NRRC Stakeholders Guidelines

Kingdom of Saudi Arabia

Application for Authorization of Dental Radiology

NRRC-SG-014

2023

هيئة الرقابة النووية والإشعاعية
Nuclear and Radiological Regulatory Commission

Stakeholder Guideline

Application for Authorization of Dental Radiology

2023
NRRC-SG-014

Preamble

In accordance with the provisions of the NRRC's approved Regulations, this stakeholder guideline describes criteria and/or techniques that are considered appropriate for satisfying the requirements stipulated in the NRRC's regulations.

This stakeholder guideline has been prepared on the basis of International Atomic Energy Agency (IAEA) standards, as well as the and the international best practices and the experiences of similar international regulatory bodies, and in accordance with the Kingdom's international commitments, and it has been approved by the NRRC's CEO resolution No.1413, dated 23/07/2023.

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1. Purpose

Nuclear and Radiological Regulatory Commission (NRRC) has developed an effective regulatory framework for the safe and secure authorization of dental radiology practice throughout its life cycle. Under the regulatory framework, the prime responsibility for safety and security within dental radiology practice lies with the authorized person.

The purpose of this guideline document is to give the applicant and/or the authorized person clear and specific guidance on the submission of the authorization application for dental radiography practice.

2. Scope

This guideline is addressed to dental radiology practice. In addition, it includes the required information relating to radiation safety and security in order to verify the adequacy of the safety and security measures as part of the authorization process.

This guideline includes the required information relating to authorization of new license, renewal as well as amendment of license.

3. Definitions

Annual dose

The dose from external exposure in a year plus the committed dose from intakes of radionuclides in that year.

Assessment

The process, and the result, of analyzing systematically and evaluating the hazards associated with sources and practices, and associated protection and safety measures.

Applicant

Any person applying to the NRRC for authorization to undertake specified activities and facilities including practices. Strictly, an applicant would be such from the time at which an application is submitted until the requested authorization is either granted or refused.

Controlled area

A defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing the spread of contamination in normal working conditions and preventing or limiting the extent of potential exposures.

Dose limit

The value of a quantity used in certain specified activities or circumstances that must not be exceeded.

Emergency plan

A description of the objectives, policy and concept of operations for the response to an emergency and of the structure, authorities and responsibilities for a systematic, coordinated and effective response. The emergency plan serves as the basis for the development of other plans, procedures and checklists.

Emergency preparedness

The capability to take actions that will effectively mitigate the consequences of an emergency for human health and safety, quality of life, property and the environment.

Exposure

The state or condition of being subject to irradiation.

Management system

A set of interrelated or interacting elements (system) for establishing policies and objectives and enabling the objectives to be achieved in an efficient and an effective manner.

Medical exposure

Exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; by carers and comforters; and by volunteers subject to exposure as part of a program of biomedical research.

Medical radiological equipment

Radiological equipment used in medical radiation facilities to perform radiological procedures that either delivers an exposure of an individual or directly controls or influences the extent of such exposure. (the term applies to X-ray units include Bitewing, Periapical, Occlusal, Panoramic, Cephalometric and Cone Beam Dental CT (CBDCT))

Occupational exposure

Exposure of workers incurred in the course of their work.

Quality Assurance (QA)

The function of a management system that provides confidence that specified requirements will be fulfilled.

Radiation protection program (RPP)

Systematic arrangements that are aimed at providing adequate consideration of radiation protection measures.

Safety assessment

Assessment of all aspects of an activity that are relevant to protection and safety; for an authorized facility. This includes siting, design and operation of the facility.

Security

Prevention and detection of any theft, sabotage, unauthorized access, illegal transfer (or any other criminal act) involving nuclear, nuclear-related or radioactive materials and associated facilities.

Supervised area

A defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though specific protection.

4. Abbreviations

Abbreviation	Definition
NRRC	Nuclear and Radiological Regulatory Commission
RPP	Radiation Protection Program.
RSO	Radiation Protection Program
QA	Quality Assurance.
QC	Quality Control.
TLD	Thermoluminescent Dosimeter.
OSL	Optically Simulated Luminescence
DRD	Direct Reading Dosimeter.

5. Format And Content of Dental Radiology Application

The following sections and subsections describe the content and level of detail that should be included within the dental Radiology application for authorization.

5.1. Management System

The following information regarding the management system implemented by the applicant should be provided:

5.1.1. Management Structure

A detailed chart of the management structure and description of the associated administrative roles and responsibilities.

5.1.2. Responsibilities Of the Workers

A detailed description of the management roles and responsibilities of:

- employees involved in radiation safety matters (e.g., RSOs).
- workers involved in activities with radiation sources (e.g., dentists, dental therapists, dental hygienists, dental assistants, radiologists, etc.)

Qualification of workers. Specification of names, education, training, position and work experience (Copy of qualification and/or relevant certificates).

5.2. Technical Information

The technical information for the facilities and the applied activities should include:

5.2.1. Description of the Facility:

a. Layout of the dental radiology department, including:

Layout of the areas where medical exposures are performed and their adjacent areas (e.g., toilets, changing rooms, image processing areas, waiting areas, etc.), in the form of a technical plan, on a suitable scale, and with information about:

- Structural features (if applicable) relevant for the radiation safety of the installation areas, such as: entrances, doors, roofs, floors, penetrations for ventilation and electricity, etc.

