Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 30 2022

ADMINISTRATIVE ORDER
No. 2022 - 0022

SUBJECT: Basic Radiation Protection and Safety Standards on the Use of Ionizing Radiation Devices in Planned Exposure Situations

I. RATIONALE

In line with the 1996 International Atomic Energy Agency (IAEA) Safety Series (ISS) No. 115 or the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, the Department of Health issued Administrative Order (AO) No. 149 s 2004, known as the "Basic Standards on Radiation Protection and Safety Governing the Authorization for the Introduction and Conduct of Practices involving X-ray Sources in the Philippines, as amended, and Department Circular No. 323 s. 2004 to establish the National Radiation Protection and Safety Standards for the Use of Radiation Devices in the Philippines.

In 2014, the IAEA published the General Safety Requirements (GSR) Part Three (3) entitled "Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards," which superseded ISS No. 115. Significant changes and additional safety provisions were included to further strengthen the previously established protection mechanisms of ISS No. 115, to which the national standards are based upon.

As such, this Administrative Order is hereby issued to update the national basic radiation protection and safety standards, effectively adopting the relevant provisions of IAEA GSR Part Three (3). Likewise, this Order aims to prescribe implementing guidelines in accordance with the IAEA graded approach in the regulation of ionizing radiation devices.

The implementation and enforcement of this Order shall be consistent with the mandate of the Food and Drug Administration (FDA), through the Implementing Rules and Regulations (IRR) of the Republic Act No. 9711 otherwise known as the "Food and Drug Administration Act of 2009," in protecting and promoting the right to health of the Filipino people by ensuring the safety, quality, and efficacy of health products like ionizing radiation devices.

It is also in line with the objectives and targets outlined in Section 5.E.a of DOH AO No. 2018-0014 or the Strategic Framework and Implementing Guidelines for FOURmula One Plus for Health (F1+) and Section 2.c of Republic Act No. 11223 or the Universal Health Care Act ensuring high quality radiation devices, facilities, and services through harmonization, benchmarking, and compliance to internationally accepted regulatory standards and health policies, such as those from the IAEA, through a whole-of-system, whole-of-government, and whole-of-society approach.

II. OBJECTIVES

To provide updated standards and guidelines for the protection of patients, occupationally exposed persons, and members of the public from the harmful effects of using ionizing radiation devices in planned exposure situations in accordance with the provisions of IAEA GSR Part 3.

III. SCOPE OF APPLICATION

This Order shall cover the use of ionizing radiation devices in radiation facilities under the jurisdiction of the Food and Drug Administration (FDA). Additionally, it shall apply to radiation facilities in the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) subject to the applicable provisions of Republic Act No. 11054 or the "Organic Law for the Bangsamoro Organic Autonomous Region in Muslim Mindanao" and its subsequent laws and issuances.

Specifically, this Order applies to the following practices:

A. The use of ionizing radiation devices in medicine, dentistry, veterinary medicine, commerce and industry, education, training and research, anti-crime, and security, including the use of associated equipment, software, or devices where such use could affect exposure to radiation;

B. The production, testing, and supply of ionizing radiation devices, including linear accelerators, and fixed and mobile radiography equipment;

C. The operation of facilities/establishments using ionizing radiation devices for medical and non-medical purposes and to all establishments using electrical/electronic devices that emit x-ray radiation or as a by-product of its operation; and

D. All types of planned exposure situations involving radiation devices in medical, occupational, and public exposures that are amenable to control.

This Order does not apply to existing and emergency exposure situations, except for emergencies arising from the planned use of ionizing radiation devices and radiation devices with radioactive materials.

IV. DEFINITION OF TERMS

A. **Carers and comforters** – refer to those who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment.

B. **Controlled areas** – refer to defined areas in wherein protection measures and safety provisions are or could be required for controlling exposures, and preventing or limiting the extent of potential exposures.

C. **Defence in depth** – refers to the application of more than a single protective measure for a given safety objective, such that the objective is achieved should one of the protective measures fail.

D. **Diagnostic reference levels** – pertain to the level used in medical imaging to indicate whether, in routine conditions, the dose to the patient in a specified radiological procedure is unusually high or unusually low for that procedure.

E. **Dose constraints** – refer to prospective and source related value of individual dose (dose constraint) or risk (risk constraint) that is used in planned exposure situations as a parameter for the optimization of protection and safety on the use of radiation device, and that serves as a boundary in defining the range of options in optimization. Specifically:

   1. For occupational exposure, a constraint on individual dose to workers established and used by licensees to set the range of options in optimizing protection and safety for the radiation device;

   2. For public exposure, the dose constraint is a source related value established or approved by FDA, taking account of the doses from planned operations of all radiation devices under control. The dose constraint for each particular use of radiation devices is intended, among other things, to ensure that the sum of doses from planned operations for all sources under control remains within the dose limit;

   3. For medical exposure, the dose constraint is a source related value used in optimizing the protection of carers and comforters of patients undergoing radiological procedures, and the protection of volunteers who are subjected to exposure as part of a biomedical research program.

   4. For emergency exposure situations, refers to a situation of exposure that arises from an accident, a malicious act or other unexpected event, which requires prompt action to avoid or reduce adverse consequences.

F. **Exemption** – refers to the determination by the FDA that a radiation device or practice need not be subject to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the radiation devices or practice are too small to warrant the application of those aspects or that such is the optimum option for protection irrespective of the actual level of the doses or risks.

G. **Existing exposure situation** – pertains to a situation when a decision is needed to control an exposure that already exists. These include exposure to natural background radiation that is amenable to control; exposure due to residual radioactive material that derives from past practices that were never subject to regulatory control or exposure due to residual radioactive material deriving from a nuclear or radiological emergency after an emergency has been declared to be ended.

H. **Facilities and activities** – for purposes of this Order, refer to the general term encompassing any facility or human activity that may cause people to be exposed to radiation risk arising from the use of radiation devices.

1. '**Facilities**' include: x-ray facilities; and any other places where radiation devices are produced, used, or where radiation devices are installed on such a scale that consideration of protection and safety is required.

2. '**Activities**' include: the production, use, import and export of radiation devices for medical and non-medical application.

I. **Graded Approach** – refers to a regulatory system or a safety system, a process or method in which the stringency of the control measures and conditions to be applied is commensurate with the level of risk; potential magnitude of exposure and hazard of facilities and activities associated with the use of radiation devices.

J. **Health screening program** – refers to a program in which a health test or medical examination is performed for the purpose of the early detection of disease.

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

L. **Medical Physicist** – pertains to 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.

M. **Occupational exposure** – refers to ionizing radiation exposure of workers incurred in the course of their work.

N. **Other parties** – refer to the following individuals: suppliers of radiation devices, Radiation Protection Officers (RPO), referring medical practitioners, Medical Physicists, Radiologic/X-ray technologists, Qualified Experts (QE), ethics committees, and any other party to whom a principal party has assigned specific responsibilities.

O. **Planned exposure situation** – for the purpose of this regulation, refers to a situation of exposure that arises from the planned operation of an ionizing radiation device or from a planned activity that results in an exposure due to the use of an ionizing radiation device.

P. **Potential exposure** – pertains to prospectively considered exposure that is not expected to be delivered with certainty but that may result from an anticipated operational occurrence or accident using a radiation device or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.

Q. **Principal parties** – refer to persons having main responsibilities for the application of these regulations. These are: (a) Registrants or licensees, or persons

or organizations responsible for notified or authorized practices or radiation devices within practices; (b) Employers of workers, in relation to occupational exposure; and (c) Radiological medical practitioners, in relation to medical exposure.

R. **Public exposure** – pertains to exposure incurred by members of the public due to radiation devices in planned exposure situations, emergency exposure situations and existing exposure situations, excluding any occupational exposure or medical exposure.

S. **Qualified expert** – refers to an individual who, by virtue of certification by appropriate boards or societies, professional license or academic qualifications and experience, is duly recognized as having expertise in a relevant field of specialization, e.g. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty.

T. **Radiation Protection Officer** – pertains to a person technically competent in radiation protection matters relevant for a given type of practice who is designated by the registrant, licensee or employer to oversee the application of regulatory requirements.

U. **Radiological medical practitioner** – refers to a health professional with specialist education and training in the medical uses of radiation, who is responsible for administering a radiation dose to a patient and competent to perform independently or to oversee radiological procedures involving medical exposure in diagnostic radiology, interventional radiology (image-guided procedures), radiation oncology and nuclear medicine.

V. **Safety assessment** – refers to 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.

W. **Safety Culture** – pertains to an assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

X. **Supervised areas** – refers to a defined area not designated as a controlled area but for which occupational exposure conditions are kept under review, even though no specific protection measures or safety provisions are not normally needed.

