ADMINISTRATIVE ORDER

No. 2017 - ______

SUBJECT: “Radiation Safety Standards and Requirements on the Operation of Diagnostic and Interventional X-ray Facilities”

I. RATIONALE/BACKGROUND

Medical uses of ionizing radiation are amongst the longest established applications of ionizing radiation. Current estimates put the worldwide annual number of diagnostic and interventional radiological procedures at over 3000 million. In the Philippines, there are about 3,000 x-ray facilities doing diagnostic and interventional procedures. These medical uses bring considerable public health benefits. However, ionizing radiation using x-rays can cause harm and a systematic approach should be applied to ensure that there is a balance between being able to utilize the benefits from medical uses of x-rays and minimizing the risk of radiation effects to patients, workers and members of the public.

In 1996, the International Atomic Energy Agency (IAEA), published the Basic Safety Standards entitled “Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources”. This standard contains recommendations on the safe use of radiation sources to serve as a guide in the harmonization of standards for radiation regulation bodies of its member states. To address the need for harmonization of standards with the IAEA, in 2004, the Department of Health adopted the international standard with the issuance of the Administrative Order (AO) No. 149 entitled “Basic Standards on Radiation Protection and Safety Governing the Authorization for the Introduction and Conduct of Practices Involving X-ray Sources in the Philippines. The Department of Health (DOH) Circular No. 323 s. 2004 (Manual on Basic Radiation Protection and Safety of X-ray Sources) was also issued as an integral part of AO.149. These AO and Department Circular contained general guidelines for the promulgation of radiation protection and safety requirements in the establishment and operation of x-ray devices and facilities.

General Safety Requirements (GSR) Part 3 was published by the IAEA in 2014 that supersedes IBSS No. 115 issued in 1996. Due to the replacement of the IBSS No. 115 by the GSR Part 3, AOs 149, 164, DOH Circular 323 and all other existing national standards and regulatory requirements has been revised and superseded by AO ______ entitled “Radiation Protection and Safety of X-ray Sources in Planned Exposure Situations : Adoption of International Basic Safety Standards, General Safety Requirements (GSR) Part 3”.

This AO provides guidance on fulfilling the requirements of GSR Part 3 with respect to medical uses of ionizing radiation. It is aimed primarily at end-users in
medical radiation facilities where radiological procedures are performed, including
management, radiological medical practitioners, medical radiation technologists,
medical physicists, radiation protection officers and other health professionals. It also
provides recommendations and guidance to health professionals who refer patients for
radiological procedures; to manufacturers and suppliers of medical radiological
equipment. This AO will supersede AO. No. 35 s. 1994 entitled “Requirements for
the Control of Radiation Hazards from Clinical Diagnostic X-ray Facilities.

This AO does not include guidance on human imaging using ionizing
radiation for purposes other than medical diagnosis, medical treatment or biomedical
research. Such human imaging using ionizing radiation for other purposes includes
exposing people to radiation for employment related, legal or health insurance
purposes without reference to clinical indications, and human imaging using ionizing
radiation for the detection of concealed objects for anti-smuggling purposes or for the
detection of concealed objects that could be used for criminal acts that pose a national
security threat.

Pursuant to Republic Act No. 9711 and its Implementing Rules and
Regulation consistent with the harmonization and adoption of the applicable IAEA
standards, and in order to strengthen the standard of safety, the DOH through the
FDA, promulgates the rules and regulations for the specific practice on the use of x-
ray devices for diagnostic radiology and interventional procedures.

II OBJECTIVE

These Rules and Regulations are promulgated in order to strengthen the
regulatory policy that will protect the patient, the workers as well as the members of
the public in the hazards on the use of x-ray devices in diagnostic radiology and
interventional procedures; ensure compliance among responsible parties, stakeholders and individuals involved in those practices; to consider advances in
technology with regards to diagnostic and interventional procedures using x-rays, and
to provide guidance in meeting the regulatory requirements.

Specifically, this Order aims to:
1. Provide the administrative, human resource, x-ray machines, physical
plant, and radiation protection requirements;
2. Provide the classification of medical diagnostic x-ray facilities; and,
3. Provide the guidelines in fulfilling a Quality Assurance Program.

III SCOPE

1. These rules and regulations shall apply to any person, firm,
corporation, establishment or entity, whether government or private,
operating and maintaining a diagnostic and interventional x-ray
facilities and to the individuals involved in those practices.

2. Exclusions: These requirements shall not apply to the following:
2.1 Therapeutic x-ray facilities utilizing medical linear accelerators,
educational, industrial, anti-crime, research, veterinary, and dental x-
ray facilities which are covered by other regulations issued by the FDA.
2.2. X-ray facilities used exclusively for forensic examinations; and
2.3. Diagnostic imaging devices using radioactive sources and
2.4 Human imaging using x-rays for purposes other than medical diagnosis, medical treatment or biomedical research

IV DEFINITION OF TERMS

Acceptance Testing – the initial inspection performed on a piece of medical equipment prior to it being put in place. When the device first arrives in the healthcare facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly (WHO definition, 2011).

Authorization – is a permission embodied in a document, granted by the DOH through the Food and Drug Administration to an authorized person or company who has satisfactorily complied the requirements in the submission of an application to operate, maintain or establish a facility using diagnostic x-ray devices. The authorization can be in the form of a license to operate (LTO) or a Certificate of Compliance (COC).

Authorized Officer - is an owner or legal person who is either natural (e.g., single proprietorship) or juridical (e.g., partnership or a corporation) person.

Chest for Heart and Lungs – is an x-ray service category capable of performing radiographic examination which produces images of the heart, lungs, airways, blood vessels and the bones of the spine and chest.

Clinically Qualified Medical Physicist – is a health professional, with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practice independently in one or more of the subfields (specialties) of medical physics.

Commissioning – procedures carried out by the facility representative usually a medical physicist specializing in radiology physics, to ensure that the equipment is ready for clinical use and to establish baseline values against which the results of subsequent routine performance be compared.

Controlled Area – a defined area in which specific protection measures and safety provisions are or could be required for controlling exposures or preventing x-ray exposures in normal working conditions. An area where a person is likely to receive an effective dose greater than 6 mSv (or an equivalent dose of greater than three-tenths of any dose limit).

Corrective Maintenance – a process used to restore the physical integrity, safety and/or performance of an x-ray machine after a failure.
**Diagnostic Radiology** – is a branch of medical practice concerned with the use of imaging techniques in the study, diagnosis and x-ray guided treatment of disease. This includes the use of x-rays in general radiography and fluoroscopy, interventional radiology, lithotripsy, computed tomography, mammography, bone densitometry, and tumor localization and simulation.

**Diagnostic and Interventional Radiology Medical Physicist** (DIRMP) - is a Clinically Qualified Medical Physicist, who, by virtue of certification by appropriate boards or societies, professional licenses or academic qualification and experience duly recognized as having expertise in diagnostic and interventional radiology medical physics and is charged with specific duties and responsibilities indicated herein and in Appendix B of this AO.

**Digital Imaging and Communications in Medicine (DICOM)** – is a standard for medical device intercommunication and for the storage and transmission of medical images.

**Dose Limit** – the value of the effective dose or the equivalent dose to individuals in planned exposure situations that is not to be exceeded.

**Facilities and Activities** – the term facilities and activities is a general term encompassing any human activity that may cause people to be exposed to radiation risk arising from naturally occurring or artificial sources. In this AO the term facilities refers to the x-ray facility conducting diagnostic and interventional procedures while activities refers to the use of x-ray devices.

**Fluoroscopy** – is a technique for obtaining continuously or periodically a sequence of x-ray patterns and presenting them simultaneously and continuously as visible images.

**International Electrotechnical Commission (IEC)** – an independent organization that prepares and publishes International Standards for all electrical, electronic and related technologies, collectively known as “electrotechnology”.

**International Organization for Standardization (ISO)** – an independent, non-governmental international organization of national standards bodies from different countries. The members develop voluntary, consensus-based, market relevant International Standards that support innovation and provide solutions to global challenges.

**Interventional Radiology** – comprises image-guided diagnostic and therapeutic procedures where access is percutaneous and is usually performed under local anaesthesia and/or sedation.

**Licensee** – is the holder of a current authorization granted to establishments by the FDA for a practice of diagnostic radiology and who has recognized rights and duties, particularly in relation to protection and safety.
Lithotripsy – is an x-ray image guided medical procedure that uses shock waves to break up the stones in the kidney, ureter, or bladder.

Medical Radiation Practitioner – is a physician with qualifications as specified in Appendix A of this AO who is responsible for the overall conduct of the procedures involving the exposure of the patient to ionizing radiation from x-rays.

Mobile X-ray Machine – is an x-ray machine that is intended to be moved from one location to another between periods of use while supported by its own wheels or equivalent means.

Picture Archiving and Communication System (PACS) – is a medical imaging technology which provides economical storage and access to images.

Radiology Information System (RIS) – computerized database used by radiology departments to store, manipulate and distribute radiological images.

Performance Testing – testing of radiologic equipment for compliance with the national radiation protection regulations and with other standards that have been adopted by the FDA. Performance Testing can either be constancy (routine) or quality control testing.

Philippine National Standards (PNS) – are documents established by consensus through a technical committee and approved by the Bureau of Product Standards, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context.

Pre-Licensing Inspection also termed as Radiation Protection Survey and Evaluation (RPSE) – is a comprehensive on-site inspection and evaluation of the x-ray facility including, but not limited to, the assessment of machine performance, x-ray tube leakage radiation, adequacy of shielding barriers, and accessories, etc.

Post-Licensing Inspection also termed as Facility Compliance Monitoring (FCM) – is an activity or procedure conducted by the regulatory body to determine whether x-ray sources are being used in accordance with the requirements of the relevant regulations and any conditions of the authorization.

Preventive Maintenance – is a planned procedure to ensure that the x-ray equipment is kept in good condition, in order to provide a long operating life.

