

Implementation of a radiation protection framework for medical and dental x-ray diagnostic services in Minas Gerais/Brazil

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Abstract -The Brazilian Sanitary Vigilance Agency is the regulatory authority for radiation protection and quality control of all practices with x-rays for diagnostic purpose. In 1998, the technical regulation “Guidelines for Radiation Protection in Medical and Dental Radiodiagnostic” was issued by the government that reflected the most updated policy recommended by the International Basic Safety Standards for Protection against Ionizing Radiation. To accomplish the objective of improving radiation protection conditions in the state of Minas Gerais, the Development Centre of Nuclear Technology (CDTN) and the Superintendence of Sanitary Vigilance (SVS) signed a formal cooperation agreement that included: an accreditation process for radiation protection professionals, a follow-up program of the services provided by those professionals, technical support from CDTN for audits carried out by SVS and training of SVS inspectors. Actions to improve and assure metrological reliability of the radiation measurements and special attention to mammography services were done. This paper provides details and results of the radiation protection framework for x-ray radiodiagnostic services in Minas Gerais; the success of the adopted model suggests that it can be used as a basic model to other regions.

1. Introduction

Among all activities with man-made radiation sources, the medical and dental practices that use x-ray for diagnostic purpose are responsible for more than 80% of radiation doses given to the people. Although the useful benefits of those practices to the man, harmful effects should be considered as a probability due to the radiation exposure. A radiation protection framework and an image quality assurance program are basic requirements to maximize the benefits of radiation exposures and to avoid unnecessary doses without affecting the quality of the image to be used for diagnostic.

The Brazilian Sanitary Vigilance Agency (ANVISA) under the Brazilian Ministry of Health is the regulatory authority for assuring the radiation protection and the good quality of all practices with x-rays for diagnostic purpose. Nowadays, the ANVISA follows the national technical regulation “Directives for Radiation Protection in Medical and Dental Radiodiagnostic” [1] that was issued in 1998; in that time, such standard reflected the most updated policy as far as it was internationally recommended [2-4]

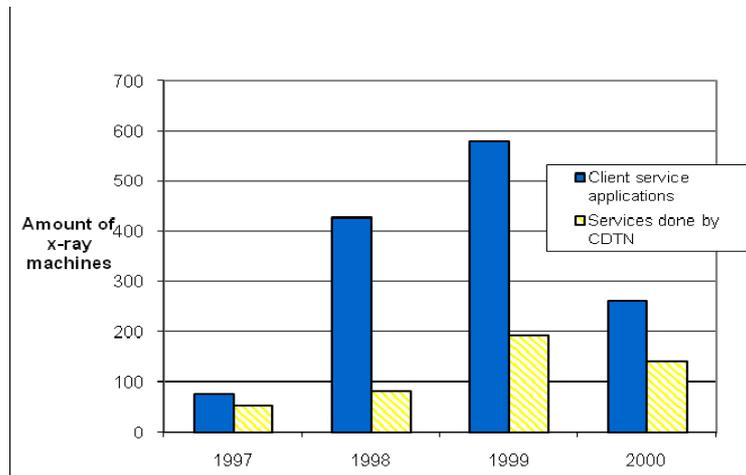
In the Brazilian state of Minas Gerais, the Superintendence for Sanitary Vigilance (SVS/MG) of the State Secretary for Health, decided to enforce the new regulation by requiring radiometric surveys and quality checks to all about 6200 institutions and clinics that offer x-ray diagnostic services. Operation

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authorization to any institution would be only provided if it showed a valid evaluation report as far as radiation protection and quality tests of the x-ray machines.

The Development Center for Nuclear Technology (CDTN) of the National Commission of Nuclear Energy used to carry out area dose-rate surveys and evaluate the performance of diagnostic x-ray machines as a routine service. The enforcement adopted by the SVS/MG caused a high increase in the demand for evaluating radiodiagnostic services that could not be fulfilled by CDTN (Fig. 1).