V. GENERAL GUIDELINES

A. No person or organization shall install, acquire, possess, use, operate, maintain, or repair an ionizing radiation device within a practice other than in accordance with the requirements of this Order.

B. The principal and other parties responsible for facilities and activities that give rise to radiation risks shall have the prime responsibility for safety and radiation protection.

C. No practice involving exposure to ionizing radiation devices shall be adopted and authorized unless the practice produces sufficient benefit or is justified considering social, economic, and other relevant factors.

D. Planned exposure situations using ionizing radiation devices shall be optimized to provide the highest level of safety that can reasonably be achieved, applying relevant dose limits and constraints where applicable.

E. The requirements of this Order shall be applied in accordance with a graded approach where the protective measures to be implemented are commensurate with the radiation hazard associated with the use of radiation devices.

F. The notification, exemption, authorization process, and requirements shall be in a graded approach consistent with the manner and forms required by the FDA in other regulations.

VI. SPECIFIC GUIDELINES

Specific radiation protection, management and technical requirements are further grouped into **parts** in **Annex A** of this Order. The FDA shall issue practice specific implementing guidelines to support its implementation.

Parts	**Basic Radiation Protection and Safety Standards**	**Brief Description**
Part 1	Requirements for Radiation Protection	Basic radiation protection and safety standards and guidelines
Part 2	Verification of Safety	Safety assessments, testing, verification and continuous compliance to safety standards and guidelines
Part 3	Human Imaging For Purposes other than Medical Diagnosis, Medical Treatment, or Biomedical Research	Radiation protection and safety standards and guidelines for non-medical exposures.
Part 4	Occupational Exposure	Practice guidelines for the safety and radiation protection of workers
Part 5	Medical Exposure	Practice guidelines for the radiation protection and safety of patients, carers and comforters, and by volunteers
Part 6	Public Exposure	Practice guidelines for the radiation protection and safety of the members of the public to sources in planned exposure situations.
Part 7	Radiation Devices	Specific standards and guidelines for the

		safe design, citing, installation, commissioning, and operation of radiation devices.

VII. ROLES AND RESPONSIBILITIES

A. Food and Drug Administration (FDA)

The FDA through the Center for Device Regulation, Radiation Health and Research (CDRRHR), having defined functions and powers to regulate the use of radiation devices, shall exercise its regulatory powers in the implementation and enforcement of this Order. Specifically, the Center shall:

1. Enforce relevant regulatory standards;

2. Establish and maintain mechanisms to implement, monitor, and maintain these standards in accordance with the graded approach;

3. Coordinate with those of other governmental authorities, and other national and international organizations with responsibilities relevant to radiation protection and safety for planned exposure situations.

B. Parties Involved in Radiation Protection and Safety

1. **Principal parties** shall be responsible for complying with this Order to ensure that protection and safety are optimized, dose limits or reference levels are applied, appropriate safety assessment and monitoring are conducted, as required in this Order. Specifically, it shall include the following:
   a. Ensure that protection and safety are effectively integrated into the overall management system of the organizations for which they are responsible;
   b. Have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system;
   c. Establish procedures for reporting on and learning from accidents and other incidents;
   d. Establish preventive measures against accidents and appropriate mitigation plans. Preventive measures shall be duly documented and shall be available for verification of the FDA and/or other relevant authorities.
   e. Establish radiation protection and safety objectives in conformity with the relevant requirements of this Order;
   f. Ensure that a radiation device is transferred only if the recipient possesses the necessary authorization;
   g. Ensure that radiation devices are shipped and received in accordance with FDA regulatory requirements;
   h. Continuously comply with the rules and regulations, authorization standards and requirements for the operation of radiation devices and facilities, as provided in this Order and related issuances;
   i. Develop, implement, and document a radiation protection and safety program including provisions for shielding and personal protective

equipment commensurate with the radiation risks associated with the exposure situation under their responsibility (graded approach) and sufficient to ensure compliance with the requirements of this Order. This program shall include the following actions:

i. Determining and keeping under continued review the measures needed to achieve the radiation safety objectives, to ensure that the radiation devices required for their implementation are provided and to regularly verify that the radiation safety objectives are being achieved;
ii. Identify and prevent, or promptly correct, any failures or shortcomings in the radiation safety measures;
iii. Facilitate consultation and co-operation among all relevant parties with respect to radiation safety;
iv. Keep appropriate records regarding the discharge of their responsibilities;

j. The principal parties shall ensure that, in the implementation of the radiation protection and safety program:
   i. The measures and radiation devices that are necessary for achieving the objectives for protection and safety have been determined and are duly provided;
   ii. The program is periodically reviewed to assess its effectiveness and its continued fitness for purpose;
   iii. Any failures or shortcomings in protection and safety are identified and corrected, and steps are taken to prevent their recurrence;
   iv. Arrangements are made to consult with interested parties;
   v. Appropriate records are maintained;
   vi. The principal and other parties having specified responsibilities in relation to protection and safety shall ensure that all personnel engaged in activities relevant to protection and safety have appropriate education, training and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgment and in accordance with procedures;
   vii. Principal parties shall ensure that qualified experts are identified and are consulted as necessary on the proper observance of this Order.

k. Registrants and licensees, as one of the principal parties and responsible for facilities and activities that give rise to radiation risks, shall have the prime responsibility for protection and safety, which cannot be delegated. Specifically, they shall:
   i. Bear the responsibility for establishing and implementing the technical and organizational measures that are needed for ensuring protection, and safety for the practices using radiation devices for which they are authorized and for compliance with all applicable requirements of this Order;
   ii. May designate suitably qualified persons to carry out actions and tasks related to these responsibilities, but they shall retain the prime responsibility for protection and safety. Registrants and licensees shall document the names and responsibilities of persons designated;
   iii. Notify the FDA of any intention to introduce modifications to any practice or radiation devices for which they are licensed whenever the

modifications could have significant implications for protection and safety, and they shall not carry out any such modification unless specifically authorized by the FDA;

iv. Establish clear lines of responsibility and accountability for protection and safety for the radiation devices for which they are authorized and shall establish organizational arrangements for protection and safety;

v. Ensure that any delegation of responsibilities by a principal party is documented;

vi. Ensure that the relevant principal parties and other parties having specified responsibilities in relation to protection and safety have appropriate education, training, and qualification so that they understand their responsibilities and can perform their duties competently, with appropriate judgment and in accordance with this Order;

vii. Have in place operating procedures and arrangements for protection and safety that are subject to periodic review and updating under a management system;

viii. Establish procedures for reporting on and learning from accidents and other incidents;

ix. Ensure that structures, systems and components, including software, that are related to protection and safety for x-ray facilities and activities using radiation devices are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable;

x. Make suitable arrangements to prevent reasonably foreseeable accidents in the x-ray facility;

xi. Establish mechanisms to mitigate the consequences of those accidents that do occur;

xii. Provide workers with the information, instruction, training, and equipment necessary to restrict potential exposures;

xiii. Ensure that there are adequate procedures for the control of the facility and the management of any reasonably foreseeable accidents;

xiv. Ensure that safety significant structures, systems and components, including software, and other equipment can be inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;

xv. Ensure that maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;

xvi. Ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond quickly enough to allow for corrective action to be taken in a timely manner to ensure that all relevant safety documentation is available in the appropriate languages.

l. Notify the FDA of any intention to introduce modifications pertaining to any practice or authority to use such radiation devices for which they are authorized whenever the modifications could have significant implications on protection and safety, and they shall not carry out any such modification unless specifically authorized by the FDA.

2. The responsibilities of **other parties**, including those for Radiation Protection Officers (RPO) and Qualified Experts (QE), are specified in the appropriate Parts of the Supplemental Requirements of this Order for the implementation of these standards.

VIII. TRANSITORY PROVISIONS

A period of three (3) years from the approval of this regulation shall be allowed to facilitate and strengthen the full implementation of the following provisions of this Order:

Relevant Provision	Details	Remarks
Annex B Part 2.A	Conduct of Safety Assessment and submission of the same to FDA for review	Requirements shall be in the graded approach in specific regulations to be issued by the FDA
Section VII.B.1.h.vii and Annex B Part 1.H	Requirements for Qualified Experts	Harmonized National Policy in a graded approach to be issued by the FDA
Annex B Part 1.C; Part 5.F and 5.H	Establishment and use of DRL's and Dose Constraints	Harmonized National Policy on the Establishment and Use to be issued by the FDA

IX. PENALTY CLAUSE

Any person, juridical or natural, found to violate any of the provisions set herein shall be imposed with administrative penalties/sanctions prescribed in Section 13 of Republic Act 9711 and Book III, Article XI of its Implementing Rules and Regulations.