Quality Assurance Program – a management tool which, through the development of policies and the establishment of review procedures, aim to ensure that every examination or treatment is necessary, appropriate and performed according to previously accepted clinical protocols by adequately trained personnel using properly selected and functioning equipment to the satisfaction of the patient and referring physicians safely and at minimum cost.
**Quality Control Program** – a component of a quality assurance program that deals with the monitoring of the technical parameters that greatly affects both the image quality and performance of the x-ray equipment.

**Quality Control Technologist** – a radiologic technologist designated by the licensee who is charged to perform or supervise all individual tasks within the quality assurance program not assigned to the medical radiation practitioner or to the medical physicist.

**Radiation Protection Officer** – a person technically competent in radiation protection matters relevant for diagnostic radiology and is designated by the licensee to oversee the application of relevant radiation protection and safety requirements established by the FDA or by international standards.

**Radiation Protection Program** – is a systematic arrangement which is aimed at providing adequate consideration of radiation protection and safety measures in an x-ray facility.

**Safety Assessment Plan** – is the assessment of all aspects of a practice that are relevant to protection and safety. For an authorized facility, this includes siting, design and operation of the facility. Safety assessment plan is the systematic process that is carried out throughout the lifetime of the facility or activity to ensure that all the relevant safety requirements are met by the proposed (or actual) design. Safety assessment plan includes, but is not limited to, the formal safety analysis.

**Supervised Area** – is any area not already designated as a controlled area but where occupational exposure conditions need to be kept under review even though specific protection measures are not normally needed.

**Supplier** – is any authorized officer to whom a licensee delegates duties totally or partially in relation to the design, manufacture, or construction of an x-ray source (an importer of an x-ray device is considered as a supplier of the x-ray source)

**Teleradiology** – is a branch of telemedicine referring to the use of computers and telecommunication networks to transmit diagnostic images acquired at one location to another for primary review and interpretation as well as specialist consultation.

**Type Tests** – are certain tests performed on a type or brand of equipment and do not need to be repeated for all pieces of equipment.

**X-ray Device** – means an electrical or electronic apparatus emitting ionizing electromagnetic radiation at the diagnostic range of energies. In this AO, the term x-ray machine, x-ray device, and x-ray equipment are used interchangeably.
X-ray Facility – pertains to the structures or installations within the establishment that houses the x-ray machine used in diagnostic radiology.

V IMPLEMENTING MECHANISMS

A. GENERAL GUIDELINES

1. All x-ray facilities shall secure an authorization from the FDA. No x-ray facility shall be allowed to operate without a valid authorization issued by the FDA.

2. Any authorized officer or organization applying for authorization:
   2.1. Shall submit to the FDA the relevant information necessary to support the application for an authorization.
   2.2. Shall refrain from carrying out any actions/activities pertaining to the use of the x-ray equipment until the authorization is issued.
   2.3. Shall assess the nature, likelihood, and magnitude of the expected exposures due to the x-ray machines and shall take all necessary measures for protection and safety.
   2.4. Shall have a safety assessment plan made and submitted to the FDA as part of the application.

3. All x-ray facilities shall comply with the existing regulations issued by the FDA. The x-ray facility shall follow the procedural guidelines set by the FDA in securing the relevant authorization.

4. All radiologic procedures shall be done with the most appropriate device that will result in the optimum diagnostic image.

5. The licensee shall hire an adequate number of appropriately trained and qualified personnel for the operation of its x-ray facility.

6. Every x-ray facility shall have an x-ray device that is tested to perform safely. A preventive maintenance program shall be provided to ensure that the x-ray equipment is functioning properly.

7. All x-ray facilities shall be properly shielded, well ventilated, well lit, clean, safe, and shall have sufficient space to accommodate its activities.

8. All x-ray facilities shall have adequate radiation protection accessories to be used in the protection of the patient, the public, and workers from possible unnecessary radiation exposure.

9. The licensee shall ensure that an individual radiation monitoring device is provided to each worker.

10. The licensee shall ensure that radiation doses to workers and members of the public do not exceed the dose limits specified by the FDA.

11. Each x-ray facility shall establish and implement a quality assurance and radiation protection program.

12. The Licensee shall permit access of the FDA to carry out inspections of their facilities and activities and of their protection and safety records, and shall cooperate in the conduct of inspection.
B. SPECIFIC GUIDELINES

1. Administrative Requirements

1.1.1 The owner/licensee shall submit an authorization application and safety assessment plan of his/her facility and activity, in a prescribed form which shall be reviewed and assessed by the FDA prior to the granting of the authorization.

1.1.2 The owner/licensee shall ensure the establishment, implementation, and maintenance of a radiation protection program as shown in Appendix C.

1.1.3 The owner/licensee shall ensure that the implementation of a quality assurance program commensurate to the radiological services the facility offers as shown in Appendix D.

1.1.4 A Quality Assurance committee shall be established to provide periodic review and evaluation of the facility’s QA program. The results of the review should be recorded, documented and assessed by the QA committee. Results that do not meet tolerance levels should lead to appropriate and timely remedial actions and all such actions should be recorded/documented.

1.1.5 The owner/licensee shall ensure that a continuing professional development program with the aim of improving such skills, maintaining familiarity with current practices and fostering a safety culture throughout the facility shall be provided.

1.1.6 The owner/licensee shall provide radiation dose monitors to all radiation workers in the facility. He/she shall ensure that records of the radiation doses of workers are kept and reviewed by the RPO.

1.1.7 The owner/licensee shall ensure that the requirements for the safety of x-ray machines used in medical exposure shall be so designed as specified in Appendix E.

2. Classification of medical diagnostic x-ray facility:

Medical diagnostic x-ray facilities shall be classified according to the x-ray service categories; appropriate x-ray machine requirements and specific radiographic examinations performed:

<table>
<thead>
<tr>
<th>X-ray Service Category</th>
<th>X-ray Machine Requirements</th>
<th>Radiographic Examinations performed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chest for Heart and Lungs</td>
<td>General Radiography Machine with tube currents of at least 100 mA except for high frequency inverter type x-ray machines and emerging technologies conforming with internationally accepted standards</td>
<td>Chest, heart and lungs examinations procedures only</td>
</tr>
<tr>
<td>Level One</td>
<td>General Radiography Machine with</td>
<td>Chest for heart and lungs,</td>
</tr>
<tr>
<td>Level</td>
<td>Equipment Details</td>
<td>Required Procedures</td>
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<tr>
<td>Tube currents of at least 100 mA except for high frequency inverter type x-ray machines and emerging technologies conforming with internationally accepted standards</td>
<td>Skeletal radiography and abdomen</td>
<td></td>
</tr>
<tr>
<td>Level Two</td>
<td>General Radiography Machine with tube currents of at least 200 mA and/or Radiography/Fluoroscopy System and/or Cardiac Catheterization Helical Computed Tomography Machine</td>
<td>All of Level one plus radiographic examinations with contrast procedures except interventional radiology</td>
</tr>
<tr>
<td>Level Three</td>
<td>General Radiography/Fluoroscopy System and/or at least 16 slice Computed Tomography Machine</td>
<td>All of Level two plus interventional radiology except cardiac catheterization procedures</td>
</tr>
<tr>
<td>Specialized</td>
<td>Computed Tomography Mammography Cardiac Catheterization Lithotripsy Bone Densitometry Tumour Localization and Simulation</td>
<td></td>
</tr>
</tbody>
</table>

3. **Human Resources:**

3.1 **Staffing:**

3.1.1 The licensee shall appoint professionals with qualifications/and or accreditation for the task assigned to them sufficient to ensure that all activities relevant to radiation protection and safety are carried out in accordance with these regulations.

3.1.2 The number of personnel should be reviewed as to adequacy as the workload increases or as new techniques and/or new or additional equipment are acquired by the facility.

3.1.3 Patient demographic and annual workload data trends should be monitored and documented for facility planning and staffing levels requirement.
3.2 Education and Training

3.2.1. The licensee shall ensure that only personnel who are qualified in terms of education, training and experience shall work in the medical diagnostic/interventional x-ray facility.

3.2.2 All medical practitioners and radiation workers whose work involves his/her presence in the delivery of radiological services shall have attended a training on radiation protection and safety in diagnostic and/or interventional radiology given by the radiation protection officer of the facility, by a CQMP-DIRMP, or any other training provider recognized/organized by the FDA.

3.2.3 The licensee shall ensure that all personnel are aware of the conditions and limitations of the license:

a. institutional radiation protection policies and procedures (including practice drills for emergency responses)

b. review and analysis of lessons learned from incidents and accidents that have occurred in the facility or elsewhere
c. the local quality assurance program and quality control procedures
d. use and operation of the equipment and other support devices
e. instruction procedures to patients, caregivers and comforters

3.2.4 The personnel shall be given instructions whenever significant changes occur in the duties and responsibilities, regulations, training including the conditions and limitations of the license or radiation safety procedures.

3.2.5 The licensee should establish a policy that encourages and provides continuing education and professional development of personnel. The owner/licensee shall ensure that a continuing professional development program with the aim of improving such skills, maintaining familiarity with current practices and fostering a safety culture throughout the facility shall be provided.

3.2.6 The licensee shall ensure that all non-diagnostic and interventional radiology staff who need to enter the controlled areas of the medical diagnostic/interventional radiology department, be provided with specific instructions on radiation protection.

3.3 Manpower Requirements:

All facilities shall employ the following personnel:
3.3.1 Medical Radiation Practitioner

3.3.1.1 The licensee shall designate a medical radiation practitioner with qualifications as stated in Appendix A.
3.3.1.2 Where applicable, the medical radiation practitioner shall have undergone appropriate training in radiation protection as stated in Appendix A conducted by an organization recognized/organized by the FDA.
3.3.1.3 A chief medical radiation practitioner shall be appointed as head of the facility.
3.3.1.4 The number of medical radiation practitioner should be reviewed as to adequacy and shall be hired as the workload increases.

