Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUL 30 2020

ADMINISTRATIVE ORDER
No. 2020 - 0035

SUBJECT: **Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorization**

I. RATIONALE

With the signing of Republic Act 11032 otherwise known as "Ease of Doing Business (EODB) and Efficient Government Service Delivery Act of 2018" on May 2018 and its Implementing Rules and Regulations on July 17, 2019, all government agencies are mandated to re-engineer and streamline their regulatory processes to establish effective practices and efficient turnaround time in the delivery of government services. In consonance with Section 5 (*Re-engineering of Systems and Procedures*) of RA No. 9485, also known as the Anti-Red Tape Act of 2007 (ARTA), as amended by RA No. 11032, the Food and Drug Administration (FDA) hereby adopts a new application process and forms for appropriate authorizations for radiation facilities which are navigable and accessible through the FDA website (*www.fda.gov.ph*).

This new guideline also aligns with the strategic objectives of the Department of Health (DOH) FOURmula One Plus for Health (F1 Plus) and RA No. 11223, or the Universal Health Care (UHC) Law. in improving health outcomes among Filipinos by ensuring the radiation protection and safety on the use of radiation devices and operation of its facilities.

The DOH, through the Center for Device Regulation, Radiation Health and Research (CDRRHR) of the FDA, shall issue authorization, monitor and regulate facilities engaged in the use of radiation devices and other activities using the same devices in the Philippines as mandated by Presidential Decree No. 480, otherwise known as the "Creation of the Radiation Health Office" in 1974 as amended by Presidential Decree 1372 in 1978 and consistent with Executive Order No. 119, s. 1992, otherwise known as the Reorganization Act of the Ministry of Health" in 1987, as revised by Executive Order No. 102, otherwise known as "Redirecting the Functions and Operations of the Department of Health in 1999 and Republic Act No. 9711 entitled "The Food and Drug Administration Act of 2009" and its Implementing Rules and Regulations (IRR).

II. OBJECTIVES

General Objective:

This Order aims to ensure the health and safety of radiation workers, patients, and the general public by regulating the activities and operation of radiation facilities, and requiring them to secure a License to Operate (LTO), Certificate of Facility Registration (CFR), and other related authorizations.

Specific Objectives:

A. To establish rules and regulations in the authorization of radiation facilities to align with the recently promulgated laws and regulations;

B. To provide updates and streamline the regulatory approaches in the issuance of appropriate authorizations for radiation facilities;

C. To ensure compliance of radiation facilities to FDA and relevant national regulatory and international standards; and

D. To prescribe the use of the online application and the corresponding procedures through the FDA website and implementation of innovations, such as but not limited to, electronic data messages, electronic submission of documents and electronic signatures in the FDA pursuant to RA No. 8792 or the "Electronic Commerce Act of 2000" and RA No. 11032 known as "Ease of Doing Business (EODB) and Efficient Government Service Delivery Act of 2018 and its Implementing Rules and Regulations.

III. SCOPE

This Order shall apply to all radiation facilities in the country, including local government units, government and controlled corporations, non-government organizations, and other government offices engaged in the use of radiation devices.

However, this Order shall not apply to radiation facilities in the country engaged in installation, testing, repair, maintenance, and disposal of radiation devices, which will be covered by another issuance.

This Order shall not apply also to radiation facilities utilizing radioactive sources which fall under the regulation of the Philippine Nuclear Research Institute and radiation facilities regulated by other related government agencies.

IV. DEFINITION OF TERMS

For purposes of this Order, the succeeding terms shall be consistently be defined as follows:

1. ***Authorization*** refers to permission embodied in a document granted by the FDA to a natural or juridical person who has submitted an application to implement the use of a radiation device and operation of its facility. The authorization can take the form of a permit, a facility registration, a license, a certificate of compliance, or certificate of safety evaluation or any similar document issued by the FDA.

2. ***Certificate of Facility Registration (CFR)*** refers to an authorization or permission granted by the FDA to any natural or juridical person engaged in the use of radiation devices and operation of its facilities and activities of medium risk, the requirements for safety assessment and the conditions or limitations applied to the facilities would be less severe than licensing, the safety can be largely ensured by the design of the facilities and equipment, the operating procedures are simple to follow, the safety training are minimal, and there is a history of few problems with safety in operation.

3. ***Certificate of Safety Evaluation (CSE)*** refers to a desktop evaluation of the NIR facility using specific NIR devices, based on the technical documents submitted regarding the NIR emitting device, nature of installation, location and site configuration of the facility. Where applicable, it contains the relevant exposure limit for occupational (radiation worker) and non-occupational (member of the public). It also includes a list of requirements that must be complied with by the facility.

4. ***Exemption*** refers to a radiation source or practice that need not be subjected to some or all aspects of regulatory control on the basis that the exposure and the potential exposure due to the source or practice are too small to warrant the application of those aspects or that this is the optimum option for protection irrespective of the actual level of the doses or risks.

5. ***Facility*** refers to a structure or installation that houses radiation devices used for medical and non-medical purposes.

6. ***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.

7. ***Licensee*** refers to the holder of a current license. The licensee is the person or organization having overall responsibility for a facility or activity.

8. ***License to Operate (LTO)*** refers to an authorization or permission granted by the FDA to any natural or juridical person engaged in the use of radiation devices and operation of its facilities and activities, where the level of risk, potential magnitude of exposure and hazard of facilities and activities associated with the practice or use of radiation devices is high, and the safety assessment requirements for the facility is more complex than registration.