X. REPEALING CLAUSE

Administrative Orders No. 149 and 164 s. 2004, Department Circular No. 323 s. 2004, and any other issuances, rules, and regulations inconsistent with or contrary to this Order shall be repealed, amended or modified accordingly.

XI. SEPARABILITY CLAUSE

If any clause, sentence, or provision of this Order shall be declared invalid or unconstitutional, the other provisions unaffected thereby shall remain valid and effective.

XII. EFFECTIVITY CLAUSE

This Order shall take effect fifteen (15) days from the date of its publication in the Official Gazette or in any national newspaper of general circulation, with three (3)

certified copies to be filed with the Office of the National Administrative Register (ONAR) of the UP Law Center.

FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health
JUN 3 0 2022

ANNEX A

Part 1. Requirements for Radiation Protection

A. Justification of Practices

1. No practice shall be authorized unless it is likely to produce sufficient benefit to the exposed individuals or to the society to offset the radiation harm that it might cause, considering social, economic, and other relevant factors. If requested by the FDA, the applicant for an authorization shall provide sufficient information and evidence on the benefits and the harm to support the justification of the use of radiation devices and operation of x-ray facilities. The FDA may deny authorization of the proposal in the application on the basis that it is not justified.

2. The following practices using radiation devices are deemed to be **not justified**:

    a. Human imaging using radiation devices that is performed as a form of art or for publicity purposes;
    b. Human imaging using radiation devices that is performed for occupational, legal or health insurance purposes, and is undertaken without reference to clinical indication shall normally be deemed to be not justified. If, in exceptional circumstances, the FDA decides that the justification of such human imaging for specific practices is to be considered, the requirements of this Order shall apply;
    c. Human imaging using radiation devices for theft detection purposes;
    d. Human imaging using radiation devices for the detection of concealed objects for anti-smuggling purposes;
    e. Human imaging using radiation devices for the detection of concealed objects that can be used for criminal acts that pose a national security threat shall be justified only by the government. If the government decides that the justification of such human imaging is to be considered, the requirements of this Order shall apply;

B. Optimization of Protection and Safety

1. Registrants and Licensees shall ensure that protection and safety is optimized.

2. For occupational exposure and public exposure, registrants and licensees shall ensure that all relevant factors are taken into account in a coherent way in the optimization of protection and safety to contribute to achieving the following objectives:

    a. To determine measures for protection and safety that are optimized for the prevailing circumstances, with account taken of the available options for protection and safety as well as the nature, likelihood and magnitude of exposures;
    b. To establish criteria, on the basis of the results of the optimization, for the restriction of the likelihood and magnitudes of exposures by means of measures for preventing accidents and for mitigating the consequences of those that do occur.

C. Dose Constraints

For occupational exposure and public exposure, registrants and licensees shall ensure, as appropriate, that relevant dose constraints are used in the optimization of protection and safety for a radiation device within a practice.

D. Dose Limits

Registrants and licensees shall ensure that the exposures of individuals due to the practices using radiation devices for which the registrants and licensees are authorized are restricted, so that neither the effective dose nor the equivalent dose to tissues or organs exceeds any relevant dose limit specified in Annex B of this Order.

E. Management Requirements

1. The principal parties shall ensure that protection and safety is effectively integrated into the overall management system of the organizations for which they are responsible.

2. The principal parties shall demonstrate commitment to protection and safety at the highest levels within the organizations for which they are responsible.

3. Licensees shall establish a management system, commensurate with the size and nature of the authorized activity, which ensures that:

    a. Policies and procedures are established that identify safety as being of the highest priority;
    b. Problems affecting protection and safety are promptly identified and corrected in a manner commensurate with their importance;
    c. The responsibilities of each individual for safety are clearly identified and each individual is suitably trained and qualified;
    d. Clear lines of authority for decisions on safety are defined;
    e. Organizational arrangements and lines of communications are established that result in an appropriate flow of information on safety at and between the various levels in the entire organization of the licensee.

4. The principal parties shall ensure that the management system is designed and implemented to enhance protection and safety by:

    a. Applying the requirements for protection and safety coherently with other requirements including requirements for operational performance, and coherently with guidelines for security;
    b. Describing the planned and systematic actions necessary to provide adequate confidence that the requirements for protection and safety are fulfilled;
    c. Ensuring that protection and safety is not compromised by other requirements;
    d. Providing for the regular assessment of performance for protection and safety and the application of lessons learned from experience;
    e. Promoting safety culture.

5. The principal parties shall ensure that the protection and safety elements of the management system are commensurate with the complexity of and the radiation risks associated with the activity.

F. Safety Culture

1. The principal parties shall promote and maintain a safety culture by:

    a. Promoting individual and collective commitment to protection and safety at all levels of the organization;
    b. Ensuring a common understanding of the key aspects of safety culture within the organization;
    c. Providing the means by which the organization supports individuals and teams in carrying out their tasks safely and successfully, with account taken of the interactions between individuals, technology and the organization;
    d. Encouraging the participation of workers and their representatives and other relevant persons in the development and implementation of policies, rules and procedures dealing with protection and safety;
    e. Ensuring accountability of the organization and of individuals at all levels for protection and safety;
    f. Encouraging open communication with regard to protection and safety within the organization and with relevant parties, as appropriate;
    g. Encouraging a questioning and learning attitude and discouraging complacency with regard to protection and safety;
    h. Providing means by which the organization continually seeks to develop and strengthen its safety culture.

G. Human Factors

1. The principal parties and other parties having specified responsibilities in relation to protection and safety, as appropriate, shall take into account human factors and shall support good performance and good practices to prevent human and organizational failures, by ensuring that:

    a. Sound ergonomic principles are followed in the design of equipment and the development of operating procedures, so as to facilitate the safe operation and use of equipment, to minimize the possibility that operator errors will lead to accidents, and to reduce the possibility that indications of normal conditions and abnormal conditions will be misinterpreted;
    b. Appropriate equipment, safety systems and procedural requirements are provided and other necessary provisions are made:
        i. To reduce, as far as practicable, the possibility that human error or inadvertent action could give rise to accidents or other incidents leading to the exposure of any person;
        ii. To provide means for detecting human errors and for correcting them or compensating for them;
        iii. To facilitate protective actions and corrective actions in the event of failures of safety systems or failures of measures for protection and safety.

2. All employees shall be informed at least annually of the importance of effective measures for protection and safety and be trained in their implementation as appropriate.

3. Training programs shall be routinely evaluated and updated as necessary.

H. Radiation Protection Officers (RPO) and Qualified Experts (QE)

1. Licensees shall arrange for qualified experts to be identified and made available for providing advice on the observance of these Regulations when so required by the FDA;

2. The qualifications of qualified experts in radiation safety shall include a level of academic knowledge and of professional experience compatible with the levels of risks associated with the authorized practices or radiation devices within a practice;

3. A radiation protection officer shall be technically competent in radiation protection matters relevant to a given type of practice. The radiation protection officer oversees the application of the requirements of this Order to that practice. Specifically, an RPO shall have the following responsibilities:

   a. In coordination with the facility management and workers, and pursuant to Section VII.B.1.g of this Order, establish a radiation protection program or manual commensurate with the scope and extent of the practice and the hazards associated with it and must adequately protect patients, workers, and the members of the public.
   b. Implement and oversee the operational aspects of the radiation protection program or manual.
   c. Review and recommend to the management any changes in the radiation protection program or manual.
   d. In coordination with the facility management: identify, investigate, initiate, recommend, and provide corrective actions for radiation safety problems.
   e. Notify facility management of any radiation safety problems, unsafe operations, and corrective actions.
   f. Liaise, notify, report, and coordinate with the FDA, any safety problems and events as required by this Order.
   g. Any additional responsibilities specified through the issuance of practice specific implementing guidelines to support the implementation of this Order.

4. Registrants and licensees may propose to use a radiation protection officer in place of a qualified expert in radiation safety on the basis of the relatively low risk of the practice;

5. Licensees and registrants shall keep the FDA informed of the arrangements and changes made with respect to (1) and (2).

Part 2. Verification of Safety

A. Safety Assessment

1. When so required by the FDA, or to meet management system requirements, the licensee shall prepare safety assessments in accordance with the graded approach for which they are responsible so as to:

    a. To identify the ways in which exposures could be incurred, account being taken of the effects of external events as well as of events directly involving the radiation devices and associated equipment;
    b. To determine the expected magnitudes and likelihood of exposures in normal operation and, to the extent reasonable and practicable, make an assessment of potential exposures;
    c. To assess the adequacy of the provisions for protection and safety.