3.3.2 Radiation Protection Officer (RPO)

3.3.2.1 The licensee shall designate a qualified RPO who is responsible for the practice of radiation protection and safety of the facility and compliance with relevant regulatory requirements.
3.3.2.2 The RPO shall ensure that radiation safety activities are performed according to approved safety policies and procedures. He/she shall have the authority to stop any activity that may endanger health and safety.
3.3.2.3 The RPO shall either be a diagnostic radiology medical physicist or a radiologic technologist.
3.3.2.4 For radiologic technologist to be RPO, he/she shall have completed an appropriate training in radiation protection conducted by an organization recognized by the FDA.
3.3.2.5 The RPO shall perform his/her duties and responsibilities as specified in Appendix I. and Section 2 of Appendix B of this AO.

3.3.3 Clinically Qualified Medical Physicist (CQMP) in Diagnostic and Interventional Radiology

3.3.3.1 For Level three, and level three x-ray facilities with equipment categorized in specialized x-ray facilities, the services of a CQMP shall be made available.
3.3.3.2 For other x-ray facilities classified in Section V.B.2, the services of a CQMP should be made available.
3.3.3.3 The CQMP shall perform his/her duties and responsibilities as specified in Appendix B.

3.3.4 Radiologic/X-ray Technologist

3.3.4.1 At least one (1) full time radiologic/x-ray technologist per 8-hour shift shall be hired per machine.
3.3.4.2 A chief radiologic technologist shall be appointed in a facility.
3.3.4.3 Only qualified female radiologic/x-ray technologist trained to perform mammography procedures shall be allowed.

3.3.4.4 For specialized x-ray facilities, the radiologic technologist should have undergone training in the operation of the appropriate x-ray machine.

3.3.5 Quality Control (QC) Technologist

3.3.5.1 For Level three x-ray facilities, the licensee shall designate a quality control technologist as specified in Appendix J of this AO.

3.3.5.2 The QC technologist shall be a radiologic technologist who is specially trained in the conduct of quality control of x-ray equipment commensurate to his/her facility or has attended a quality assurance/quality control course conducted by the FDA or an organization recognized/organized by FDA.

4. X-ray Machine Requirements

4.1 The owner/licensee in specific cooperation with suppliers, shall ensure that, with regard to the x-ray machine:

4.2.1 Whether imported into or manufactured in the Philippines where it is used, the equipment conforms to applicable standards of the IEC and ISO or to equivalent national standards. Evidence of such compliance shall be provided such as type tests, and acceptance tests in the absence of type tests.

4.2.2 Performance specifications and operating and maintenance instructions, including protection and safety instructions, be provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to “accompanying documents”.

4.2.3 Where practicable, the operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major language acceptable to the user.

4.2.4 Adequate maintenance (preventive and corrective) shall be performed as necessary to ensure that the equipment retain their designed specification for image quality, radiation protection and safety for their useful lives.

4.2 Each type of x-ray machine shall conform to the minimum performance criteria of an x-ray machine as specified in Table 1 of Appendix F and shall comply with the specific x-ray machine
requirements and accessories shown in Appendix E.

4.3 All newly installed, transferred, and modified x-ray machines shall undergo acceptance and commissioning tests conducted by a supplier and a CQMP –Diagnostic and Interventional Radiology or by an establishment providing QA testing services recognized by the Philippine Accreditation Bureau of the Department of Trade and Industry and the FDA. After acceptance testing and commissioning, performance tests shall be done within a specified number of years as indicated in Table 2 of Appendix F.

4.4 For the supplier, evidence of competence for the acceptance testing, maintenance and servicing of medical equipment shall consist of the following:

4.4.1. Certification, ideally from the manufacturer of having completed a training program on the type of x-ray machine.

4.4.2. A course on radiation protection on which the contents, the methodology and the teaching institution or training provider is recognized/organized by the FDA.

5. Physical Plant Requirements

5.1 X-ray Examination Room

5.1.1 The x-ray room size shall satisfy the following specifications:

5.1.2.1. X-ray room for x-ray machines not equipped with radiographic table shall have a minimum width of 2.5 meters and minimum length of 3.0 meters.

5.1.2.2. X-ray room for x-ray machine equipped with radiographic table shall have a minimum width of 3.5 meters and minimum length of 4.0 meters.

5.1.2.3. X-ray room for x-ray machine equipped with radiographic/fluoroscopic machine shall have a minimum width of 4.5 meters and minimum length of 5.0 meters.

5.1.2. For a transportable x-ray facility, the x-ray examination room shall be at least 1.0 m x 2.0 m. Due to the limited x-ray room size, only upright chest x-ray examinations shall be allowed.

5.2 X-ray Room Design

5.2.1. All walls in the x-ray examination room shall be made of any of the following materials to a height of at least 2 meters from the floor level/ground outside the x-ray room:

5.2.1.1. at least 15 cm poured concrete;
5.2.1.2. at least 20 cm thickness of properly filled concrete hollow blocks and cement plaster.

5.2.1.3. at least 1.5 mm thick lead sheet. Care should be taken to avoid punctures in the lead sheet which may occur during installation. The lead sheet should be glued onto and sandwiched between wooden panels.

5.2.1.4. Other shielding material may be used but shall have a thickness equivalent to at least 1.5 mm of lead.

5.2.2. Radiation level measurements at the other side of the walls and door/s shall not exceed 25 μSv/hr (2.5 mR/hr).

5.2.3. The base of the x-ray room window/s shall be located at a height of at least 2 meters from the floor of the adjacent area or room.

5.2.4. Means for viewing and two way communication between the patient and the x-ray/radiologic technologist during x-ray examination shall be provided.

5.2.5. A protective barrier shall be placed at the control console to shield staff, who should not wear protective clothing while at the console. The protective barrier shall be constructed or provided inside the x-ray examination room. The barrier with a dimension of 1m in width and 2m in height should be made of any of the materials enumerated in Section 5.2.1.

5.2.6. A red warning light bulb shall be installed outside the x-ray examination room above the x-ray room door. It shall be illuminated when the x-ray machine is switched on.

5.2.7. A patient’s dressing area shall be provided inside the x-ray examination room.

5.2.8. A toilet shall be provided inside the x-ray examination room where procedures with contrast media are performed.

5.3 Darkroom

5.3.1. Where applicable, there shall be a separate darkroom constructed adjacent to the x-ray examination room.

5.3.2. The size of the darkroom shall be at least 1m by 1.5m

5.3.3. The darkroom shall be light tight, clean and large enough to accommodate the darkroom equipment and accessories.

5.3.4. The darkroom shall be well ventilated. It shall be provided with an air inlet and an air outlet with an exhaust fan. However, these openings shall be designed such that no light can enter the room while darkroom work is done.

5.3.5. For manual film processing, the processing tank shall consist of a master tank and two (2) insert tanks inside a master tank. The insert tanks shall be made of stainless
steel or fiber glass. Separate paddles for mixing the developer and fixer solutions shall be provided.

5.3.6. There shall be an adequate supply of water in the master tank.

5.3.7. For manual processing, the time-temperature method of processing shall be observed. A countdown timer and an alcohol/digital thermometer shall be provided.

5.4 **Image Interpretation**

5.4.1 A separate film interpretation room/area shall be provided. A negatoscope with luminance of at least 1500 nit for general radiography and 3000 nit for mammography shall be provided. The room illuminance shall be 50 lux or less for mammography.

5.4.2 In mammography, the negatoscope shall be provided with a mask to limit the light/luminance to the area of the film.

5.4.3 Digital display devices used for interpretation of digital images shall have a resolution of at least 2 megapixels except for mammography which shall have at least 5 megapixel of resolution.

5.5 **Use of Teleradiology**

5.5.1 Diagnostic x-ray facilities utilizing the practice of teleradiology, the communication protocols, file formats, and image data compression shall conform to Digital Imaging and Communication in Medicine (DICOM) standards.

5.5.2 There shall be no reduction of clinically diagnostic image quality whenever the image is compressed and transmitted for image interpretation. Means to ensure that the image is properly identified and delivered in a timely manner to the patient shall be provided.

5.5.3 Integration of PACS in the departmental workflow should be provided. If PACS is available, the use of an electronic source of identity, ordering and scheduling information, and the integration of disparate sources of information shall be provided.

5.5.4 The official interpretation of clinical images, emergency examinations in on call situations and additional opinions by external consultation shall be done by a physician with qualifications stated in Appendix A.
5.5.5 The x-ray facility shall notify the FDA all qualified physicians or organization interpreting radiology images through teleradiology.

6. Radiation Protection Requirements:

6.1. The radiation protection requirements on justification of the practice, dose limitation, and optimization of protection and dose constraints as stated in Section IV of A.O. 149 s. 2004 or as revised shall apply.

6.1.1 The owner/licensee shall ensure compliance to the dose limits for planned exposure situation as provided in Appendix G of this A.O.

6.1.2 The owner/licensee shall ensure compliance to the operational requirements for medical, occupational and public exposure situations as provided in Appendix H of this A.O.

6.2. Classification of Areas

Relevant areas of a practice can be classified as controlled or supervised. In applying the requirements outlined in the International Basic Safety Standards (IBSS), the following can be designated as a:

6.2.1 Controlled Area

6.2.1.1. All x-ray rooms shall be classified as controlled areas.

6.2.1.2. Arrangements for classifying areas where mobile equipment is used during the time in which radiological work is being carried out.

6.2.2. Supervised Area

6.2.2.1. Areas for staff circulation other than the x-ray room such as the darkroom/image processing, reading/interpretation and storage rooms, control booth, and internal corridors.

6.2.2.2. All areas surrounding the x-ray rooms.

6.2.2.3. Areas for circulation of patients such as reception, waiting rooms, corridors from which the x-ray rooms can be accessed through the dressing cabinets.