Figure 1 - Trend in the demand for evaluating radiodiagnostic services in comparison to the CDTN capability.



In order to overcome the demand problem and to accomplish the objective of improving radiation protection conditions in Minas Gerais, the CDTN and the SVS/MG signed a formal co-operation agreement that included: an accreditation process for radiation protection professionals, a follow-up program of the services provided by those professionals, training of SVS/MG inspectors and technical support of CDTN to SVS for audits to be carried out by SVS/MG [5,6].

To assure metrological reliability of the radiation measurements, the CDTN has fostered the implementation of the calibration procedure of radiodiagnostic dosimetric equipments in the CDTN Dosimeter Calibration Laboratory (LCD/CDTN). X-ray machines and standard dosimeters were acquired and reference x-ray radiations were reproduced in LCD/CDTN with the support of the International Atomic Energy Agency, the Brazilian Research Sponsors (FINEP, CNPQ and FAPEMIG) and the Institute of Radioprotection and Dosimetry (IRD).

Description of the updated radiation protection framework and results achieved from 1999 to 2008 are presented in this paper.

2. Methodology

2.1. The co-operation agreement

The mutual co-operation agreement between SVS/MG and CDTN put together the CDTN technical know-how and the SVS/MG regulatory power; the main aim of the agreement was to improve the radiation protection conditions and to control the quality of x-ray radiodiagnostic services in Minas Gerais.

The mutual SVS/MG and CDTN main responsibilities were stated in the agreement as:

- to create, participate and consider the recommendations of the Evaluation Group of Radioprotection in Radiodiagnostic (GARR);
- to promote technical meetings and scientific events aiming to improve the radiological protection and the quality of radiodiagnostic images in Minas Gerais;

- to suggest and participate in joint R&D&I projects
- to publish technical papers in scientific events

The main specific SVS/MG responsibilities are:

- to maintain a registration and publish the list of the radiation protection professionals authorized to provide services in Minas Gerais
- to establish and maintain an audit program to control the quality of the services provided by the registered professionals.

The main specific CDTN responsibilities are:

- to establish and carry out an accreditation process of candidates who are interest on being registered by SVS/MG;
- to keep a file of all evaluation reports issued by registered professionals about radiation protection and quality tests of radiodiagnostic services;
- to provide technical support to the SVS/MG audit program.

2.2. Accreditation of radiation protection professionals

Considering that in Minas Gerais there were not recognized specialists in radiodiagnostic as required in the “1998 Directives”, it was decided that the SVS/MG would register radiation protection professionals to perform evaluations in medical and dental x-ray radiodiagnostic facilities. Minimum requirements as experience and formal training in radiation protection in radiodiagnostic were established. The registration process consisted in five steps: analysis of the application documents, written examination, practical examination, dosimetric instrument evaluation and signature of the term of responsibility.

To start the process, one professional from CDTN was registered in the SVS/MG based on his large experience and academic education on the matter; two other CDTN professionals were also registered after being submitted to practical examinations that were done by the first. All others candidates were evaluated by CDTN registered professionals and the head of the CDTN radiation protection department.

2.2.1 – Application analysis

Applications sent to the GARR should included the candidate’s curriculum vitae, the certification in a technologic or biomedical university course, certification of training course and evidence of experience in radiation protection in medical or dental radiodiagnostic. In the beginning of the process, professionals with more than 5 years experience in the field might be exempted to do the written test; latter on such exemption was excluded.

2.2.2 Written test

Many concepts and procedures related to radiation protection and dosimetry in radiodiagnostic were formulated to the candidates to verify their knowledge as far as Brazilian and international regulation. Candidates were expected to achieve at least 70% of the maximum score to avoid being eliminated. In the beginning of the process, candidates who achieved score close to 70% were given a second chance to explain orally the questions; this procedure was excluded latter on.

