the radiation detector (8).

Finally, Entrance Skin Dose (ESD) was estimated using Equation 4, which was adapted from the ARCAL XLIX document, considering the term BSF (backscatter factor) a constant linked to backscattering (9).

$$ESD = K_i \, BSF \qquad (4)$$

where: BSF[4] = 1.2, and K_i is the incident air kerma at the exit of the X-ray tube.

III. RESULTS AND DISCUSSIONS

From January 2016 to December 2018, data were collected from 990 intraoral dental machines – a quantity that is higher than the estimated sample size, so the data are sufficient to determine a regional DRL. However, the collected data do not account for all the machines, so it is necessary to verify if the values for the air kerma rate are representative of the entire population. To do this, the Bootstrap resampling procedure was used, as shown in Table 1. It was observed that there are no significant discrepancies in the means, standard deviations and confidence interval, so the sample of the present case is representative of the entire population.

[1] Some detectors consider the factor according to the reading displayed or require the user to enter the value in the detector's memory.

[2] Methods that do not depend on analyses of series of observations.

[3] Methods involving statistical analyses of series of observations.

[4] Factor by which the patient radiation dose is increased by the dispersed radiation of the body (15).

Sample (n = 990)		Mean	SD	95% Confidence Interval
		2.3903	1,598	2.312 – 2.463
Number of Resampling	10	2.3998	1.337	2.331 - 2.411
	15	2.4001	1.425	2.335 - 2.437
	100	2.3925	1.334	2.316 - 2.461
	325	2.3871	1.335	2.312 - 2.454
	1000	2.3924	1.344	2.316 - 2.458
	6525	2.3888	1.333	2.312 - 2.461
	10000	2.3886	1.339	2.312 - 2.463

Table 1: Resampling

In the first clinic used for data collection, the intraoral radiograph machine was Gnatus Times 70C. The radiation meter RaySafe X2 with R/F sensor was used for collecting the following parameters, as described in Table 2.

Table 2: Values measured in the first case

Tube Voltage (kV)		Exposure time provided by the operator (ms)		Source-detector distance measured (cm)	Detector's output reading (mGy)
Nominal	Measured	Nominal	Measured	Measured	Measured
70	68.3	1000	999.9	20	2.01
	68.2		999.8	20	2.00
	68.2		999.8	20	2.00

The instrument has a valid calibration certificate issued by the LabProSaud Laboratory of the Federal Institute of Education, Science and Technology of Bahia (IFBA), Brazil. The calibration certificate provides that for the voltage and quality range RQR 5 (70 kV), the correction factor is $N_{KV} = 1.00$ with an uncertainty of 1.6%, therefore the voltage must be corrected by adopting Equation 5.

$$KV_c = KV_m \,.\, N_{KV} \qquad (5)$$

where KV_m is the measured value.

To estimate uncertainty, Equation 3 was used, where u_B is 1.6% and u_A is the standard deviation of the measured values for the 6% voltage.

$$u_c = \sqrt{(u_A^2 + u_B^2)}$$

$$u_c = \sqrt{(5.77^2 + 1.6^2)}$$

$$u_c = \sqrt{35.85}$$
$$u_c = 5.98\ \%$$

Therefore, the measured voltage mean is (68.3 ± 4) kV
The same is valid for the other measured values, except for the value of mA since the measurement instruments used do not allow estimating it. For the exposure time in the calibration certificate, the uncertainty provided is 1.9%; since there is no correction factor, only uncertainty must be estimated:

$$u_c = \sqrt{(u_A^2 + u_B^2)}$$

$$u_c = \sqrt{(5.77^2 + 1.9^2)}$$
$$u_c = \sqrt{36.90}$$
$$u_c = 6.07\ \%$$

Therefore, the exposure time mean is 999.8 ± 60.6 ms. The ruler used has a calibration certificate provided by the metrology laboratory of the Foundation Centers of Reference in Innovative Technologies (CERTI) and provides an absolute value, so the source-detector distance mean is 20 cm $\pm$ 0.04.

Table 3 in Appendix A shows, in a simplified way, the measured exposure parameters (kV and exposure time), the nominal mA for each manufacturer and model, the incident air kerma at the exit of the X-ray tube, and the ESD estimation. The voltage mean value was 61.96 ± 3 kV, in that the lowest value was 37.2 ± 2 kV measured by a Gnatus XR 6010 device, and the highest value was 76.4 ± 4 kV measured by a 70X Ion Proton. Regarding exposure times, the mean was 727.22 ± 14.4 ms, with the lowest limit of 60 ± 1.2 ms measured by a Sirona Heliodent Plus high frequency device, and the highest one of 5001.2 ± 100.2 ms measured by a Dabi Atlante Spectro 70X single phase device. The ionization current values described by the manufacturers are between 2 mA to 11 mA with an average of 8 mA, the lowest value being the one measured by a Micro Image Diox 602 and the highest one by a Procion IonX10 device.