7. Quality Assurance Program (QAP)

7.1. As required in A.O. 149, s. 2004 or as revised, a comprehensive QAP shall be established and maintained to ensure adequate assurance that the specified requirements, quality control mechanisms and procedures relating to the diagnostic uses and image quality from the use of x-ray imaging
equipment is achieved. Guidelines for the establishment of a QAP is provided in Appendix D of this AO or as revised.

7.2 A quality manual has to be prepared which shall be realistic and regularly reviewed for relevance to existing practices. This shall be made available during the conduct of RPSE and FCM.

VI TRANSITORY PROVISIONS

1. All existing x-ray facilities and facilities that are planning to put up an x-ray facility shall be given **three (3) years** from the effectivity date of this AO to comply with the quality assurance program requirements as specified in section V.B.7
2. All existing x-ray facilities shall be given **three (3) years** from the effectivity date if this AO to comply with the x-ray machine requirements as specified in Section V.B.4.2 and 4.3
3. All x-ray facilities classified as Level 3 needing the services of a CQMP shall be given **five (5) years** to comply.

VII. AMENDMENT CLAUSE

Any amendment with respect to this Administrative Order shall be put in writing.

VII SEPARABILITY CLAUSE

If any of the provisions of these regulations is found by a court of competent jurisdiction to be void and unenforceable, in whole or in part, such provision shall be deemed deleted from these regulations but the remaining provisions thereof shall remain in full force and effect.

VIII REPEALING CLAUSE

All provisions of existing DOH administrative orders, circular, regulations and other issuances inconsistent herewith are hereby repealed, amended, or modified accordingly, provided that nothing in these regulations shall be deemed to modify the existing regulations issued to special laws implemented by the FDA.

IX. PENALTY CLAUSE
Any person or establishment found to violate any of the rules and regulations set herein shall be imposed with the penalty prescribed in the Republic Act 9711 and its Implementing Rules and Regulation.

X. EFFECTIVITY

This Order shall take effect fifteen (15) days upon publication in a newspaper of general circulation and filed at the UP – Law Center, Office of the National Administrative Register (ONAR).

FRANCISCO T. DUQUE III, MD
Secretary of Health
### Appendix A

#### QUALIFICATIONS OF MEDICAL RADIATION PRACTITIONERS

<table>
<thead>
<tr>
<th>Classification of X-ray Facility</th>
<th>Medical Radiation Practitioner</th>
<th>Additional Qualification</th>
</tr>
</thead>
</table>
| Chest for Heart and Lungs        | Diplomate of the Philippine Board of Radiology (PBR) or a fellow of the Philippine College of Radiology (PCR) in good standing  
Fellow, Philippine College of Chest Physicians  
Non-radiologist physicians doing image guided fluoroscopic procedures (orthopedic surgeons, internists, urologists, nephrologists and obstetric-gynecologists) | With additional training in radiation protection  
With additional training in radiation protection |
| Level 1 – Level 3                | Diplomate of the Philippine Board of Radiology (PBR) or a fellow of the Philippine College of Radiology (PCR) in good standing  
Non-radiologist physicians doing image guided fluoroscopic procedures (orthopedic surgeons, internists, urologists, nephrologists and obstetric-gynecologists) | With additional training in radiation protection |
| Specialized                      | **Interventional Radiology:**  
- Fellow of the Philippine Society of Vascular and Interventional Radiology (PSVIR)  
- Fellow of the Philippine Heart Association (FPHA) with specialization in interventional cardiology  
- Fellow of the Philippine Society of Cardiac Catheterization Interventionalists (PSCCI) | PHA and PSCCI: With additional training in Radiation Protection in Interventional Radiology |
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Required Qualifications</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mammography:</strong></td>
<td>Diplomate of the Philippine Board of Radiology (PBR) or a fellow of the Philippine College of Radiology (PCR) in good standing.</td>
</tr>
<tr>
<td><strong>Computed Tomography:</strong></td>
<td>Diplomate of the Philippine Board of Radiology (PBR) or a fellow of the Philippine College of Radiology (PCR) in good standing. Fellow, CT-MRI Society of the Philippines.</td>
</tr>
<tr>
<td><strong>Bone Densitometry:</strong></td>
<td>Member, Osteoporosis Society of the Philippines. Member, Philippine Society of Nuclear Medicine. With additional training in radiation protection.</td>
</tr>
<tr>
<td><strong>Lithotripsy:</strong></td>
<td>Member, Philippine Urological Association. With additional training in radiation protection.</td>
</tr>
</tbody>
</table>
| **Tumor Localization and Simulation:** | DPBR/FPCR  
DPBR-RO  
FPROS |
|                                    |  
|
Appendix B

ROLES AND RESPONSIBILITIES OF A CLINICALLY QUALIFIED MEDICAL PHYSICIST IN DIAGNOSTIC AND INTERVENTIONAL RADIOLOGY

(References: IAEA HUMAN HEALTH SERIES No. 25)

(a) Installation design, technical specification, acceptance and commissioning of equipment, including the establishment of criteria for acceptable performance: Within the technical specification, acceptance, commissioning and supervision of the proper operation of equipment, and the establishment of criteria for its acceptable performance, the following roles and duties must be considered:

(i) CQMPs are an essential part of the design team for new installations. They are responsible for shielding and installation design of new or modified radiology rooms, ensuring that all safety requirements are complied with. They calculate and provide the thickness, material composition and placement of shielding needed to protect patients, staff and the general public, and supervise the construction, thus guaranteeing that all requirements of safety and functionality are met. They also verify the adequacy of the shielding after installation.

(ii) CQMPs have a leading role in preparing equipment specifications and they participate in the tender evaluation and purchase recommendation of equipment. They perform analysis of the functional requirements for clinical use, and specify conditions for integration, compatibility and connectivity of the equipment to be purchased.

(iii) Following the installation of new equipment, or after any significant change or service, CQMPs are responsible for specifying the basic standards to be applied for its acceptance and subsequent commissioning. They ensure that all units and systems function according to their technical specifications and provide advice on any deviation of equipment performance from acceptable criteria, including guidance on decommissioning when appropriate. CQMPs also have, often in collaboration with computer engineers, responsibility for the verification of the computer systems; they assist medical practitioners in evaluating imaging or diagnostic algorithms for their safe and effective clinical use.

(b) Radiation safety and protection of patients, staff and the general public: CQMPs have responsibilities in the development and implementation of a clinical radiation safety programme for the radiation protection of patients in areas where DIR equipment is used. In the majority of cases, however, the CQMP also has responsibilities with respect to the radiation safety of the staff and the public, as it pertains to the radiology service and infrastructure. CQMPs are responsible for developing procedures for testing the integrity of the equipment and accessories, for the proper operation of dosimetry equipment and other safety features. They also participate in the investigation of incidents involving radiation and they provide the appropriate report and documentation.

c) Patient dosimetry: CQMPs are responsible for establishing procedures for the calculation and verification of the radiation dose received by the patient. Their duties include dosimetry measurements as well as the development of methods to analyse the results of the
measurements and verify the accuracy of doses delivered to patients. In special cases, duties also involve individual patient dose calculations. Tasks related to patient dosimetry include:

i) Measurements and calculation of absorbed doses: CQMPs use data acquired during commissioning and information from dosimetry measurements to estimate the absorbed dose by patients during different clinical procedures. This requires the use of analytical calculations, computerized models or in-phantom measurements. Judgement with respect to the applicability of the models used and the ability to synthesize new models is necessary, as well as knowledge to estimate dosimetry uncertainties.

(ii) Specific patient dose calculations: CQMPs are responsible for the measurement and/or calculation of individual patient doses and foetal doses in cases where a patient is found to be pregnant. This may include detailed measurements. They establish tolerances and make judgements on the appropriateness of the measured data, including advice to the medical practitioner and the patient on any associated risks, especially those related to the induction of cancer.

(iii) Patient dose estimations to establish diagnostic reference levels (DRLs), or to verify conformity with recommended DRLs by national or international regulations: CQMPs have responsibilities in reviewing procedures and equipment when DRLs are consistently exceeded in standard procedures (d) Optimization of physical aspects of diagnostic and interventional procedures: CQMPs have responsibilities in the optimization of the physical and technical aspects of the different processes used to produce medical images and the necessary imaging equipment (analogue and digital x-ray units, CT, angiography units, etc.). They also assist medical practitioners in the evaluation of examination efficacy and participate in image quality and perception studies.

(e) Quality management of the physical and technical aspects: CQMPs participate as team members in establishing a quality management programme and have responsibility for the physical and technical aspects. They are primarily responsible for developing and implementing procedures for the initial and continuing evaluation of the DIR equipment as well as for the calibration of dosimetry equipment. Related tasks comprise:

(i) Developing institutional policies and procedures for the continuous optimization of radiation use, which includes responsibility for writing new policies and procedures, or updating existing ones, related to: — Policies and procedures related to objectives, such as improvement of quality of service, productivity of personnel, handling of new equipment and information systems, and training of personnel; — Procedures related to patient investigations, e.g. for patients with special needs, and review of patient dosimetry information, immediately reporting any anomalous finding to the responsible medical practitioner; — Procedures related to safety, e.g. procedures related to radiation protection, personnel monitoring, reporting of incidents and accidents, QA, and patient and personnel radiation dose and associated risks; — Procedures related to equipment, for the immediate notification of equipment failure to technical staff.
(ii) Establishing a QA programme for verifying, setting and accepting the initial reference values of parameters for optimal image quality and the initial reference state of the imaging equipment: This includes developing and implementing QC, ensuring that periodic QC measurements are carried out for the x ray units and associated equipment for image visualization, processing, storage and printing. CQMPs are also responsible for ensuring compliance of the imaging equipment with government and accreditation agency regulations and recommendations.

(iii) Performing risk assessments and identifying possible radiation emergencies, such as incidents resulting from equipment malfunction or human error: CQMPs develop action procedures to be followed in the event of such occurrences and carry out drills to verify that procedures can be carried out correctly.