2. The safety assessment shall include, as appropriate, systematic critical review of:

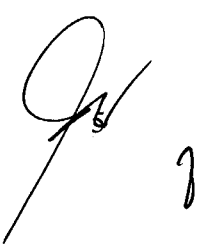
    a. The operational limits and conditions for the operation of a facility;
    b. The ways in which structures, systems and components, including software, and procedures relating to protection and safety might fail, singly or in combination, or might otherwise give rise to exposures, and the consequences of such events;
    c. The ways in which external factors could affect protection and safety;
    d. The ways in which operating procedures relating to protection and safety might be erroneous, and the consequences of such errors;
    e. The implications for protection and safety of any modifications;
    f. The implications for protection and safety of security measures or of any modifications to security measures;
    g. Any uncertainties or assumptions and their implications for protection and safety.

3. The licensee shall take into account in the safety assessment:

    a. Factors that could give rise to unintended operation of any radiation devices or a loss of shielding, and the measures available to detect and to prevent or control such occurrences;
    b. The extent to which the use of redundant and diverse safety features, that are independent of each other so that failure of one does not result in failure of any other, is appropriate to restrict the likelihood and magnitude of potential exposure.

4. Licensees shall ensure that the safety assessment is documented and, where appropriate, that it is independently reviewed under the relevant management system.

5. Licensees shall perform additional reviews of the safety assessment as necessary to ensure that the technical specifications or conditions of use continue to be met when:



a. Significant modifications to the facility or to its operating procedures or maintenance procedures are envisaged;
b. Significant changes occur on the site that could affect the safety of the facility or of activities on the site;
c. Information on operating experience, or information about accidents and other incidents that could result in exposures, indicates that the current assessment might be invalid;
d. Any significant changes in activities are envisaged;
e. Any relevant changes in guidelines or standards have been made or are envisaged.

6. If as a result of a safety assessment, or for any other reason, opportunities to improve protection and safety appear to be available and improvement seems desirable, any consequential modifications shall be made cautiously and only after favorable assessment of all the implications for protection and safety. The implementation of all improvements shall be prioritized so as to optimize protection and safety.

B. Monitoring, Testing and Verification of Compliance

1. Licensees and employers shall ensure that:

a. Monitoring and measurements of parameters are performed as necessary for verification of compliance with the requirements of regulations and license conditions;
b. Suitable equipment is provided and procedures for verification are implemented;
c. Equipment is properly maintained, tested and calibrated at appropriate intervals with reference to standards traceable to national or international standards;
d. Records are maintained of the results of monitoring and verification of compliance, as required by the FDA, including records of the tests and calibrations carried out in accordance with regulations and license conditions;
e. The results of monitoring and verification of compliance are shared with the FDA, as required.

C. Prevention and Mitigation of Accidents

Registrants and licensees shall apply good engineering practices and shall take all practicable measures to prevent accidents and to mitigate the consequences of those accidents that do occur.

Good engineering practice

1. The registrant or licensee, in cooperation with other responsible parties, shall ensure that the siting, location, design, manufacture, construction, assembly, commissioning, operation, maintenance and decommissioning (or closure) of facilities or parts thereof are based on good engineering practice which shall, as appropriate:

a. Take account of international and national standards;
b. Be supported by managerial and organizational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;
c. Include adequate safety margins in the design and construction of the facility, and in operations involving the facility, so as to ensure reliable performance in normal operation, and take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating the consequences of those accidents that do occur and restricting any possible future exposures;
d. Take account of relevant developments concerning technical criteria, as well as the results of any relevant research on protection and safety and feedback of information on lessons learned from experience.

Defence in depth

2. Registrants and licensees shall ensure that a multilevel (defence in depth) system of sequential, independent provisions for protection and safety that is commensurate with the likelihood and magnitude of potential exposures is applied to sources for which the registrants and licensees are authorized.

3. Registrants and licensees shall ensure that if one level of protection were to fail, the subsequent independent level of protection would be available. Such defence in depth shall be applied for the purposes of:

   a. Preventing accidents;
   b. Mitigating the consequences of any accidents that do occur;
   c. Restoring the sources to safe conditions after any such accidents.

Accident Prevention

4. Registrants and licensees shall ensure that structures, systems and components, including software, that are related to protection and safety for facilities and activities are designed, constructed, commissioned, operated and maintained so as to prevent accidents as far as reasonably practicable.

5. The registrant or licensee for any facility or activity shall make suitable arrangements:

   a. To prevent reasonably foreseeable accidents in the facility;
   b. To mitigate the consequences of those accidents that do occur;
   c. To provide workers with the information, instruction, training and equipment necessary to restrict potential exposures;
   d. To ensure that there are adequate procedures for the control of the facility and for the management of any reasonably foreseeable accidents;
   e. To ensure that safety significant structures, systems and components, including software, and other equipment can be inspected and tested regularly for any degradation that could lead to abnormal conditions or inadequate performance;

f. To ensure that maintenance, inspection and testing appropriate to the preservation of the provisions for protection and safety can be carried out without undue occupational exposure;
g. To ensure that abnormal operating conditions that could significantly affect protection and safety are detected by systems that respond quickly enough to allow for corrective action to be taken in a timely manner;
h. To ensure that all relevant safety documentation is available in the appropriate languages understandable to users.

D. Investigations and Feedback of Information on Operating Experience

1. Licensees shall ensure that information on normal operation performance as well as abnormal conditions and events significant to radiation safety is disseminated or made available, as appropriate, to the FDA and other relevant parties, including other users, as specified in relevant guidelines issued by the FDA.

2. In addition, and where applicable, licensees shall make suitable arrangements with suppliers of radiation devices to establish and maintain mechanisms for transfer from licensees to suppliers of any information on the use, maintenance, disposal and malfunctioning that may be relevant for future improvements in the design and fabrication of the radiation devices they have supplied.

3. Licensees shall conduct an investigation in the event that:

   a. A quantity or operating parameter relating to protection and safety on the use of radiation devices exceeds an investigation level or is outside the stipulated range of operating conditions; or
   b. Any equipment failure, accident, error, mishap or other unusual event or condition occurs that has the potential for causing a quantity to exceed any relevant limit or operating restriction.

4. The licensee shall conduct an investigation as soon as possible after an event and shall prepare a written record of its causes, or suspected causes, including a verification or determination of any doses received or committed and recommendations for preventing the recurrence of the event and the occurrence of similar events.

5. The licensee shall communicate to the FDA and to any other relevant parties, as appropriate, a written report of any formal investigation relating to events prescribed by the FDA, including exposures giving rise to doses exceeding a dose limit. The licensee also shall immediately report to the FDA any event in which a dose limit is exceeded.

E. Requirements for Reporting to the FDA

1. Licensees shall:

   a. Notify the FDA by telephone, facsimile, email, or any form of formal communication immediately of any event in which a dose limit is exceeded.

b. Notify by telephone, facsimile, email, or any form of formal communication as soon as practicable, but not later than 24 hours after discovery, of any significant unintended or accidental medical exposures.
c. Submit to the FDA, within 30 days after discovery of any significant unintended or accidental medical exposures, a written report which states the cause of any significant unintended or accidental medical exposures and includes information on the doses, corrective measures, and any other relevant information.
d. Report a summary of the public exposure monitoring results to the FDA at approved intervals and promptly inform the FDA of any abnormal results which lead or could lead to an increase of public exposure.

F. Non-Compliance and Accidents

1. In the event of a breach of any applicable requirement of this Order, principal parties shall, as appropriate:

   a. Investigate the breach and its causes, circumstances and consequences;
   b. Take appropriate action to remedy the circumstances and to prevent a recurrence of similar situations;
   c. Report to the FDA within 24 hours, or as required, on the causes of the breach, its circumstances and consequences, and on the corrective or preventive actions taken or to be taken;
   d. Take whatever other actions are necessary as required by this Order.

2. Failure to take corrective or preventive actions within a reasonable time in accordance with this Order shall be grounds for enforcement for appropriate action in accordance with the relevant regulations issued by the FDA.

G. Inventory and Records

1. Licensees shall establish, maintain and be able to retrieve records relating to:

   a. Inventory of radiation devices;
   b. Records of doses from occupational exposures;
   c. Records relating to x-ray facilities and activities using radiation devices;
   d. The testing of instruments and safety systems, and calibrations carried out in accordance with the requirements of this Order.

2. Licensees shall provide the FDA as required with appropriate information from their inventory records of radiation devices. Licensees shall check inventory periodically to confirm that radiation devices are in their assigned locations and are under control.