- Position(s) of X-ray and auxiliary equipment.

- Boundaries of controlled and supervised areas (if applicable).

- Information on the flow of patient and employee movements (workflow).

- Location and technical characteristics of the safety features and warning systems, such as: emergency

buttons, door interlocks, use of key control, access control measures, barriers, monitors, and warning signals and notices.

b. Shielding Assessment:

Shielding calculations and associated assumptions (e.g., workload, occupancy factors, distances, beam position(s), barrier material, etc.) with description of the applied calculation methodology/protocol.

c. Results of the measurements for the verification of the shielding adequacy.

5.3. Information on Medical Radiological Equipment:

5.3.1. Information on imaging equipment in use, including:

- Type (e.g., Periapical X-rays, Bite-wing X-rays, Panoramic, CBCT)
- Manufacturer
- Model
- Serial number
- Maximum kVp and mA/mAs.

5.4. Safety Assessment

5.4.1. Safety Assessment Document:

The safety assessment report should cover the following:

- Information on expected doses (occupational, public and from medical exposure) arising from normal operation of the facility.

- Estimation of potential doses (occupational, public and from medical exposure) from anticipated operational occurrences and accidental conditions.

- Description of accident initiating events, the severity of the potential consequences, and the existing safety barriers to prevent or mitigate the accidents.

5.5. Radiation Protection Program (RPP)

The RPP should be developed and implemented covering the following areas:

5.5.1. Control of occupational exposure

- Assignment of individual responsibilities for the RPP.

- Provisions for the assessment and monitoring of occupational exposures. It should include the comprehensive description of the individual and workplace monitoring program.

- Information on the implemented quality assurance (QA) program covering all components and devices supporting the control of occupational and public

exposure (dosimetry monitoring devices, emergency buttons, interlocks, signs, warning lights, communication system, etc.). It should include the description of the applied quality control (QC) procedures (maintenance program, tests, equipment, established tolerance limits, implementation of corrective actions, etc.) and the related responsibilities.

- Local rules and procedures that are necessary for the protection and safety of workers.
- Arrangements for adequate information, instruction and training and periodic retraining in protection and safety.
- Procedural and technical arrangements for the designation of controlled and supervised areas.
- Arrangements, including instructions to be provided, for the protection and safety of pregnant employees.
- Personal protective equipment.
- Health surveillance program for workers.
- System of records. It should include records on:
    - Individual and workplace monitoring
    - Inventory of imaging equipment and accountability.

- Incident and accident investigation reports.
- Maintenance and repair work.
- Training provided to individual workers.
- Procedures for reporting to NRRC.

5.5.2. Control of public exposure

- Training of personnel with functions relevant to protection and safety of members of the public.
- Local rules and procedures that are necessary for the protection and safety of the members of the public.
- Provisions for the assessment and monitoring of public exposure including associated records.
- Description of the measures to prevent the exposure of the public, such as signs, labels, marks, and notices. Confirmation that they all are in Arabic and English language.
- Procedures for reporting to NRRC.

5.5.3. Control of medical exposure

- Assignment of responsibilities and procedures applied with respect to the justification of the medical exposures performed (e.g., Criteria for patient selection,

patient identification, prescription of examinations, etc.).

- Assignment of responsibilities and procedures applied with respect to the optimization of the medical exposures performed.

- Information on the implemented quality assurance (QA) program for ensuring the quality of the medical exposures performed. It should include description of the applied quality control (QC) procedures (tests, equipment, established tolerance limits, implementation of corrective actions, etc.) and the related responsibilities.

- Program established for the corrective and preventive maintenance of all the Xray devices and imaging equipment.

5.5.4. Audits and procedure for the RPP review.

Periodic reviews of the radiation protection program, Specify the methods for periodic auditing and review of implementation of the RPP.

5.6. Emergency Preparedness and Response Plan

Information on the arrangements in place regarding emergency preparedness and response should include:

5.6.1. General elements:

- Identification of foreseeable accidental or unintended exposure

- Action plan including assignment of responsibilities and procedures to be implemented for each foreseeable emergency to ensure the protection and safety of the workers and the patients.

- Investigation of accidental or unintended exposure occurring in medical exposures

6. Related documents and files

Document Name	Document Type	Document Number	Relation to the guideline
Radiation Safety	Technical Regulation	NRRC-R-01	This Regulation set out the general safety requirements in ensuring protection of people and the environment against the harmful effects of ionizing radiation and for the safety of radiation sources.in addition, this regulation harmonize the requirements applicable in the Kingdom with the international best practices in order to achieve the highest standards of safety in activities and facilities that give rise to radiation risks

Notification on and Authorization of Facilities and Activities with Radiation Sources	Technical Regulation	NRRC-R-02	Prescribes the general requirements for notification on and authorization of activities, facilities and practices with radiation source, nuclear material and/or ore containing uranium and thorium in the Kingdom

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