(iv) Investigating unintended or accidental medical exposures, such as sentinel events in interventional radiology: CQMPs provide consultation on the doses received by patients or personnel and on the associated risks, and recommend measures to minimize the chances for accidents to happen again.

(f) Collaboration with other clinical professionals: CQMPs are key members of the team of clinical professionals, including radiological medical practitioners and other clinical specialists, technologists and nursing staff, that work together for the diagnosis and treatment of patients. The contribution of medical physicists in this respect includes:

(i) Consultations to medical practitioners on special patient cases that may be encountered during diagnostic or interventional procedures that require additional actions to those routinely established: The collaboration between the medical practitioners and the CQMPs helps in establishing the optimal approach for each case.

(ii) Supervision of the technologists in the implementation of new clinical procedures, being key members of the team responsible for the introduction of new clinical procedures in the institution: CQMPs are also responsible for developing methods for QA of the new procedures.
Appendix C

RADIATION PROTECTION PROGRAMME IN DIAGNOSTIC RADIOLOGY
(Adapted from IAEA Safety Report Series No. 39)

The radiation protection programme of the diagnostic x-ray facility shall include the following information:

I. General Information of the Facility
   a. Description of the whole facility including the services it offers.
   b. Description of the radiology department, equipment, radiology services, and patient workload.
   c. Organizational structure including the management commitment on compliance to regulatory requirements and the practice of radiation protection.
   d. Number of staff involved in the operation of the x-ray facility. Provisions to ensure that only qualified personnel assume the responsibility for using radiation.
   e. Appointment of the radiation protection officer and its qualification.
   f. Roles and responsibilities of the RPO, diagnostic radiology medical physicist, and radiologic technologists. Provisions that these roles and responsibilities are understood by personnel concerned.

II. Radiation Protection Program
   A. Security of X-ray Sources
      1. Describe the procedure for inventory of all x-ray equipment and policy to prevent unauthorized access and use of x-ray machines.
      2. Describe the rules and procedures for purchasing, use, and repairs of the x-ray equipment.
   B. Protection for Occupational Exposure
      1. Provisions to inform the workers about their obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of sources.
      2. Description of the policy on pregnant workers.
      3. Classification/Identification of controlled and supervised areas including the policies on the access of these areas. Arrangements for classifying areas where mobile equipment is used during the time in which radiological work is being carried out.
      4. Local Rules and Supervision - Procedures for ensuring adequate levels of protection and safety of workers; Provisions to make sure that these procedures, the protective measures, and safety provisions are known to those workers to whom they apply and to other persons who may be affected by them; Supervision to ensure observance of the procedures; and Investigation levels in place.
      5. Describe the procedure for inventory of personal protective equipment including the policy on their proper use.
      6. Individual monitoring and exposure assessment – Discuss the arrangements to provide individual personnel radiation dose monitoring from an accredited service provider. This includes the identification of staff members requiring individual
monitoring; Establishment of the monitoring period, frequency for reading and recording the accumulated doses, and rules for returning and changing dosimeters. Provisions to ensure that details of doses are made available to the staff and procedures for estimating the worker’s dose if a personal dosimeter is lost or damaged.

7. Health Surveillance – Describe the program for health surveillance of workers based on general principles of occupational health designed to assess the initial and continuing fitness of workers for their intended tasks.

C. Protection for Medical Exposure

1. Responsibilities — Assignment of the overall responsibility for patient protection and safety to a medical practitioner; Assignment of the responsibility for conducting or supervising calibration of equipment, clinical dosimetry and QA to a qualified expert on diagnostic radiology physics; Provision and documentation of continuous education and training of all staff; Training shall include lessons from accidents and their prevention included in the training.

2. Justification of medical exposure — Describe the policies and procedure in place for the prescription and administration of medical exposure to ensure that these are justified; If applicable, indicate the department’s policy to justify research involving application of radiation on humans.

3. Optimization – Policy for optimization to ensure that the exposure of patients is the minimum required to achieve the intended diagnostic objective, taking into account relevant information from previous examinations in order to avoid unnecessary additional examinations, and taking into account the relevant guidance levels for medical exposure.

4. Clinical Dosimetry – procedures in the determination of representative values for average sized adult patients of entrance doses, dose area products, dose rates, or organ doses.

5. Investigation of accidental medical exposure - Policies in place to investigate and report: (a) Any diagnostic exposure substantially greater than intended or resulting in doses repeatedly and substantially exceeding the established guidance levels; and (b) any equipment failure, accident, error, mishap or other unusual occurrence with the potential to cause a patient exposure which is significantly different from that intended; Provisions to estimate the doses received, and indicate and implement corrective measures and to follow-up of patients who received high exposure procedures with the potential for deterministic effects, such as prolonged interventional procedure.

D. Protection for Public Exposure - Shielding design with due consideration of public exposure; Control of access of public and visitors in place; Design of pathways designed to minimize interference from the public with console control space and radiology rooms to avoid potential exposure.
Appendix D

QUALITY ASSURANCE PROGRAM

The responsibility for long-range planning of quality assurance goals and activities shall be assigned to the QA/QC committee especially for large facilities.

1. Requirements of a Quality Assurance Program (QAP):

Implementation, monitoring and overall quality assurance program of the institution/facility is one of the primary responsibilities given to the licensee. The licensee shall ensure the following:

1.1 Creation of a QA/QC Committee.

Creation of this committee ensures the commitment for the establishment and maintenance of a quality assurance program. This committee shall be responsible for all the QA activities in the radiology department. The QA/QC committee shall be composed of the following personnel/staff in a radiology department:

a. Head of the X-ray Facility
b. Medical Physicist, if available
c. Chief Radiologic Technologist
d. Radiologic Technologists
e. Resident physician/s
f. other radiology staff (e.g. nurses, administrative staff, etc.)

Each member shall have clearly identified roles and responsibilities and should be documented. Meetings regarding QA/QC must be conducted periodically. Records of the minutes of the meetings must be kept.

1.2 Establishment of Standards or Criteria in the Evaluation of Radiographs/Images per x-ray examination or procedures performed in the x-ray facility.

Each x-ray examination performed in the facility shall have basis for classifying radiographs as either good, poor or reject. It is the responsibility of all the radiologists to come up with standards/criteria in the classification of radiographs/images.

1.3 Conduct of an Image/Film Analysis Program.

This shall be done prior to and after the establishment of a QAP. Film/image analysis is conducted to ensure the reduction of repeated radiographs. Monthly reports of film analysis shall be kept and reviewed by the QA/QC Committee to verify frequent causes of poor and reject images, which shall consequently initiate corrective actions and improvement of the image quality.
1.4 Formulation of a Standard Radiographic Technique Chart per X-ray equipment.

A standard radiographic technique chart shall be formulated for each x-ray equipment. The chart shall be posted in a conspicuous place in the control console booth. A copy of the technique parameters for the x-ray procedures shall be kept for anatomically programmed x-ray equipment.


The quality assurance manual should be written in a format permitting convenient revision as needed. It should be made readily available to all personnel. The content of the manual should be determined by the facility staff. The quality assurance manual should also be reviewed, at least annually, to determine effectiveness and improvement of the QAP. The manual shall contain the following:

1.5.1 List of the individuals responsible for the monitoring and maintenance of QAP;
1.5.2 Description of the radiographic examinations performed and standard operating procedures, including a description of the standards, criteria of quality, or limits of acceptability for images/radiographs;
1.5.3 Description of the quality control procedures and criteria of acceptability for each x-ray equipment;
1.5.4 Description of procedures to be followed when errors are detected;
1.5.5 Description of appropriate training to be attended by all personnel involved with quality assurance responsibilities;
1.5.6 Description of the standards for image quality to ensure that they are consistent with the needs and resources of the facility;
1.5.7 Description of the preventive maintenance program for each x-ray equipment; and,
1.5.8 Description of service arrangement with other organizations and qualified experts.

1.6 Maintenance of room logs containing the records of quality control (QC) test results per x-ray equipment, darkroom accessories and other ancillary equipment e.g. laser printers, CR readers, etc.

1.7 Records of maintenance and repair work for each x-ray equipment.

1.8 Provisions of appropriate training for all personnel with responsibilities to quality assurance program.

2. Scope of a Quality Assurance Program:

The QAP shall include:

2.1. Image quality assessments: Image quality assessments are assessed by quantitative measurements and clinical images based on anatomical criteria.
2.2. Image reject analysis/Reject Analysis Program: This has to be performed prior to the establishment of QAP and thereafter. Image quality criteria shall be
discussed among the radiologists and radiologic technologists so as to come up with a
standard image quality and radiographic techniques.

2.3. **Provision for Comfort and Privacy of Patients.** Analysis of patient waiting
time, clean and well-ventilated room as well as provision of clean and comfortable
patient gown, linen, pillows and couch is of importance in this aspect

2.4. **Patient dose evaluations.** Establishment of reference doses based on the output
measurements conducted on the x-ray equipment and the technique parameters used
for each x-ray procedure.

2.5. **Periodic Quality Control Program for all X-ray Units:** Quality Control
includes the visual/mechanical inspection and performance testing of all available x-
ray units and accessories in the hospital/institution.

2.6. **Monitoring and maintenance:** Routine quality control monitoring and
maintenance procedures for x-ray equipment and accessories shall be established and
conducted on a regular schedule. The purpose of monitoring is to permit evaluation of
the performance of the facility’s x-ray system/s in terms of the standards for image
quality established by the facility and compliance with the relevant regulatory
requirement/s. The maintenance program should include preventive maintenance,
which could prevent unexpected breakdowns of equipment and disruption of
departmental routine. This should also include corrective maintenance to eliminate
equipment problems before they have a serious deleterious impact on patient care.