Part 3. Human Imaging for the Purposes other than Medical Diagnosis, Medical Treatment or Biomedical Research

A. Justification of Practices of Any Type of Human Imaging Using Radiation

1. The justification process applied to the practice of any type of human imaging procedure in which radiation is used for purposes other than for medical diagnosis or medical treatment or as part of a program of biomedical research shall include the consideration of:
   a. The benefits and detriments of implementing the type of human imaging procedure;
   b. The benefits and detriments of not implementing the type of human imaging procedure;
   c. Any legal or ethical issues associated with the introduction of the type of human imaging procedure;
   d. The effectiveness and suitability of the type of human imaging procedure, including the appropriateness of the radiation equipment for the intended use;
   e. The availability of sufficient radiation devices to conduct the human imaging procedure safely throughout the intended period of the practice.

2. If it has been determined through the process specified above that a particular practice of human imaging using radiation is justified, then, such a practice shall be subject to the requirements of this Order.

B. Optimization of Protection and Safety

1. For human imaging using radiation conducted by medical personnel using medical radiological equipment, which exposes humans to radiation for employment related, legal or health insurance purposes without reference to clinical indications, the licensee shall ensure that the appropriate optimization requirements for medical exposure specified in this Order are applied, with dose constraints used instead of diagnostic reference levels.

2. Procedure with anti-crime radiation devices in which radiation is used to expose persons for the purpose of detection of concealed weapons, contraband or other objects on or within the body shall be considered to give rise to public exposure. Licensees shall apply the requirements for public exposure as required in this Order. In particular, licensees shall ensure that optimization of protection and safety is subject to any dose constraints for public exposure set by the government or the FDA.

3. Licensees shall ensure that all persons who are to undergo procedures with anti-crime x-ray devices in which ionizing radiation is used are informed of the possibility of requesting the use of an alternative inspection technique that does not use ionizing radiation, where available.
4. The licensee shall ensure that any anti-crime x-ray device used for the detection of concealed objects on or within the body, whether it is manufactured in or imported into the country in which it is used, conforms to applicable Philippine National

Standards (PNS) or equivalent International Electrotechnical Commission (IEC) or International Organization for Standardization (ISO) standards.

Part 4. Occupational Exposure

A. General Responsibilities

1. For workers who are engaged in activities in which they are or could be subject to occupational exposure in planned exposure situations, licensees and employers shall be responsible for:

   a. Protection of workers against occupational exposure;
   b. Compliance with relevant requirements of this Order and license conditions.

2. Licensees and employers shall ensure, for all workers engaged in activities in which they are or could be subject to occupational exposure, that:

   a. Occupational exposure is controlled so that the relevant dose limits for occupational exposure specified in Annex B of this Order are not exceeded;
   b. Protection and safety are optimized in accordance with the requirements specified in this Order;
   c. Decisions with regard to measures for protection and safety are recorded and made available to relevant parties, through their representatives where appropriate, as specified by the FDA;
   d. Policies, procedures and organizational arrangements for occupational protection and safety are established to implement the relevant requirements of this Order, with priority given to design measures and technical measures for controlling occupational exposure;
   e. Suitable and adequate facilities, equipment and services for protection and safety are provided, the type and extent of which are commensurate with the expected likelihood and magnitude of the occupational exposure;
   f. Necessary workers' health surveillance and health services for workers are provided;
   g. Appropriate monitoring equipment and personal protective equipment are provided and arrangements are made for its proper use, calibration, testing and maintenance;
   h. Suitable and adequate human resources and appropriate training in protection and safety are provided, as well as periodic retraining as required to ensure the necessary level of competence;
   i. Adequate records are maintained in accordance with the requirements of this Order and license conditions;
   j. Arrangements are made to facilitate consultation and cooperation with workers, with regard to protection and safety, through their representatives where appropriate, on all measures to achieve effective application of this Order;
   k. Necessary conditions for promoting a safety culture are provided.

3. Licensees and employers shall:

   a. Involve workers, through their representatives where appropriate, in optimization of protection and safety;
   b. Establish and use, as appropriate, constraints as part of optimization of protection and safety.

4. Licensees and employers shall ensure that workers exposed to radiation from radiation devices within a practice that are not required by or directly related to their work have the same level of protection against such exposure as members of the public.

5. Licensees and employers shall take such administrative actions as are necessary to ensure that workers are informed that ensuring protection and safety is an integral part of a general occupational health and safety program in which they have specific obligations and responsibilities for their own protection and the protection of others against radiation exposure and for the safety of radiation devices.

6. Licensees and employers shall record any report received from a worker that identifies any circumstances that could affect safety conditions or compliance with the requirements of this Order and shall take appropriate remedial actions.

7. Employers and licensees shall facilitate compliance by workers with the requirements of this Order.

B. Cooperation between Employers and Licensees

1. Employers and licensees of ionizing radiation facilities shall cooperate to the extent necessary for compliance by all responsible parties to the pertinent rules and regulations set forth by the FDA.

2. If workers are engaged in work that involves or that could involve the use of radiation devices that is not under the control of their employer, the licensee responsible for the radiation devices and the employer shall cooperate to the extent necessary for compliance by both parties with the requirements of this Order.

3. Cooperation between the employer and the licensee shall include, where appropriate:

    a. The development and use of specific restrictions on exposure and other means of ensuring that the measures for protection and safety for workers who are engaged in work that involves or could involve the use of a radiation devices that is not under the control of their employer are at least as good as those for employees of the licensee;
    b. Specific assessments of the doses received by workers as specified in (a);
    c. A clear allocation and documentation of the responsibilities of the employer and those of the licensee for protection and safety.

4. As part of the cooperation between parties, the licensee responsible for the radiation devices or for the exposure shall, as appropriate:

    a. Obtain from the employers, including self-employed individuals, the previous occupational exposure history of workers as specified in Part 4.A.1, and any other necessary information;

b. Provide appropriate information to the employer, including any available information relevant for compliance with the requirements of these Standards that the employer requests;
c. Provide both the worker and the employer with the relevant exposure records

C. Classification of Areas

1. Controlled Areas:

a. Registrants and licensees shall designate as a controlled area any area in which specific measures for protection and safety are or could be required for:
   i. Controlling ionizing radiation exposures in normal operation;
   ii. Preventing or limiting the likelihood and magnitude of exposures in anticipated operational occurrences and accident conditions.
b. In defining the boundaries of any controlled area, registrants and licensees shall take account of the magnitude of the exposures expected in normal operation, the likelihood and magnitude of exposures in anticipated operational occurrences and in accident conditions, and the type and extent of the procedures required for protection and safety.
c. Registrants and licensees:
   i. Shall delineate controlled areas by physical means or, where this is not reasonably practicable, by some other suitable means provided that the established special measures shall be observed.
   ii. Shall, where a radiation device is only intermittently brought into operation or energized, or is moved from place to place, delineate an appropriate controlled area by means that are appropriate under the prevailing circumstances and shall specify exposure times.
   iii. Shall display the symbol/s recommended by the FDA and shall display instructions at access points to and at appropriate locations within controlled areas.
   iv. Shall establish measures for protection and safety, and local rules and procedures for controlled areas.
   v. Shall restrict access to controlled areas by means of administrative procedures such as the use of work permits, and by physical barriers, which could include locks or interlocks, the degree of restriction being commensurate with the likelihood and magnitude of exposures.
   vi. Shall provide, as appropriate, at entrances to controlled areas personal protective equipment, equipment for individual monitoring and workplace monitoring, and suitable storage for personal clothing.
   vii. Shall periodically review conditions to assess whether there is any need to modify the measures for protection and safety or the boundaries of controlled areas.
   viii. Shall provide appropriate information, instruction and training for persons working in controlled areas.

2. Supervised Areas

a. Registrants and licensees shall designate as a supervised area any area not already designated as a controlled area but for which occupational exposure

conditions need to be kept under review, even though specific measures for protection and safety are not normally needed.

b. Registrants and licensees, taking into account the nature, likelihood and magnitude of exposures in the supervised areas:
   i. Shall delineate the supervised areas by appropriate means;
   ii. Shall display approved signs, as appropriate, at access points to supervised areas;
   iii. Shall periodically review conditions to assess whether there is any need for further measures for protection and safety or any need for changes to the boundaries of supervised areas.

D. Local Rules and Procedures and Personal Protective Equipment

1. Employers and registrants and licensees shall minimize the need to rely on administrative controls and personal protective equipment for protection and safety by providing well engineered controls and satisfactory working conditions, in accordance with the following hierarchy of preventive measures:

   a. Engineered controls;
   b. Administrative controls;
   c. Personal protective equipment.