2.2.3. Practical test

The practical examination aimed to verify the candidate’s ability to handle the dosimetric instrumentation, to collect relevant data, to carry out the area radiation survey, to perform main x-ray machine performance tests. The examination could be done in the LCD/CDTN or in a radiological clinic; candidates might use their own instrumentation or the CDTN one (Fig. 2). The performance of the candidate was evaluated as *insufficient*, *fair* or *good*; candidates with *insufficient* were eliminated;

fair candidates were given a second chance (latter on the procedure was changed to *insufficient* or *sufficient* without a second opportunity).

Figure 2 - Practical examination of a professional candidate during the evaluation of a medical x-ray machine in CDTN laboratory.



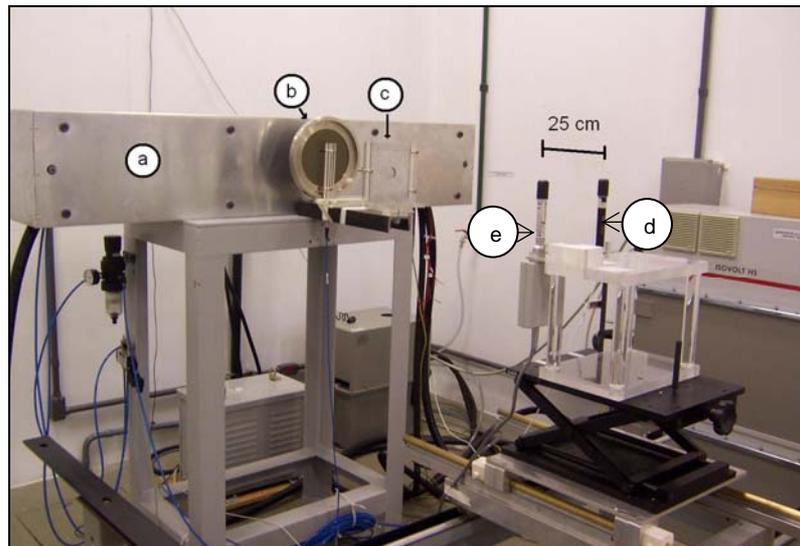
2.2.4 Evaluation of the dosimetric instrumentation

In 1999, Brazil had not yet a metrology laboratory to provide calibration for dosimetric instruments (mainly ionization chambers) in radiodiagnostic radiation references as internationally recommended [7]. To assure a minimum metrological coherence, in that date instruments were compared against standard dosimeters in x-ray beams at the LCD/CDTN. Figure 3 shows the set-up for the first comparison against the CDTN standard ionization chamber in a beam produced by a dental x-ray machine. The comparison allowed rejecting some instruments with long dead-time response that causes unacceptable underestimation of air-kerma values (some reached to -300%). As soon one Brazilian metrology laboratory started providing calibration to radiodiagnostic dosimetric instruments [8], comparison in CDTN was replaced by calibration requirement. Figure 4 shows the present x-ray set-up of the LCD/CDTN where IEC reference radiations were reproduced and calibration of ionization chambers can now be done [9].

Figure 3 – Set-up for the first comparison of radiodiagnostic ionization chambers against a reference dosimeter in a beam produced by a dental x-ray machine



Figure 4 – Set-up for calibration of radiodiagnostic ionization chambers in IEC reference radiations at the LCD/CDTN (a: lead housing x-ray tube; b: transmission chamber; c: lead collimator; d: reference ionization chamber; e: chamber under calibration)



2.2.5 Term of responsibility

To finalize the registration process, the approved candidate must sign a term of responsibility that establishes that he/she will perform by his/her own all experimental measurements without transferring such task to anybody else; additionally he/she compromises himself/herself to send monthly a copy of all issued technical evaluation report to the CDTN.

The term of responsibility also states that if it is disobeyed the candidate might be excluded of the registration list, which it is available at the internet site of the SVS/MG.