2.7. **Verification and review of the appropriate physical and clinical factors used
in patient’s diagnosis of diseases.**

2.8. **Written records of relevant procedures and results.**

3. **Quality Control (QC) Program:**

Identification of the various parameters to be monitored in a radiography,
fluoroscopy, CT, mammography, and interventional radiography equipment that greatly
affects both the image quality and its performance shall be carried out prior to the
establishment of QCP.

Routine Performance testing and QC comprises those tests that are undertaken either
regularly or after maintenance or repairs, to detect whether any change in the performance of
the equipment has occurred that would require corrective action.

Routine performance tests are really a subset of the commissioning tests and will
generally involve staff with different levels of expertise, some of whom may be external to
the radiology facility. The more frequent tests that are to perform are usually undertaken
locally with advice from a medical physicist, while the more complex and time consuming
tests may require special expertise and instrumentation. A collaborative, multidisciplinary
approach to routine performance testing is essential.

Outline of QC Tests:
These tests are intended to verify the stability in the operation of the equipment or elements used to acquire the image. The tests can be described in three ways with some of their key characteristics described below:

3.1 Frequency—The recommended frequency of a routine performance test varies from daily to yearly. It is often given as a range (e.g. three to six monthly) because the frequency selected should depend on the equipment characteristics (e.g. age reliability) and the clinical workload to which the equipment is subjected. A lower frequency of tests may be appropriate for simple imaging equipment that is used less frequently or for equipment where experience shows that parameters are unlikely to change. The frequency of tests may also be designated as essential and desirable, for example, a test may be essential every year but desirable every six months.

3.2 Priority: The priorities for indicating whether a routine performance test is recommended may be denoted as:

3.2.1 Essential: Represents the minimum recommended standard; conformance to this standard of testing would be regarded good practice.

3.2.2 Desirable: The inclusion of this level of testing would be regarded as best practice. However, it is recognized that the implementation of these tests may be constrained by test equipment costs, personnel availability, equipment characteristics, clinical workload or other factors.

3.3 Performance standards: QC tests help maintain equipment performance through the use of tolerance criteria that are applied to QC test results. These performance standards can be characterized as acceptable and achievable;

3.3.1 Acceptable: Indicates that performance must be within these tolerances and if it is not, the equipment should not be used.

3.3.2 Achievable: Indicates the level of performance that should be attained under favorable circumstances; if feasible, this is the level at which a facility should work.
Appendix E  
SPECIFIC X-RAY MACHINE REQUIREMENTS AND ACCESSORIES

A. SPECIFIC X-RAY MACHINE REQUIREMENTS:

1. Radiographic/Fluoroscopic X-ray Machines

1.1. For digital radiography systems, a program/software that automatically stores rejected images into an image reject folder shall be provided. Such folder shall only be accessible to the medical physicist or quality control technologist.

1.2. Fluoroscopy machines shall be provided with:
   1.2.1 user selectable mode of operations such as low dose, normal, or high dose fluoroscopy, and pulsed fluoroscopy.
   1.2.2 Where practicable, protective materials shall be affixed to the x-ray equipment or otherwise installed in such a way as to be interposed between sources of scattered radiation and x-ray personnel. These materials shall have a lead equivalence of not less than 0.5 mm. Protective materials shall be effective in any position of the image intensifier assembly. They shall not obstruct palpation or other necessary manipulation of the patient.
   1.2.3 For remote controlled fluoroscopy systems, a protective barrier shall be provided for the operator.
   1.2.4 Image intensification device shall be provided on all fluoroscopic equipment.
       The use of direct viewing fluoroscopes shall not be allowed.
   1.2.5 Fluoroscopic devices shall be equipped with a last image hold system which keeps on display the last fluoroscopic image obtained.

2. Mammography X-ray Machine

   a. A permanent radiation protection barrier for the technologist shall be provided. The lead viewing glass of the barrier shall have a lead equivalence of at least 0.3 mm
   b. A mechanical compression and decompression device shall be provided. The paddle shall be flat with minimal chest wall radius and shall remain parallel to the breast support at an acceptable compression force. It shall automatically release the compression force after radiation exposure.
   c. An indicator of breast thickness and compression force shall be made available.
   d. A face shield used to restrict the head of the patient from the useful radiation beam shall be provided.

3. Computed Tomographic Machine

   3.1. A slice positioning light localizer shall be provided.
3.2. An emergency stop switch shall be provided on or near the patient support and/or gantry to immediately terminate the motion of the equipment and the emission of X-rays.

3.3. Information of the accumulated radiation dose per CT procedures should be displayed in the image acquisition monitor.

3.4. Controls to adjust the position of the couch shall be provided in the gantry.

4. For interventional radiology, bone densitometry, and lithotripsy, requirements for radiographic and/or fluoroscopic machines shall apply.

5. For tumor localization and simulation utilizing conventional x-ray machines, requirements for radiography and/or fluoroscopy machines shall apply.

6. Digital imaging systems shall be equipped with the following:

6.1. Image acquisition system which shall be of direct image detector, indirect image capture using computed radiography, or medical grade radiographic film scanner with a minimum of 2.5 lp/mm for general radiography and 5.0 lp/mm for mammography. Image acquisition systems shall be compliant to Digital Imaging and Communications in Medicine (DICOM) standards.

6.2. Workstation monitors to display and process newly acquired x-ray images. The workstation shall be capable to display patient demographics, contrast adjustment, magnification and pan functions, rotation or flipping of images, measurements, and calculation and display of appropriate pixel value or exposure indicators.

6.3. Medical grade image displays to be used for the interpretation of x-ray images. The monitors shall have a resolution of at least 2 megapixels except for mammography which shall have at least 5 megapixel of resolution.

6.4. Image archiving, retention, and retrieval system appropriate and compliant with the requirements for teleradiology.

6.5. Ambient operating temperatures between 18° and 30° Celsius and between 20% and 80% condensing humidity shall be maintained since digital devices are based on electronics and are computer controlled.

B. REQUIRED ACCESSORIES FOR SPECIFIC X-RAY MACHINES:

Where applicable, each x-ray machine shall be provided with the following radiological accessories:

1. For general radiography and fluoroscopy.
   1.1. A caliper to measure the thickness of the patient.
   1.2. A set of contact gonad shields for male, female and infant with a minimum lead equivalence of 0.25 mm.
   1.3. A pair of lead rubber gloves with minimum lead equivalence of 0.25 mm.
   1.4. A lead rubber apron with minimum lead equivalence of 0.25 mm.
1. For fluoroscopy, each personnel present during fluoroscopic examination shall be provided with the following:
   1.5. A wrap around lead rubber apron with minimum lead equivalence of 0.25 mm.
   1.6. Thyroid shields with minimum lead equivalence of 0.25 mm.
   1.7. Lead goggles with a minimum lead equivalence of 0.2 mm.

2. For computed tomography
   2.1. A quality assurance phantom and other ancillary equipment necessary for the conduct of routine quality assurance program shall be provided. This is to assure that the performance of the computed tomography system is reproducible within a range specified by the particular manufacturer.
   2.2. Automatic contrast injector shall be provided.
   2.3. A lead rubber apron with minimum lead equivalence of 0.25 mm.
   2.4. Thyroid shields with minimum lead equivalence of 0.25 mm.

3. For Mammography
   3.1. A quality assurance phantom and other ancillary equipment necessary for the conduct of routine quality assurance program shall be provided. This is to assure that the performance of the mammography system is reproducible within a range specified by the particular manufacturer.
   3.2. Densitometer and sensitometer shall be provided. For digital mammography units, sensitometer is not required.
## Appendix F

### Table 1. Minimum Performance Criteria for X-ray Equipment

<table>
<thead>
<tr>
<th>Type of Equipment</th>
<th>Test Parameters</th>
<th>Performance Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Radiography</td>
<td>Visual/Mechanical Checks</td>
<td>All moving parts shall be properly working and free from obstruction. Surfaces in contact with the patient shall be smooth. Cables shall be properly kept.</td>
</tr>
<tr>
<td></td>
<td>Collimation Accuracy:</td>
<td>The total misalignment shall be within ±2% of SID. Each side shall be within ±1% of SID.</td>
</tr>
<tr>
<td></td>
<td>-Check for X-ray and light field misalignment</td>
<td>The misalignment between x-ray field and image receptor shall be within ±1% of the SID.</td>
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<tr>
<td></td>
<td>Generator Tests:</td>
<td></td>
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<tr>
<td></td>
<td>-Check for kVp Accuracy and Reproducibility</td>
<td>For 100 kVp and below: The actual kVp shall be within ±6% of the set kVp.</td>
</tr>
<tr>
<td></td>
<td>-Check for Output Reproducibility</td>
<td>For 101 kVp and above: The actual kVp shall be within ±6 kVp of the set kVp.</td>
</tr>
<tr>
<td></td>
<td>-mA or mAs Linearity Check</td>
<td>-The coefficient of variation (COV) for the output measurements shall be within 0.05.</td>
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<td></td>
<td></td>
<td>-The overall coefficient of linearity shall be ≤ 0.1</td>
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<td></td>
<td>-Same as the criteria for the general radiography.</td>
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<tr>
<td></td>
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<td>-The edges of the collimation for fluoroscopy shall be visible. If not visible, the measurement of the</td>
</tr>
<tr>
<td>Radiographic/Fluoroscopy, Lithotripsy,</td>
<td></td>
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<tr>
<td>bone densitometry and interventional</td>
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<tr>
<td>radiology</td>
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<tr>
<td>Computed Tomography</td>
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<tr>
<td>Auto Collimation Function Test (This test is done if the SID is variable only)</td>
<td>-The size of the collimation shall be the same regardless of SID setting.</td>
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<tr>
<td>Generator Tests:</td>
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</tr>
<tr>
<td>-Check for “Fluoroscopy” kVp Accuracy and Reproducibility</td>
<td>For 100 kVp and below: The actual kVp shall be within ±6% of the set kVp.</td>
<td></td>
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<tr>
<td></td>
<td>For 101 kVp and above: The actual kVp shall be within ±6 kVp of the set kVp.</td>
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<td></td>
<td>The coefficient of variation (COV) for the set kVp measurements shall be within 0.05.</td>
<td></td>
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<tr>
<td></td>
<td>The coefficient of variation (COV) for the output measurements shall be within 0.05.</td>
<td></td>
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<tr>
<td>-Check for output reproducibility</td>
<td></td>
<td></td>
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<tr>
<td>-Maximum Fluoroscopic Exposure Rate</td>
<td></td>
<td></td>
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<tr>
<td>-Check for Maximum Fluoroscopic Time</td>
<td></td>
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<tr>
<td>-Visual and Mechanical Checks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Scan Localization Light Accuracy</td>
<td></td>
<td></td>
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<tr>
<td>-Patient Table Position</td>
<td></td>
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<tr>
<td></td>
<td>The intensity of x-ray beam at tabletop shall not exceed 10 R/min for units equipped with ABS and 5 R/min for units without ABS.</td>
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<tr>
<td></td>
<td>An audible signal shall be activated whenever the 5 minute fluoroscopy time is reached. Means shall be provided to reset the fluoroscopy time.</td>
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<td></td>
<td>All switches and buttons shall be functioning properly. Patient couch shall move smoothly and free from obstructions.</td>
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<tr>
<td></td>
<td>The misalignment between the scan plane and the scan localization light position shall be within ±2 mm.</td>
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<tr>
<td></td>
<td>The maximum “in” and “out” movement</td>
<td></td>
</tr>
<tr>
<td>Mammography</td>
<td>Reproducibility</td>
<td></td>
</tr>
<tr>
<td>-------------</td>
<td>----------------</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- CT Number Accuracy</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- CT Number Uniformity</td>
<td></td>
</tr>
<tr>
<td>- Visual/Mechanical Checks</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>- Check for the compression device</td>
<td></td>
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<tr>
<td></td>
<td>- Check for the Collimation Accuracy</td>
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</tr>
</tbody>
</table>