Equation 2 was used to obtain the incident air kerma at the exit of the tube, with the calibration factor for RQR 5 (70 kV) being $N_{K,Q_o} = 0.974$, a uncertainty = 1.8%, and K_{TP} = 1:

$$K_i = \bar{M}.N_{K,Q_o}.K_{TP} \pm \sqrt{(u_A^2 + u_B^2)}$$

$$K_i = 2.00\, mGy\, .0.974\, .1\, .\, \pm \sqrt{(1^2 + 1.8^2)}$$

$$K_i = (1.978 \pm\ 0.039\ )mGy$$

The value in Equation 4 was substituted to obtain ESD:

$$ESD = (1.978\ \pm\ 0.039\ )\, mGy\, .1.2$$

$$ESD = (2.374\ \pm 0.047)\, mGy$$

The remaining 889 readings underwent the same procedure taking into account the calibration and uncertainty factors of the relevant radiation detector adopted.

As previously mentioned, the DRL is represented by the values in the third quartile of the sample. The values for the incident air kerma at the exit of the tube ranged from 0.21 ± 0.004 mGy to 21.77 ± 0.43 mGy with the third quartile of 2.84 ± 0.07 mGy, being the lowest value obtained by a digital imaging system and the highest value by an analog one. In the estimation of the ESD that represents the RDRLs for the incident air kerma at the exit of the X-ray tube, the value is approximately 9.9% lower than that recommended by the current legislation in Brazil, as shown in Table 2. Overall, approximately 89.09% of the devices analyzed are below 3.5 mGy and only 10.91% are above that.

For ESD, the range was 0.26 ± 0.005 mGy at 26.13 ± 0.53 mGy with the third quartile of 3.05 ± 0.06 mGy, as shown in Table 2. In the present study, that value was compared with seventeen studies, and in ten of them the values were lower. In NCRP 72 (10) and UKR (11), DRL is approximately 50% of the value stipulated in the present study, and in the 1996 IAEA it is more than double that, as shown in Figure 2 (12,13 and 14).

Table 4: Statistical Analysis

Dosimetric measurement (mGy)	Sample size	Limit Below	Limit Above	Mean	First Quartile (25%)	Third Quartile (75%)
Air Kerma	990	0.21 ±0.004	21.27± 0.43	2.11	1.68	2.84
ESD		0.26 ±0.005	26.13± 0.53	2.52	2.02	3.05

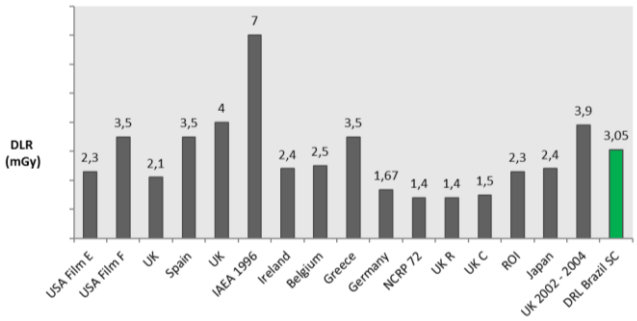

Fig. 2 Comparison between DLRs obtained in Brazil and in other countries.

The State of Santa Catarina, Brazil, has the Normative Resolution No. 002/DIVS/SES (16) which recommends a reference level for air kerma at the entrance of the skin in intraoral procedures. In an upper molar of an adult patient, the reference level is less than or equal to 3.5 mGy for incidences. The mean for the air kerma rate was 2.11 mGy with the third quartile of 2.84 mGy, so the RDRL for the incident air kerma rate at the exit of the X-ray tube is approximately 9.9% lower than the value recommended by the current legislation, as shown in Table 3. Overall, approximately 89.09% of the analyzed devices are below 3.5 mGy and only 10.91% are above this value.

III. CONCLUSIONS

With the method tested, it was possible to establish two Regional Diagnostic Reference Levels (RDRL) for incident air kerma and another for ESD. The data obtained confirmed that patients subjected to intraoral radiography in the State of Santa Catarina, Brazil, will not be exposed to limits above that recommended in the current normative resolution. As Brazil's large territorial extension impedes data collection, this study suggests that each State of the country should establish its own value and gather data to stipulate their own reference level regionally.

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Note from the Editors: The paper is supported with an Appendix A of 24 pages. It includes real data from the practical measurements, described in the paper (see below a sample from Appendix A - Table 3). In case of need the Appendix can be requested directly from the corresponding author.

Appendix A

Table 3: Exposure parameters

Mean of the measurements of tube voltage (kV)	mA nominal	Mean of the measurements of the exposure time (ms)	Mean of the measurements of the source-detector distance measured (cm)	Mean of the measurements of the detector's output reading (mGy)	ESD (mGy)
68.2	8	998.9	20	2.00	2.40
48	10	835	18	2.42	2.90
70	8	500	20	1.46	1.75

……. Etc.