2.3 Controlling the services of registered professional

All evaluation reports issued by new registered professional are analyzed by CDTN experts; after some time, only few samples of reports are selected to be analyzed. Corrections, if needed, are required to be done in a due time; limited help is provided as far as misinterpretation of technical matters. Reports should be issued according to a code number provided to each registered professional; this enable CDTN to assure that all issued reports are sent to CDTN besides to the evaluated institution. In order to facilitate the understanding of the reports by the SVS/MG auditors, a standard format is required.

Meetings among all registered professionals are expected to happen to harmonize concepts, procedures and to disseminate new steps towards the fully adoption of the national requirements.

2.4. Radiation protection training in radiodiagnostic

Training is the basic action to be adopted to implement the new radiation protection policy for radiodiagnostic; conceptual and practical training was included in the framework as a requirement to candidates of the SVS/MG registration. Until now, no specific course exist in Brazil; people look to attend courses provided by universities or institutions and they get experience by jointing registered professionals for on-the-job training.

One important adopted action was the training of SVS/MG inspectors; the CDTN provided many training courses to inspectors from all relevant towns in Minas Gerais. The main aim of such training was to ability the inspectors to analyze the evaluation reports and to carry out a reliable local

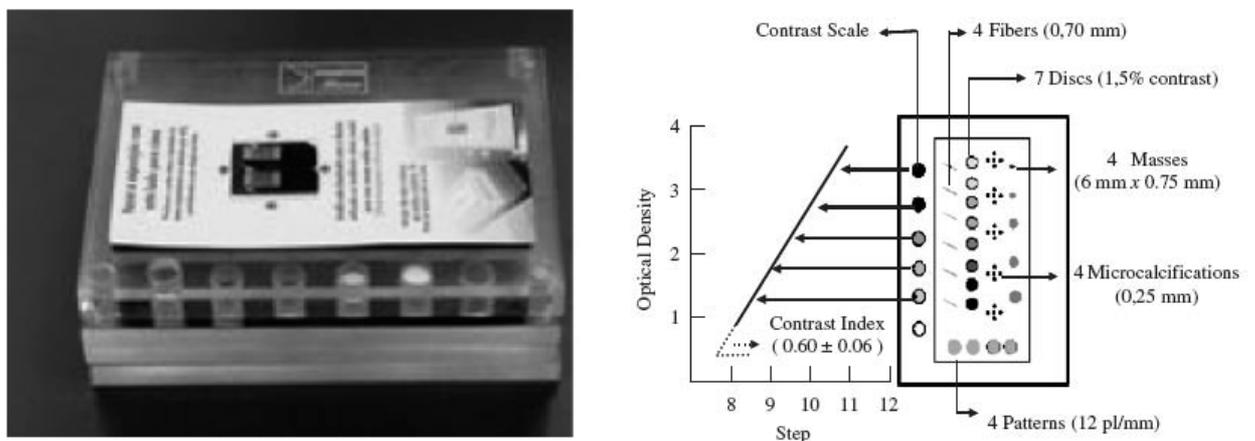
inspection in any x-ray radiodiagnostic service. Consultancy is also provided by CDTN experts to any SVS/MG inspector any time he/she needs.

2.5. A specific quality program for mammography

Doses in mammography should be maintained as low as possible without reducing the high image quality needed for early detection of the breast cancer and it is unacceptable that any mammography unit might show an inadequate performance. Considering that the SVS/MG decided to adopt a specific quality program for all 360 mammographic services in Minas Gerais [10].

SVS/MG inspectors and CDTN experts carried out local measurements to evaluate the average glandular dose and to verify the image quality on a standard phantom. Besides experimental measurements a practical training course was provided to all medical and technical staff of the radiological service. Dose measurements were carried out with TLD-100 thermoluminescent detectors and images were obtained with a breast standard phantom (Fig.5) [10].

Figure 5 – The standard breast phantom used to evaluate the average glandular dose and the image quality of mammography units [9].



3. Main results

Since 1999 the co-operation agreement between CDTN and SVS/MG has resulted in important results that have contributed to improve the radiological protection and image quality in radiodiagnostic area.