**Generator Tests:**

- Check for the kVp Accuracy and Reproducibility

**Reproducibility**
- CT Number Accuracy shall be reproducible within ±1 mm.
  - The CT Number of air shall be within 1000±100 HU; while the CT Number for water is 0±4 HU.
  - The CT numbers of the outer ROIs in the peripheries shall not deviate from the central ROI by ±2 HU.

- CT Number Uniformity
  - All moving parts, switches, knobs and buttons shall be properly working and free from obstruction. Accessories and surfaces in contact with the patient shall be smooth. Cables shall be properly kept.
  - The initial compression force shall be 25 lbs, and the maximum compression force shall not exceed 45 lbs.
  - The decompression device shall automatically release the breast compression after the radiation exposure or when necessary.
  - The total misalignment shall be within ±2% of SID. Each side shall be within ±1% of SID.
  - The edge of the compression paddle shall not be seen on the image receptor and shall be projected beyond the chest wall edge of the image receptor by more than ±1%SID.

- Visual/Mechanical Checks
  - The actual kVp shall be within ±5% of the set kVp. The COV of all the measurements for the set kVp shall be ≤0.05.
- Check for the output reproducibility

- AEC Performance Assessment

- Image Quality Evaluation

- Measurement of Average Glandular Dose

The coefficient of variation (COV) for the output measurements shall be within 0.05.

The AEC shall be capable of maintaining the optical density within ± 0.15 or MPV by ±15 % when the thickness of the phantom is varied from 2-6 cm and the kVp is varied over the range of those used clinically for those thicknesses.

The criteria set by the phantom manufacturer for image quality evaluation shall be followed.

The average glandular dose shall not exceed 3 mGy per view for image receptor with grid and 1 mGy for image receptor without grid.

Table 2. Frequency of testing

<table>
<thead>
<tr>
<th>X-ray Machine</th>
<th>Frequency of Performance Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Radiography and/or Fluoroscopy</td>
<td>Once every Four years</td>
</tr>
<tr>
<td>Bone Densitometry</td>
<td>Once every Four years</td>
</tr>
<tr>
<td>Lithotripsy</td>
<td>Once every Four years</td>
</tr>
<tr>
<td>Mammography</td>
<td>Once every Two years</td>
</tr>
<tr>
<td>Interventional Radiology Machine</td>
<td>Once every Two years</td>
</tr>
<tr>
<td>Computed Tomography</td>
<td>Once every Two years</td>
</tr>
<tr>
<td>Tumor Localization and Simulation</td>
<td>Once every Two years</td>
</tr>
</tbody>
</table>
APPENDIX G

DOSE LIMITS FOR PLANNED EXPOSURE SITUATIONS

(Reference: IAEA GSR Part 3 Schedule III)

OCCUPATIONAL EXPOSURE

1. For occupational exposure of workers over the age of 18 years, the dose limits are:

   a. An effective dose of 20 mSv per year averaged over five consecutive years\(^1\) (100 mSv in 5 years) and of 50 mSv in any single year;
   b. An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
   c. An equivalent dose to the extremities (hands and feet) or to the skin\(^2\) of 500 mSv in a year.

Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast-feeding (Section --- AO on GSR Part 3).

PUBLIC EXPOSURE

2. For public exposure, the dose limits are:

   a. An effective dose of 1 mSv in a year;
   b. In special circumstances, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years does not exceed 1 mSv per year;
   c. An equivalent dose to the lens of the eye of 15 mSv in a year;
   d. An equivalent dose to the skin of 50 mSv in a year.

\(^1\) The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Standards, with no retrospective averaging.

\(^2\) The equivalent dose limits for the skin apply to the average dose over 1 cm\(^2\) of the most highly irradiated area of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.
Appendix H

GUIDELINES ON OPERATIONAL REQUIREMENT FOR THE SPECIFIC RADIATION EXPOSURE CATEGORIES

1. Medical Exposures:

1.1. All x-ray examination shall be performed only when necessary for obtaining diagnostic information.

1.2. If two or more medical x-ray examinations that provide the appropriate diagnostic information are readily available, then the procedure that yields the least overall risk to the patient shall be chosen.

1.3. Any radiological examination for occupational, legal, or health insurance purposes that are undertaken without reference to clinical indications, shall deemed to be not justified, unless it is expected to provide useful information on the health of the individual examined, or unless the specific type of examination is justified by those requesting it in consultation with relevant professional bodies.

1.4. Mass screening of population groups involving medical exposure is deemed to be not justified unless the expected advantages for the individual examined or for the population as a whole are sufficient to compensate for the economic and social costs, including radiation detriment.

1.5. A medical x-ray examination shall only be performed if there is a request from a referring physician. However, when a physician refers a patient for an imaging procedure, it should be understood that the patient is being referred for an opinion. If there is a significant risk to the patient or it is believed that such a request is inappropriate, it is both the right and duty of the qualified medical radiation practitioner as described in Section V. B. item 3.3.1 to refuse to undertake any particular procedure. A legitimate and logical reason for such refusal shall be provided to the referring physician.

1.6. All x-ray examinations shall be performed only by or under the immediate supervision of qualified personnel described in Section V.B. item 3.3.4.

1.7. Requests for x-ray examination shall be signed by the referring physician and shall include the following information in legible form:

  1.7.1 Patient’s name, age, sex, status and address
  1.7.2 Date of request, brief clinical history and examination requested.
  1.7.3 Tentative diagnosis
  1.7.4 Name and signature of referring physician

1.8. Protocols on patient referral shall be documented. Where practicable, x-ray examinations shall be performed inside a room that is properly shielded in accordance with Section V.B item 5.2

1.9. A radiographic technique established by the radiologic technologist and approved by the medical radiation practitioner shall be provided for each x-ray machine.
1.10. The technique chart signed by the radiologic/xray technologist and the medical radiation practitioner should be posted in a conspicuous place near the control console.

1.11. Doors leading to the x-ray examination room shall be closed during the conduct of x-ray examinations.

1.12. All x-ray examination shall be performed with a properly functioning x-ray machine.

1.13. In order to minimize the frequency of unintentional irradiation of the embryo or fetus, the following advisory notice shall be posted at several places within diagnostic x-ray department and other areas where diagnostic x-ray equipment is used: **IF IT IS POSSIBLE THAT YOU MIGHT BE PREGNANT, NOTIFY THE PHYSICIAN OR RADIOLOGIC/X-RAY TECHNOLOGIST BEFORE YOUR X-RAY EXAMINATION.**

1.14. When a pregnant woman is required to undergo an x-ray examination in which the x-ray beam irradiates the fetus directly, special care has to be given and that it should not be delayed until after the pregnancy. Sometimes the radiation risk to the fetus is less than that of not making the necessary diagnosis, so that the x-ray examination should still be done when medical indications are appropriate. In such cases, greater than usual care should be taken to minimize the absorbed dose in the fetus for each irradiation. However, alterations of technique should not reduce unduly the diagnostic value of the x-ray examination.

1.15. Sensitive body organ (e.g. lens of the eye, gonads) shall be shielded whenever they are likely to be exposed to the useful beam provided that such shielding does not eliminate useful diagnostic information.

1.16. When patients must be held during examinations, all efforts shall be undertaken to avoid having assistance provided by persons who work within the x-ray department.

1.17. No pregnant woman or persons under the age of 18 years shall be permitted to hold patients.

1.18. Persons holding the patients shall wear protective aprons and gloves. Even if protective clothing is worn, those holding the patients shall make sure as far as practicable, that no part of their body, even if covered by protective clothing is in the path of the useful beam.

1.19. Only persons whose presence is necessary shall be in the x-ray room during exposures. All such persons shall wear appropriate protective devices. All medical x-ray examinations shall have written results signed by the qualified medical radiation practitioner as given in Section V. B. item 3.3.1

1.20. The written result shall reflect the name and signature of the radiologic/x-ray technologist who performed the radiographic examination.

