

Essential Requirements for Medical Radiation Protection Programs

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Introduction

Radiation Protection Program (RPP) is a written program by Healthcare provider (HCP) to achieve the radiation protection principles and to keep occupational doses and doses of the related public that are “as low as reasonably achievable” (ALARA). Any HCP that uses medical radiation sources for medical procedure, either, radiation X-ray generator or radioactive material is required to develop, document, and implement an RPP. The HCP shall audit the program every two years to ensure that the RPP remains within the scope and the level of protection required in accordance to the HCP’s radiology department scope and the level of radiation activities exist.

To ensure compliance with the Saudi Food & Drug Authority (SFDA) requirements, this document is intended to clarify the general requirement for the implement of the RPP for any HCP that obtain a radiation X-ray medical device or radioactive material for medical use.

General requirements for the radiation protection program

The RPP should include, but not be limited to, the following items:

1. Organization and Administration

The HCP shall document the delegation and responsibility for each aspect of the RPP and provisions for ensuring enforcement of radiation safety policies and procedures.

2. ALARA Program

The HCP shall use, to the extent practicable, procedures and engineering controls based upon radiation protection principles to achieve occupational doses and doses to members of the public that are ALARA and document procedures addressing this requirement.

3. Dosimetry Program

The HCP is responsible for the protection of individuals that enter the controlled areas, and for ensuring that the public are protected and that the public dose does not exceed the limits. The HCP must evaluate whether or not personnel monitoring for occupational exposures is required. If a facility chooses to or is required to monitor, then those who are occupationally exposed to radiation should be instructed in the following:

- a) Types of personal monitoring devices used and exchange frequency.
- b) Use of control badges.
- c) Instructions to employees on proper use of personal monitoring devices, including consequences of deceptive exposure of the device.
- d) Procedures for ensuring that the combined occupational total effective dose equivalent (TEDE) to any employee receiving occupational exposure at the HCP and at other facilities does not exceed 50 mSv per year.
- e) Procedures for obtaining and maintaining employees' concurrent occupational doses during that year.

- f) Procedures for addressing a declaration of pregnancy.
- g) Procedures for maintaining documentation of dose to the embryo/fetus and associated documentation for the declared pregnant worker.
 - (1) Occupational Pregnant Workers.
 - (2) Pregnant Workers.
 - (3) Dose to Fetus.

4. Area Monitoring and Control

4.1 Area Radiation Monitoring

The need for area monitoring shall be evaluated and documented.

4.2 Instrument Calibration and Maintenance

- Instruments used to verify compliance with SFDA requirements must be appropriate for use and calibrated at required frequencies. Specify instruments to be used and procedures to verify conformity.
- Maintenance of the machine should be addressed. This can be specified in part by the operator's manual from the manufacturer.

5. Radiological Controls

5.1 Entry and Exit Controls

- Entry and exit from controlled areas must be adequate to ensure radiation safety.
- Design of emergency escape routes shall comply with applicable building codes.
- Document procedures addressing this requirement.

5.2 Posting

Areas that are required to be posted should be identified in the RPP, in addition to procedures for ensuring that such areas are properly posted. Furthermore, include procedures for ensuring that areas or rooms containing as the only source of radiation are posted with a sign or signs that read "CAUTION X-RAY" in both Arabic and English. Identify who is responsible for maintaining those signs and/or labels. In addition, certain documents must be posted.

5.3 Disposal of Equipment

HCP shall report in writing to the SFDA the sale, transfer, or discontinuance of use of any reportable source of radiation.

5.4 Other Controls

The HCP should evaluate the need for other controls in addition to those mentioned above. The following items should be considered:

- (1) Types of controls used to reduce or control exposure to radiation, such as positioning aids, gonadal shielding, protective aprons, protective gloves, mobile shields, etc.
- (2) Procedures for routine inspection/maintenance of such controls.

6. Emergency Exposure Situations and Radiation Accident Dosimetry

Identify any possible emergency exposure situations or radiation accidents and document procedures to address such, to include dose assessment.

7. Record Keeping and Reporting

All record keeping and reporting requirements are specified in regulations. Document the applicable requirements and commitments to compliance. The facility must also maintain all records of the RPP, including program audits and program content review. The following items should also be identified:

- a) The person responsible for maintaining all required records.
- b) Where the records will be maintained.
- c) The format for maintenance of records and documentation.
- d) Procedures for record keeping regarding additional authorized sites (mobile providers).

8. Reports to Individuals

The HCP shall provide reports of individual exposure when requested in accordance. Document procedures addressing this requirement.

9. Radiation Safety Training

9.1 Operating and Safety Procedures

The HCP is required to have a written operating and safety procedure manual. This may be the operating manual that comes with a radiation unit which may include safety procedures. However, if safety procedures are not included in the manual they must be developed. These safety procedures must be posted on the machine or where the operator can observe them while using the machine.

Document all training for the employees, both occupationally exposed and non-occupationally exposed workers, are required to have before using radiation machines including continuing education. Also, document other training provided to employees or visitors such as radiation safety and protection program review, safety meetings, formal classroom training, etc.

HCP shall:

- (1) Inform all individuals working in or frequenting any portion of a controlled area of the use of radiation in such portions of the controlled area.
- (2) Instruct such individuals in the health protection problems associated with exposure to radiation, in precautions or procedures to minimize exposure, instruct such individuals in, and instruct them to observe, to the extent within their control, the applicable provisions of department regulations for the protection of personnel from exposures to radiation occurring in such areas.
- (3) Instruct such individuals of their responsibility to report promptly to the HCP any condition that may lead to or cause a violation of department regulations or unnecessary exposure to radiation, and of the inspection provisions.
- (4) Instruct such individuals in the appropriate response to warnings made in the event of any unusual occurrence or malfunction that may involve exposure to radiation and advise such individuals as to the radiation exposure reports which they may request pursuant to.

9.2 Quality Assurance Programs

Document and explain quality assurance programs (QAPs) for all radiation devices. The explanation should include the types of checks that are performed, the interval at which they are performed, what actions are taken if problems are noted, and who is responsible for those checks. Such checks should be performed on the device to ensure that it is functioning properly and that all safety controls are in effect.

10. Internal Audit Procedures

The HCP must audit the RPP on a two-year basis. Documentation of the annual audits may be requested during the inspection. The following items should be addressed depending on the scope of the radiologic health protection problems:

- a) Identification of inspection types and program audits conducted, to include radiation machines, personnel and procedures.
- b) Identification of the individual(s) who are responsible for performing inspections and/or audits.
- c) Identification of where and at what intervals the inspections and/or audits are conducted.
- d) Procedures for conducting the inspections and/or audits.
- e) Instructions on identification of proper use of instrumentation if staff performs machine maintenance.

Annexes

Annex (1): Abbreviations

ALARA	As low as reasonably achievable
HCP	Healthcare provider
mSv	milliSievert
OSL	Optically stimulated luminescence
QAPs	Quality Assurance Programs
RPP	Radiation Protection Program
SFDA	Saudi Food & Drug Authority
TEDE	Total effective dose equivalent