2. Employers, registrants and licensees, in consultation with workers, or through their representatives where appropriate:

   a. Shall establish in writing local rules and procedures that are necessary for protection and safety for workers and other persons;
   b. Shall include in the local rules and procedures any relevant investigation level or authorized level, and the procedures to be followed in the event that any such level is exceeded;
   c. Shall make the local rules and procedures and the measures for protection and safety known to those workers to whom they apply and to other persons who may be affected by them;
   d. Shall ensure that any work in which workers are or could be subject to occupational exposure is adequately supervised and shall take all reasonable steps to ensure that the rules, procedures, and measures for protection and safety are observed;
   e. Shall designate, as appropriate, a radiation protection officer in accordance with criteria to be established by the FDA.

3. Employers, registrants and licensees shall ensure that:

   a. Workers are provided with suitable and adequate personal protective equipment that meets relevant standards or specifications, such as protective aprons, protective gloves, thyroid and organ shields;
   b. Tasks requiring the use of certain personal protective equipment are assigned only to workers who on the basis of medical advice are capable of safely sustaining the extra effort necessary;

c. All personal protective equipment, including equipment for use in an emergency, is maintained in proper condition and, if appropriate, is tested at regular intervals; and
d. If the use of personal protective equipment is considered for any given task, account is taken of any additional exposure that could result owing to the additional time taken or the inconvenience, and of any non-radiological risks that might be associated with using personal protective equipment while performing the task.

E. Monitoring of the Workplace

1. Licensees, in cooperation with employers if appropriate, shall establish, maintain and keep under review a program for the monitoring at the workplace under the supervision of a radiation protection officer or qualified expert, commensurate with the graded approach.

2. The type and frequency of monitoring of workplaces shall:

   a. Be sufficient to enable:
      i. Evaluation of the radiological conditions in all workplaces;
      ii. Assessment of the exposure of workers in controlled areas and supervised areas;
      iii. Review of the classification of controlled and supervised areas.

3. Licensees, in cooperation with employers where appropriate, shall maintain records of the findings of the workplace monitoring program. The findings of the workplace monitoring program shall be made available to workers, where appropriate through their representatives.

4. The program for monitoring of the workplace shall specify:

   a. The quantities to be measured;
   b. Where and when the measurements are to be made and at what frequency;
   c. The most appropriate measurement methods and procedures;
   d. Investigation levels and the actions to be taken if they are exceeded.

F. Occupational Exposure Assessment

1. Licensees and employers shall be responsible for making arrangements for the assessment of the occupational exposure of workers, on the basis of individual monitoring where appropriate, and shall ensure that arrangements are made with appropriate or approved dosimetry service providers that operate under a quality management system.

2. For any worker who regularly works in a supervised area or who enters a controlled area only occasionally, the occupational exposure shall be assessed on the basis of the results or workplace monitoring or of individual monitoring, as appropriate.

G. Records of Worker Exposure

1. Employers and licensees shall maintain records of occupational exposure for each worker for whom assessment of occupational exposure is required under Part 4.F in line with line with their own document retention policy or by any relevant law, as appropriate.

2. Records of occupational exposure for each worker shall be maintained during and after the worker's working life, at least until the worker attains or would have attained the age of 75 years, and for not less than 30 years after cessation of the work in which the worker was subject to occupational exposure.

3. Records of occupational exposure shall include:

    a. Information on the general nature of the work in which the worker was subject to occupational exposure;
    b. Information on dose assessments, exposures and intakes at or above the relevant recording levels and the data upon which the dose assessments were based;
    c. When a worker is or has been exposed while in the employ of more than one employer, information on the dates of employment with each employer and on the doses, and exposures in each such employment;
    d. Records of any assessment of doses, exposures and intakes due to actions taken in an emergency or due to accidents or other incidents, which shall be distinguished from doses, exposures and intakes due to normal conditions of work and which shall include references to reports of any relevant investigations.

4. Employers and licensees shall:

    a. Provide workers with access to records of their own occupational exposure;
    b. Provide the supervisor of the program for workers' health surveillance, the FDA and the relevant employer with access to workers' records of occupational exposure;
    c. Facilitate the provision of copies of workers' exposure records to new employers when workers change employment;
    d. Make arrangements for the retention of exposure records for former workers by the employer or licensee in line with line with their own document retention policy or by any relevant law, as appropriate;
    e. In complying with (a)–(d) above, give due care and attention to maintaining the confidentiality of records in accordance with Republic Act No. 10173 or the Data Privacy Act of 2012, and other data privacy laws and regulations.

5. If employers and licensees cease to conduct activities in which workers are subject to occupational exposure, they shall make arrangements for the retention of workers' records of occupational exposure by the FDA (or other designated organization) or by relevant employer or licensee.

H. Workers' Health Surveillance

1. Employers and licensees, in accordance with the rules established by the FDA, shall make arrangements for appropriate health surveillance based on the general principles of occupational health and designed to assess the initial fitness and continuing fitness of workers for their intended tasks.

2. If one or more workers are to be engaged in work in which they are or could be exposed to radiation from a radiation device that is not under the control of their employer, the licensee responsible for the radiation device shall, as a precondition for the engagement of such workers, make with the employer any special arrangements for workers' health surveillance that are needed to comply with the rules established by the FDA or other relevant authority.

I. Information, Instructions and Training

Employers, in cooperation with licensees:

1. Shall provide all workers with adequate information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions, adequate instruction and training and periodic retraining in protection and safety, and adequate information on the significance of their actions for protection and safety;

2. Shall provide those workers who could be involved in or affected by the response to an emergency with appropriate information, and adequate instruction and training and periodic retraining, for protection and safety;

3. Shall maintain records of the training provided to individual workers.

J. Conditions of Service

1. The conditions of service of workers shall be independent of whether they are or could be subject to occupational exposure. Special compensatory arrangements or preferential consideration with respect to salary, special insurance coverage, working hours, length of vacation, additional holidays or retirement benefits and in line with current shall neither be granted nor be used as substitutes for measures for protection and safety in accordance with the requirements of this Order.

2. Employers shall make all reasonable efforts to provide workers with suitable alternative employment in circumstances for which it has been determined, either by the FDA or in the framework of the program for workers' health surveillance in accordance with the requirements of this Order, that workers, for health reasons, may no longer continue in employment in which they are or could be subject to occupational exposure.

K. Special Arrangements for Female Workers and for Persons Under 18 years of age Undergoing Training

1. Employers, in cooperation with licensees, shall provide female workers who are liable to enter controlled areas or supervised areas or who may undertake emergency duties with appropriate information on:

   a. The risk to the embryo or fetus due to exposure of a pregnant woman;
   b. The importance for a female worker of notifying her employer as soon as possible if she suspects that she is pregnant.

2. Notification of the employer by a female worker if she suspects that she is pregnant shall not be considered a reason to exclude a female worker from work. The employer of a female worker, who has been notified of her suspected pregnancy shall adapt the working conditions in respect of occupational exposure so as to ensure that the embryo or fetus or the infant is afforded the same broad level of protection as is required for members of the public.

3. Employers and licensees shall ensure that no person under the age of 16 years is or could be subject to occupational exposure.

4. Employers and licensees shall ensure that persons under the age of 18 years are allowed access to a controlled area only under supervision and only for the purpose of training for employment in which they are or could be subject to occupational exposure or for the purpose of studies in which radiation devices are used.

Part 5. Medical Exposure

A. General Responsibilities of Licensees

1. Licensees shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless:

   a. It is radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening program;
   b. The medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening program;
   c. A radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in Part 5.A.4.a of the supplemental requirements of this Order.
   d. The patient or the patient's legal authorized representative has been informed, as appropriate, of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

2. Licensees shall ensure that no individual incurs a medical exposure as part of a program of biomedical research unless the exposure has been approved by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority) as required in paragraph 5 of this Part and a radiological medical practitioner has assumed responsibility as specified in Part 5.A.4.a of this Order. Licensees shall ensure that the requirements are met for the optimization of protection and safety for persons subject to exposure as part of a program of biomedical research.

3. Licensees shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure. Licensees shall ensure that the requirements specified in Part 5.H.1 are fulfilled for the optimization of protection and safety for any radiological procedure in which an individual acts as a carer or comforter.