From 1999 to 2008, five accreditation processes for registration of radiation protection professionals were done. The amount of candidates approved in each accreditation phase is shown in Table 1. Data suggest that it is hard for a candidate to achieve the registration; only 24 good professionals were selected from 82 candidates. In 2004, 2005 and 2006 no process was offered by the SVS/MG.

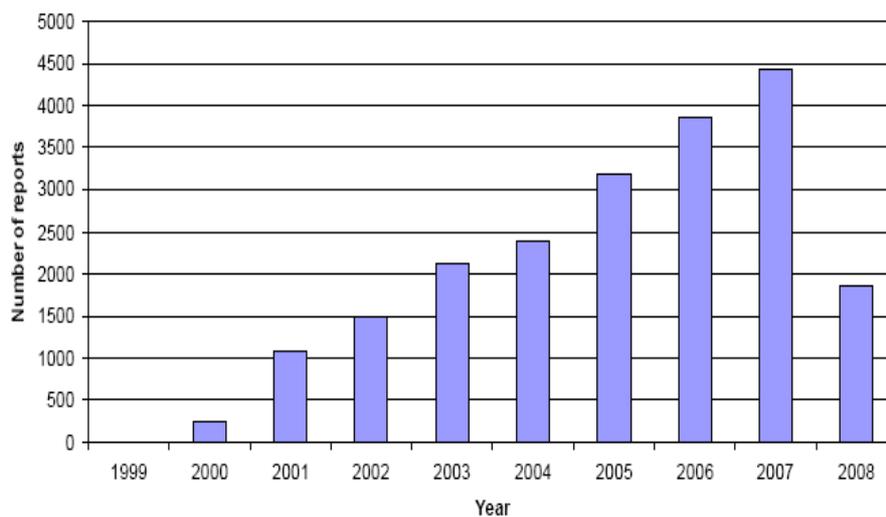
Table 1 – Results of the accreditation process of radiation protection professionals in Minas Gerais.

Year	Candidates	Approved candidates in each phase				Registered professionals
		Application	Written test	Practical test	Instrumentation	
1999	18	18	9	9	8	8
2000	20	20	10	9	9	9
2001	11	10	3	1	0	0
2002	12	11	4	3	3	3
2006	21	18	5	4	4	4

The registered professionals have sent the evaluation reports to CDTN (besides the copy they provide to the client who pays for the service), as describe. Figure 6 shows that amount of reports received by CDTN that has reached to 20,714 reports until the first semester of 2008; they suggest that the amount of inspected hospitals and clinics have increased and it is expected that radiation protection conditions too.

To harmonize actions and procedures, two meetings were held at CDTN for all registered professionals and SVS/MG inspectors. In the 2002 meeting, 15 professionals, 12 SVS/MG inspectors and 5 GARR members have discussed and agreed on the standard format of the evaluation reports and the technical procedure for specific performance tests. In the 2008 meeting, 14 registered professionals, 16 SVS/MG inspectors and 2 GARR members have discussed and agreed on the implementation of performances testes that were not performed yet; a time for starting the realization of the testes was also established.

Figure 6 – Annual growth of evaluation reports issued by radiation protection professionals in Minas Gerais (until the first semester of 2008).



Since 1999 the CDTN has provided training courses to 397 Sanitary Vigilance inspectors to improve their actions during inspections in radiodiagnostic services. Besides radiation protection concepts the inspectors are trained to perform local inspections and to understand evaluation reports issued by the registered professionals in a 24 h course. The main course contents are:

- Basic concepts on nuclear physics and radiation sources (1.5 h)
- Basic framework of the radiation protection system (1.5 h)
- X-ray equipments (3 h)
- Law and regulatory system for x-ray radiodiagnostic (3 h)
- Radiation protection program and documentation of radiodiagnostic services (3 h)
- Radiation survey and quality tests in x-ray machines (1.5 h)
- Nuclear medicine and radiotherapy – an overview (1.5 h)
- Mammography (3 h)
- Non-ionizing radiation machines used to produced images (1 h)
- Radiation protection framework in Minas Gerais (2 h)
- Check-list for visual inspections (3 h)

Table 2 shows the course period and the amount of trained participants. Since 2003, well-trained SVS/MG inspectors have become instructors to disseminate the training to many other inspectors; the CDTN has been asked to provide training course to other Brazilian states.