1.21. Fluoroscopy shall not be used as a substitute for radiography.

1.22. During the use of the computed tomography machine, the slice thickness shall be as big as possible and the number of slices shall be as small as practicable.
1.23. During mammographic procedures, the proper compression of the breast shall be observed.

1.24. For mobile radiography, the radiologic/x-ray technologist shall ensure that no person other than the patient will be exposed to the useful beam.

2. Occupational Exposures:

2.1. The radiologic/x-ray technologist shall wear a personal monitoring device.

2.2. The radiologic/x-ray technologist shall stay behind the protective barrier and shall observe the patient during x-ray examination.

2.3. Protective aprons and thyroid shields shall be worn in the fluoroscopy room by each person, except the patient. People who must move around the room during the procedure shall wear a wrap-around protective apron.

2.4. Mobile x-ray machine shall be used only when it is not possible to transfer patients to fixed installations. If this were the case, the technologists and the other persons within the area shall stay at least 2 meters from the patient, the x-ray tube and the useful beam.

2.5. During the use of a mobile x-ray machine the radiologic/x-ray technologist shall wear a protective apron with 0.25 mm lead equivalence.

2.6. For occupational exposure of workers over the age of 18 years, the dose limits are:

   2.6.1 An effective dose of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
   2.6.2 An effective dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
   2.6.3 An equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a single year.

2.7. For occupational exposure of apprentices of 16 to 18 years of age who are being trained for employment workers over the age of 18 years, the dose limits are:

   2.7.1 An effective dose of 6 mSv in a year;
   2.7.2 An effective dose to the lens of the eye of 20 mSv in a year;
   2.7.3 An equivalent dose to the extremities (hands and feet) or to the skin of 150 mSv in year.
3. **Public Exposures**

3.1. All areas accessible to the members of the public shall be situated away from the x-ray examination rooms.

3.2. The walls of the x-ray examination room near the waiting area shall be properly shielded from scattered radiation.

3.3. For public exposure, the dose limits are:

   3.3.1 An effective dose of 1 mSv in a year.

   3.3.2 In special circumstances, a higher value of effective dose in a single year could apply, provided that the average effective dose over five consecutive years The dose to the members of the public shall not exceed 1 mSv/year.

   3.3.3 An equivalent dose to the lens of the eye of 15 mSv in a year;

   3.3.4 An equivalent dose to the skin of 50 mSv in a year.
Appendix I

DUTIES AND RESPONSIBILITIES OF A RADIATION PROTECTION OFFICER

- Establish, implement, maintain and administer a radiation protection program of the facility.
- Prepare and or revise a radiation protection manual.
- Ensures that all relevant regulations and license conditions are followed.
- Arranges and administers appropriate individual and workplace monitoring and ALARA programs for practices and interventions of the facility.
- Assess, review and keep records of the individual and workplace monitoring reports.
- Institutes education and training of personnel in radiation protection.
- Determines the shielding required for new or renovated equipment rooms for ionizing radiation.
- Design of special shielding devices.
- Facilitates compliance with all regulating and certifying agencies, Commission, Joint Commission on the Accreditation of Healthcare Organizations, Occupational Safety and Health Administration, and appropriate state and local agencies.
- Review of policies and procedures related to radiation safety and action levels.
Appendix J

DUTIES AND RESPONSIBILITIES OF A QUALITY CONTROL TECHNOLOGIST

All staff in the radiology department should be involved in quality control. However, specific tests are usually performed more effectively by specially trained technologists. The amount of time spent on QC should be adequate to perform the functions required for an effective quality control program. QC technologists should be allowed to devote at least 50 per cent of their time to a QC program in small institutions (200 beds or less) and full time in larger institutions. Institutions with more than 500 beds may require additional help. Among the activities of the QC technologist(s) should be:

1. Carry out the day-to-day QC tests on the department's photographic, radiographic and fluoroscopic imaging equipment as prescribed by the QC test schedule;
2. Record and/or chart the QC test measurement data;
3. Evaluate the test results;
4. Report any deterioration or trends in equipment performance to the radiology manager and staff using the equipment;
5. Initiate prompt corrective action and/or preventive measures when necessary;
6. Oversee the repair of defective equipment performed by the hospital biomedical or electronic maintenance staff or by private service companies;
7. Perform the required tests to confirm that defective equipment was repaired and restored to the original level of performance;
8. Maintain equipment performance records;
9. Provide monthly reports on QC activities to the radiology manager; and
10. Develop new QC monitoring and maintenance procedures as required.
Appendix K

SAFETY ASSESSMENT PLAN FOR MEDICAL X-RAY FACILITIES AND PRACTICES
(References: IAEA GSR PART IV-Rev. 1 2016)

Safety has to be assessed for all facilities and activities, consistent with a graded approach. Safety assessment plan involves the systematic analysis of normal operation and its effects, of the ways in which failures might occur as a consequence of such failures. Safety assessment plan plans cover the safety measures necessary to control the hazard, and the design and engineered safety features are assessed to demonstrate that they fulfill the safety functions required of them. Where control measures on operator actions are called on to maintain safety, an initial safety assessment plan has to be carried out to demonstrate that the arrangements made are robust and that they can be relied on.

The safety assessment plan shall include, as appropriate, a systematic critical review of:

1. The operational limits and conditions for the operation of the facility.
2. The ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures and the consequences of such events;
3. The ways in which external factors could affect protection and safety.
4. The ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such events.

A. SAFETY ASSESSMENT PLAN FOR INITIAL FACILITIES

I. Name and location of the facility: (Provide a detailed location of the facility)

II. Layout of the facility:

- Describe factors such as the layout of the facility and its immediate surroundings, building materials, shielding.
- Provide sketch or drawing of the above conditions reflecting the actual room size, x-ray machine placement, control console, darkroom, waiting area, interpretation room, and other adjacent areas to the x-ray room.
- Delineate controlled and supervised areas.

III. Type of x-ray equipment: (General Radiography, Radiographic/Fluoroscopic, Computed Tomography, Mammography, etc.)

- Provide detailed condition and specification of the x-ray equipment (brand new, reconditioned, refurbished, modified, etc.)
- Provide acceptance testing and commissioning report for the x-ray machine/s.
IV. Safety assessment plan of the facility

- Installation of grounding for the x-ray equipment, electrical and mechanical safety checks.
- Measurements for the x-ray room shielding, protective barrier, and adjacent areas.
- Warning signs and notices.

V. Inventory of Personal Protective Equipment (PPE):

- Presence of lead apron, lead gloves, contact gonad shields, upright gonad shields, etc. and other applicable PPEs
- Safety assessment plan procedure for the above PPE
- Subscription of Personal Monitoring Devices

VI. Notarized Certificate that the above requirements are complete and totally verified by the owner/licensee

VII. Proposed date of operation: ________________________________

VIII. Name, signature and contact details of the authorized representative of the authorized officer (Medical Radiation Practitioner Or Radiation Protection Officer)

B. SAFETY ASSESSMENT PLAN FOR RENEWAL FACILITIES

I. Name and location of the facility: (Provide an updated detailed location of the facility)

II. Layout of the facility:

- Describe factors such as the layout of the facility and its immediate surroundings, building materials, shielding.
- Provide sketch or drawing of the above conditions reflecting the actual room size, x-ray machine placement, control console, darkroom, waiting area, interpretation room, and other adjacent areas to the x-ray room.
- Delineate controlled and supervised areas.

III. Type of x-ray equipment: (General Radiography, Radiographic/Fluoroscopic, Computed Tomography, Mammography, etc.)

- Provide preventive maintenance reports and records pertaining to the
IV. Safety assessment plan of the facility

- Provide workplace monitoring reports including the measurement points, frequency of monitoring

V. Inventory of Personal Protective Equipment (PPE):
- Presence of lead apron, lead gloves, contact gonad shields, upright gonad shields, etc.
- Preventive maintenance reports of the above PPEs
- Keep updated dose evaluation reports and describe policy for reviewing the occupation doses and the actions to be taken when dose limits are exceeded

VI. Notarized Certificate that the above requirements are complete and totally verified by the owner/licensee

VII. Name, signature and contact details of the authorized representative of the authorized officer (Medical Radiation Practitioner Or Radiation Protection Officer)

Note: Complete information is expected from the facility as to the actual operation. The FDA may require additional information to fully consider this application prior to issuance of authorization.
## APPENDIX L

List of Acronyms and Abbreviations

1. AEC – Automatic Exposure Control
2. AO – Administrative Order
3. COC – Certificate of Compliance
4. COL – Coefficient of Linearity
5. COV – Coefficient of Variation
6. CQMP – Clinically Qualified Medical Physicist
7. CT – Computed Tomography
8. DICOM – Digital Imaging and Communication in Medicine
9. DIRMP – Diagnostic and Interventional Radiology Medical Physicist
10. DPBR – Diplomate, Philippine Board of Radiology
11. FCM – Facility compliance Monitoring
12. FDA – Food and Drug Administration
13. FPCR – Fellow, Philippine College of Radiology
14. FPHA – Fellow, Philippine Heart Association
15. FPROS – Fellow, Philippine Radiation Oncology Society
16. IBSS – International Basic Safety Standards
17. IEC – International Electrotechnical Commission
18. ISO – International Organization for Standardization
19. LTO – License to Operate
20. MPV – Mean Pixel Value
21. PAB – Philippine Accreditation Bureau
22. PACS – Picture Archiving and Communication System
23. PBR – Philippine Board of Radiology
24. PCR – Philippine College of Radiology
25. PNS – Philippine National Standards
26. PSCCI – Philippine Society of Cardiac Catheterization Interventionalists
27. PSVIR – Philippine Society of Vascular and Interventional Radiology
28. QA/QC – Quality Assurance/Quality Control
29. QAP – Quality Assurance Program
30. RIS – Radiology Information System
31. RPO – Radiation Protection Officer
32. RPP – Radiation Protection Program
33. RPSE – Radiation Protection Survey and Evaluation
34. SID – Source to Image Distance