4. Licensees shall ensure that:

   a. The radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure, including the justification of the radiological procedure as required in Section Part 5.B and the optimization of protection and safety, in cooperation with the medical physicist and the medical radiologic technologist;
   b. Radiological medical practitioners, medical physicists, radiologic/x-ray technologists and other health professionals with specific duties in relation to

protection and safety for patients in a given radiological procedure are specialized in the appropriate area;

c. Sufficient medical personnel and paramedical personnel are available as required by DOH / FDA;
d. Medical personnel and paramedical personnel are specialized in the appropriate area and meet the respective requirements for education, training and competence in radiation protection (as specified by the FDA);
e. The names of all medical and paramedical personnel are named in a list maintained up to- date;
f. For therapeutic radiological procedures, the requirements of this Order for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Part 5.D, Part 5.A.1, and Part 5.F of the supplemental requirements of this Order, are conducted by or under the Supervision of a medical physicist;
g. For diagnostic radiological procedures and image guided interventional procedures, the requirements of these Standards for medical imaging, calibration, dosimetry, and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in Parts 5.A.1, 5.A.2, 5.G.1, 5.H, and 7.B, are fulfilled by or under the oversight of or with the documented advice of a medical physicist, whose degree of involvement is determined by the complexity of the radiological procedures and the associated radiation risks;
h. Any delegation of responsibilities by a principal party is documented.

B. Justification of Medical Exposure

1. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

2. The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or pediatric, of:

   a. The appropriateness of the request;
   b. The urgency of the radiological procedure;
   c. The characteristics of the medical exposure;
   d. The characteristics of the individual patient;
   e. Relevant information from the patient's previous radiological procedures.

3. Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

4. Justification for radiological procedures to be performed as part of a health screening program for asymptomatic populations shall be carried out by the health authority in conjunction with appropriate professional bodies.

5. Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening program, shall require specific justification for that individual by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

6. The exposure of volunteers as part of a program of biomedical research is deemed to be not justified unless:

   a. It is in accordance with the provisions of the World Medical Association Declaration of Helsinki, Ethical Principles for Medical Research Involving Human Subjects and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences (CIOMS) in collaboration with the WHO, International Ethical Guidelines for Biomedical Research Involving Human Subjects; and
   b. It is subject to approval by an ethics committee (or other institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority), subject to any dose constraints that may be specified (as required in Part 5.H.2), and subject to applicable national regulations and local regulations.

C. Optimization of Protection for Medical Exposures

1. Licensees and radiological medical practitioners shall ensure that protection and safety is optimized for each medical exposure.

Design considerations

2. In addition to ensuring that the responsibilities stated in Part 7.A are discharged, as applicable, licensees, in cooperation with suppliers, shall ensure that medical radiological equipment, and software that could influence the delivery of medical exposure are used only if they conforms to the applicable standards of the International Electrotechnical Commission (IEC) and the International Organization for Standardization (ISO) or to national standards adopted by the FDA.

Operational considerations

3. For diagnostic radiological procedures and image guided interventional procedures, the radiological medical practitioner, in cooperation with the medical radiologic technologist and the medical physicist, shall ensure that the following are used:

   a. Appropriate medical radiological equipment and software;
   b. Appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfill the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable

image quality established by relevant professional bodies and of relevant diagnostic reference levels established in accordance with Part 5.F.

4. For therapeutic radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiologic technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.

5. Licensees shall ensure that the aspects of medical exposures are considered in the optimization process for:

   a. Pediatric patients subject to medical exposure;
   b. Individuals subject to medical exposure as part of a health screening program;
   c. Volunteers subject to medical exposure as part of a program of biomedical research;
   d. Relatively high doses to the patient;
   e. Exposure of the embryo or fetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the useful radiation beam or could otherwise receive a significant dose;

D. Calibration

In accordance with Part 5.A.4.f and g, the medical physicist shall ensure that:

1. All radiation devices giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols;

2. Calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals required by the FDA in other regulations;

3. Calibrations of radiotherapy units are subject to independent verification prior to clinical use;

4. Calibration of all dosimeters used for dosimetry of patients and for the calibration of radiation devices is traceable to a standard dosimetry laboratory.

E. Dosimetry of Patients

1. Licensees shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and following internationally accepted or nationally accepted protocols, including dosimetry to determine the following:

   a. For diagnostic radiological procedures, typical doses to patients for common procedures;
   b. For image guided interventional procedures, typical doses to patients;

c. For therapeutic radiological procedures, absorbed doses to the planning target volume for each patient treated with external beam therapy and absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner.

F. Diagnostic Reference Levels

1. Licensees shall ensure that:

   a. Local assessments, on the basis of the measurements required in Part 5.A, are made at approved intervals for those radiological procedures for which diagnostic reference levels have been established by FDA, through consultation with relevant professional bodies.
   b. A review is conducted to determine whether the optimization of protection and safety for patients is adequate, or whether corrective action is required if, for a given radiological procedure:
      i. Typical doses or activities exceed the relevant diagnostic reference level; or
      ii. Typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit to the patient.

G. Quality Assurance for Medical Exposure

1. Licensees shall establish a comprehensive program of quality assurance for medical exposures with the active participation of medical physicists, radiological medical practitioners, medical radiologic technologists and in conjunction with other health professionals as appropriate.

2. Licensees shall ensure that programs of quality assurance for medical exposures include, as appropriate to the medical radiation facility:

   a. Measurements of the physical parameters of medical radiological equipment made by or under the supervision of, a medical physicist:
      i. At the time of acceptance and commissioning of the equipment prior to its clinical use on patients;
      ii. Periodically thereafter;
      iii. After any major maintenance procedure that could affect protection and safety of patients;
      iv. After any installation of new software or modification of existing software that could affect protection and safety of patients;
   b. Implementation of corrective actions if measured values of the physical parameters mentioned in (a) are outside established tolerance limits;
   c. Verification of the appropriate physical and clinical factors used in radiological procedures;
   d. Maintaining records of relevant procedures and results;
   e. Periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

3. Licensees shall ensure that regular and independent audits are made of the program of quality assurance for medical exposures, and that their frequency is in accordance with the complexity of the radiological procedures being performed and the associated risks.

H. Dose Constraints

1. Licensees shall ensure that relevant dose constraints are used in the optimization of protection and safety in any radiological procedure in which an individual acts as a carer or comforter.

2. Licensees shall ensure that dose constraints specified or approved by the ethics committee, or by another institutional body that has been assigned functions similar to those of an ethics committee by the relevant authority, on a case by case basis as part of a proposal for biomedical research (Part 5.B.6) are used in the optimization of protection and safety for person subject to exposure as part of a program of biomedical research.

I. Pregnant Patients

1. Licensees shall ensure that there are arrangements in place for appropriate radiation protection in cases where a female patient is or might be pregnant.

2. Licensees shall ensure that signs in appropriate languages are placed in public places, waiting rooms for patients, cubicles and other appropriate places, and that other means of communication are also used as appropriate, to request female patients who are to undergo a radiological procedure to notify the radiological medical practitioner, medical radiologic technologist or other personnel in the event that she is or might be pregnant;

3. Licensees shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or fetus, so that this information can be considered in the justification for the radiological procedure (Part 5.2.1) and in the optimization of protection and safety.

J. Unintended and Accidental Medical Exposures

Licensees, in accordance with the relevant requirements of Section VII.B.i.h.3 of this Order, and Part 1.F and Part 7 of its supplemental requirements, shall ensure that all practicable measures are taken to minimize the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors in software, or as a result of human error.

K. Investigation of Unintended and Accidental Medical Exposures

1. Licensees shall promptly investigate any of the following unintended or accidental medical exposure:

a. Any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;
b. Any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;
c. Any exposure for diagnostic purposes that is substantially greater than was intended;
d. Any exposure arising from an image guided interventional procedure that is substantially greater than was intended;
e. Any inadvertent exposure of the embryo or fetus in the course of performing a radiological procedure;
f. Any failure of medical radiological equipment, failure of software or system failure, accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

2. Licensees shall, with regard to any unintended or accidental medical exposures investigated as required above:

a. Calculate or estimate the doses received and the dose distribution within the patient;
b. Indicate the corrective actions required to prevent recurrence of such an unintended or accidental exposure;
c. Implement all the corrective actions that are under their own responsibility;
d. Produce and keep, as soon as possible after the investigation or as otherwise required by the FDA, a written record that states the cause of the unintended or accidental medical exposure and includes the information specified in (a) to (c) above, as relevant, and any other information as required by the FDA; and for significant unintended or accidental medical exposures or as otherwise required by the FDA, submit this written record, as soon as possible, to the FDA, and to the relevant health authority if appropriate;
e. Ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorized representative of the unintended or accidental medical exposure.

L. Radiological Reviews

Licensees shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility, in cooperation with the medical radiologic technologists and the medical physicists. The radiological review shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimization for the radiological procedures that are performed in the medical radiation facility.