Table 2 – Training courses for radiodiagnostic inspectors by CDTN since 1999.

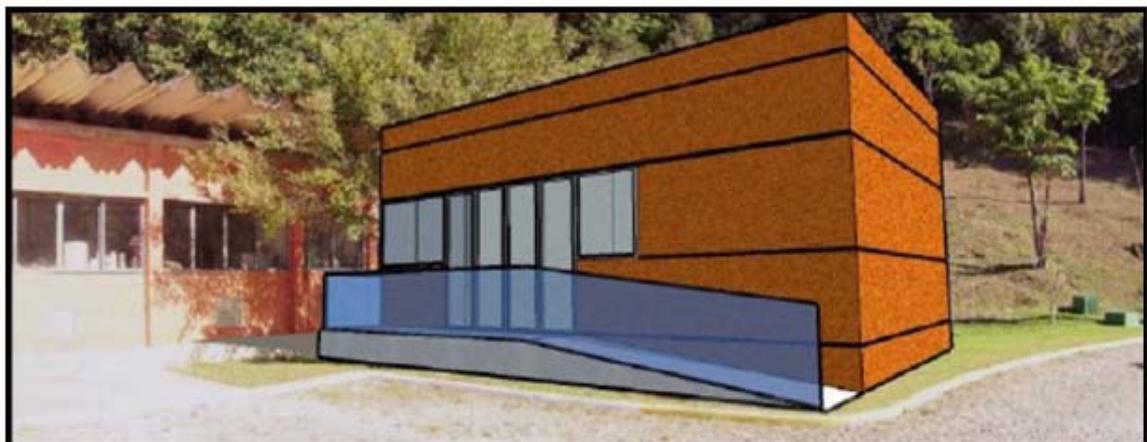
Course number	Period	Participants	Institution
01	September 1999	34	SVS/MG
02	October 2000	80	SVS/MG
03	November 2001	34	SVS/MG
04	June 2002	15	SVS/MG
05	June 2003	80	SVS/ Belo Horizonte
06	October 2003	80	SVS/ Belo Horizonte
07	November 2003	12	SVSof Cuiabá – MT
08	December 2003	2	SVS of Palmas – TO
09	April 2008	60	SVS of Belo Horizonte

Besides the actions to assure the radiation protection and the image quality for mammographic units in Minas Gerais as described before [10], a joint CDTN and SVS/MG project was approved by FAPEMIG - the Minas Gerais sponsor for R&D&I. Due to the need of training and establishing requirements for digital processing in mammography, a mammographic unit with digital processing was bought and temporarily installed in LCD/CDTN (Fig. 7); a new laboratory will be built until the end of 2008 (Fig.8). It is expected that many professionals and inspectors will be trained in such facility.

Figure 7 – Mammographic and digital image processing units temporarily installed in LCD/CDTN.



Figure 8 – New laboratory for research, development and training in mammography at CDTN.



4. Conclusions

The CDTN role in radiation protection for x-ray radiodiagnostic has significantly changed from a service provider to a scientific Institution that provides technical support to the regulatory authority. A formal co-operation agreement between the CDTN and the Superintendence of Sanitary Vigilance of Minas Gerais besides personal interest and efforts of all staff have been very important to implement, maintain and improve the adopted radiation protection framework.

The CDTN actions in the co-operation program for x-ray radiodiagnostic are seen as important social contribution to the Brazilian community. All efforts to establish the radiation protection framework for medical and dental radiodiagnostic services given by CDTN and SVS/MG as far as technical expertise, research, infrastructure and training have improved the radiation protection conditions in Minas Gerais/Brazil. The success of this experience suggests that it can be used as a model to be adopted by other regions.

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