M. Records Related to Medical Exposures

1. Licensees shall maintain for a period as specified by the FDA and shall make available, as required, the following personnel records:

a. Records of any delegation of responsibilities by principal parties (as required in Part 5.A.4.h;
b. Records of training of personnel in radiation protection.

2. Licensees shall maintain for a period as specified by the FDA and shall make available, as required, the following records of calibration, dosimetry and quality assurance:

   a. Records of the results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;
   b. Records of dosimetry of patients, as required in Part 5.E;
   c. Records of local assessments and reviews made with regard to diagnostic reference levels, as required in Part 5.F;
   d. Records associated with the quality assurance program, as required in Part 5.G.2.d.

3. Licensees shall maintain for a period as specified by the FDA and shall make available, as required, the following records for medical exposure:

   a. For diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;
   b. For image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of the fluoroscopic component and the number of images acquired;
   c. For external beam radiation therapy, a description of the planning target volume, the absorbed dose to the center of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition, for external beam radiation therapy, the dose fractionation and the overall treatment time;
   d. Exposure records for volunteers subject to medical exposure as part of a programme of biomedical research;
   e. Reports on investigations of unintended and accidental medical exposures as required in Part 5.K.2.d.

Part 6. Public Exposure

A. General Responsibilities

1. Licensees in cooperation with suppliers, in applying the principle of optimization of protection and safety in the design, planning, operation of an radiation devices, shall take into account:

   a. Good design and construction of the facility;
   b. Good practice in the operation of the facility using radiation devices.

2. Licensees, using radiation devices under their responsibility, shall establish, implement and maintain:

   a. Policies, procedures and organizational arrangements for protection and safety in relation to public exposure, and in accordance with the requirements of this Order;
   b. Measures for ensuring:
      i. Optimization of protection and safety;
      ii. Limitation of exposure of members of the public from such radiation devices, in order that the total exposure is not higher than the dose limits for members of the public as specified in Annex B of this Order;
   c. Measures for ensuring the safety of such radiation devices;
   d. Provision for suitable and adequate radiation devices (including facilities, equipment and services) for the protection and safety of members of the public, commensurate with the likelihood and magnitude of the exposures;
   e. Programmes for appropriate training of personnel having functions relevant to the protection and safety of the public, as well as periodic retraining as required, to ensure the necessary level of competence;
   f. Provision for appropriate monitoring equipment, monitoring programmes and methods for assessing public exposure;
   g. Emergency plans, emergency procedures and emergency response arrangements, in accordance with the nature and magnitude of the radiation risks associated with the radiation devices;
   h. Adequate records of monitoring programmes.

B. Control of Visitors

Licensees, in cooperation with employers where appropriate, shall:

1. Apply the relevant requirements of this Order in respect of public exposure for visitors to a controlled area or a supervised area;

2. Ensure that visitors are accompanied in any controlled area by a person who knows the measures for protection and safety for the controlled area;

3. Provide adequate information and instructions to visitors before they enter a controlled area or a supervised area so as to provide protection and safety for visitors and other individuals who could be affected by their actions;

4. Ensure that adequate control is maintained over the entry of visitors to a controlled area or a supervised area, including the use of signs for such areas.

C. Radiation Devices of External Irradiation

Licensees shall ensure that if a radiation device can give rise to external exposure of members of the public:

1. The floor plans and arrangements of equipment for all new installations utilizing such radiation devices, as well as all significant modifications to existing installations, are subject, as appropriate, to review and approval by the FDA prior to commissioning;

2. Shielding and other measures for protection and safety, including access controls, are provided as appropriate for restricting public exposure, in particular at open sites such as for some applications of industrial radiography.

D. Monitoring of Public Exposure

Licensees shall, as appropriate:

1. Establish and implement monitoring programs to ensure that public exposure due to radiation devices under their responsibility is adequately assessed and that the assessment is sufficient to verify and demonstrate compliance with the authorization. These programs shall include monitoring of the external exposure from radiation devices and other parameters for the assessment of public exposure;

2. Maintain appropriate records of the results of the monitoring programs and estimated doses to members of the public;

3. Report promptly to the FDA any levels exceeding the operational limits and conditions relating to public exposure, in accordance with reporting criteria established by the FDA;

4. Report promptly to the FDA any significant increase in dose rate in accordance with reporting criteria established by the FDA in specific regulations;

5. Establish and maintain a capability to carry out monitoring in an emergency, in the event of unexpected increases in radiation levels due to accidents or other unusual events attributed to the authorized use of radiation devices or operation of the x-ray facility;

6. Verify the adequacy of the assumptions made for the assessment of public exposure;
7. Publish or make available on request by the FDA, results from radiation devices monitoring and assessments made of doses from public exposure.

Part 7. Radiation Devices

A. General Responsibilities

1. The licensee, in cooperation with other responsible parties, shall ensure that the siting, location, design, construction, assembly, commissioning, operation, maintenance and closure of facilities using radiation devices are based on good engineering practice which shall, as appropriate:

    a. Take account of international and national standards;
    b. Be supported by managerial and organizational features, with the purpose of ensuring protection and safety throughout the lifetime of the facility;
    c. Include adequate safety margins in the design and construction of the facility, and in operations involving the facility using radiation devices, so as to ensure reliable performance in normal operation, and take account of the necessary quality, redundancy and capability for inspection, with emphasis on preventing accidents, mitigating the consequences of those accidents that do occur and restricting any possible future exposures;
    d. Take account of relevant developments concerning technical criteria, as well as the results of any relevant research on protection and safety and feedback of information on lessons learned from experience.

2. Where applicable, licensees shall make suitable arrangements with suppliers of radiation devices and radiation devices, the FDA and relevant parties for the purposes of:

    a. obtaining information on conditions of use and operating experience that may be important for protection and safety;
    b. providing feedback and information that may have implications for protection and safety for other users, or that may have implications for the possibility for improvements in protection and safety for radiation devices.

B. Design of Radiation Devices

1. Licensees who are manufacturers and suppliers of ionizing radiation devices shall:

    a. supply well-designed, well-manufactured and well- constructed radiation devices;
    b. demonstrate radiation devices meets specifications in conformance to applicable technical standards, such as the IEC and ISO – equivalent standards or where applicable, Philippine National Standards (PNS);
    c. provide instructions on installation, operating and maintenance;
    d. ensure that the radiation device meets quality standards commensurate with the significance for protection and safety of systems and components, including software;
    e. ensure protective devices (e.g. shielding) are optimized;
    f. provides clear displays, gauges and instructions on operating consoles in a language understandable to the users) (local language or in English);

g. ensure that radiation devices are tested to demonstrate compliance with the relevant specifications. Ensuring that the protection provided by shielding and by other protective devices is optimized.

2. Licensees shall ensure that arrangements are made promptly for the safe management of and control over radiation devices, including appropriate financial provision, once it has been decided to take them out of use or decommissioned.

Annex B. Dose Limits for Planned Exposure Situations

(Reference: IAEA GSR Part 3 Schedule III)

Occupational Exposure

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

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. 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;

3. 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 this Order, with no retrospective averaging.

4. An equivalent dose to the extremities (hands and feet) or to the skin of 500 mSv in a year.

5. 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.

Additional restrictions apply to occupational exposure for a female worker who has notified pregnancy or is breast-feeding pursuant to Annex B, Part 4.K.2.

Public Exposure

B. For public exposure, the dose limits are:

1. An effective dose of 1 mSv in a year;

2. In special circumstances, such as but not limited to authorized, justified and planned operational conditions that may lead to transitory increases in exposures, 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;

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

4. An equivalent dose to the skin of 50 mSv in a year.

Annex C. References

DOH. (2004a). *DOH Administrative Order (AO) No. 149 s. 2004 or Basic Standards on Radiation Protection and Safety Governing the Authorization for the Introduction and Conduct of Practices Involving X-ray Sources in the Philippines.*

DOH. (2004b). *DOH Department Circular No. 323 s. 2004 or the Manual on Basic Radiation Protection and Safety. Of X-ray Sources in the Philippines.*

DOH. (2004c). *DOH Administrative Order No. 164 s. 2004 or the Amendment to the Basic Standards on Radiation Protection and Safety Governing the Authorization for the Introduction and Conduct of Practices involving X-ray Sources in the Philippines.*

DOH. (2018). *DOH Administrative Order (AO) No. 2018-0014 or Strategic Framework and Implementing Guidelines for FOURmula One Plus for Health (F1+).*

IAEA. (1996). *International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources. IAEA Safety Series No. 115.* https://www.ilo.org/global/topics/safety-and-health-at-work/resources-library/publications/WCMS_152685/lang--en/index.htm

IAEA. (2014). *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards. General Safety Requirements Part 3*

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