9. ***Notification*** refers to a document submitted to the FDA by a person or organization to notify an intention to carry out a practice or other use of a radiation device. A permission shall be granted to the facility wherein exposure on the use of a radiation device is unlikely to exceed a small fraction of the relevant exposure limits; the level of risk is low and the likelihood and magnitude of potential exposures and any other potential detrimental consequences are **negligible.**

10. ***Pre- Licensing Inspection also known as Radiation Protection Survey and Evaluation (RPSE)*** refers to a comprehensive and complete on-site inspection and evaluation of the radiation facility including, but not limited to the verification of submitted/compliance documents, evaluation of the qualification and number manpower requirements, safety and quality of equipment, radiation safety programs, quality assurance programs, verification test and actual measurements to assess the performance of the machine, x-ray tube leakage radiation, checking adequacy of shielding barriers, accessories, and compliance with the appropriate requirements of this Order.

11. ***Post-Licensing Inspection (PLI) also known as Facility Compliance Monitoring (FCM)*** refers to a post-approval inspection conducted to all radiation facilities classified as high risk facilities, as part of surveillance / investigation activities to monitor continuous compliance with the licensing requirements, accident/incident follow up, and special

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inspection made because of reported violations of the relevant rules and regulations issued by the FDA.

12. ***Post-Registration Inspection (PRI) also known as Facility Compliance Monitoring (FCM)*** refers to a post-approval inspection conducted to all radiation facilities classified as medium risk facilities as part of surveillance/investigation activities to monitor continuous compliance with the facility registration requirements or because of reported violations of the relevant rules and regulations issued by the FDA.

13. ***Registrant*** refers to the holder of a current facility registration. The registrant is the person or organization having overall responsibility for a facility or activity.

14. ***Variation*** refers to a post-FDA approval changes in the status, condition or activity of an authorized radiation facility.

Additional terms are also defined in Annex A of this Order to support its implementation.

V. GENERAL GUIDELINES

1. All radiation facilities shall abide by the guidelines on electronic submission and process of appropriate authorization through the e-portal found at the FDA website (*www.fda.gov.ph*). In the event of FDA website system failure, guidelines for manual procedures of submitting and processing of applications for appropriate authorization shall be observed.

2. The authorization process and requirements shall be in a graded approach commensurate with the nature of hazard and level of risk associated with facilities and activities.

3. All ionizing and non-ionizing radiation facilities and other activities covered in this Order shall first secure the appropriate LTO, CFR or/other related authorization from the FDA prior to engaging in the use of radiation devices and operation of its facilities.

4. All radiation facilities shall be required to demonstrate compliance to technical standards as a requirement to licensing, registration, and issuance of other related authorization. The technical standards are the requirements formulated by the FDA-CDRRHR and are issued in the form of AO, circulars, and/or other related issuances.

5. For Extremely Low Frequency (ELF) Radiation Facility and Radiofrequency (RF) Radiation Facility, no person shall engage in activities, which involve practices using non-ionizing radiation devices, unless the requirements of these Regulations, including requirements specified in the Administrative Order No. 2007-0033 (Amendment to Implementing Rules and Regulations of Chapter XX- " Pollution of the Environment" of the Code of sanitation of the Philippines, PD 856) and Administrative Order No. 175 s. 2004 (Radiation Protection Standards for Radiofrequency Radiation in the Frequency Range 3 kHz – 300 GHz) or as revised are met. For other NIR facilities, requirements and appropriate authorization shall be covered in separate regulations and guidelines.

6. The radiation facility shall permit representatives of the FDA access to premises and facilities in which radiation devices are located or expected to be located in order to obtain information about the status of the radiation safety and verify compliance with the regulatory

requirements. Facility shall make available to the representatives of the FDA relevant information, documents, and records regarding radiation safety.

7. For radiation facilities under the DOH One-Stop-Shop Licensing System, the electronic submission through the Integrated DOH Licensing Information System (IDLIS) or as revised shall apply.

8. Every radiation facility and other activities shall have a Radiation Protection Officer (RPO) and where applicable Qualified Expert/s (QE) with qualification requirements, duties and responsibilities are specified in a separate AO, FDA issuances, policy, and guidelines or as revised.

9. The licensee/registrant shall have the prime responsibility of ensuring the radiation protection and safety on the use of radiation devices and operation of its facility. The licensee/registrant may appoint other parties or people to carry out actions and tasks but the overall responsibility for protection and safety remains always at the licensee/registrant.

10. A safety assessment and quality assurance program shall be established, implemented, documented in accordance with the graded approach for the authorization of facilities and activities for which they are responsible.

11. The licensee/registrant shall post in a conspicuous area within the radiation facility the appropriate authorization; personnel professional qualification and certificate of proficiency in the specialty.

12. All ionizing and non-ionizing radiation facilities shall demonstrate continuous compliance with the relevant technical standards and regulations as a requirement for the issuance of appropriate authorizations. Otherwise they may be ordered closed or their licenses be suspended or revoked *motu proprio* or upon petition by any affected person.

13. Any change affecting the conditions of the LTO and other relevant authorization shall be reported in writing within 15 days to the FDA for notation and approval. Failure to do so will justify the revocation of the LTO.

VI. SPECIFIC GUIDELINES

A. ISSUANCE OF AUTHORIZATION

1. The issuance of authorization shall be in graded approach in accordance with the type of radiation, level of risk, magnitude of exposure, practice complexity or use, installation and application.

2. Classification of radiation facilities and authorization issued is summarized in the table shown in Annex B of this Order.

B. APPLICATION PROCESS

For applications of authorization for radiation facility, a highly technical transaction that involves activities which pose danger to public health and safety, the prescribed processing time shall be in strict compliance with the ARTA-approved FDA Citizens' charter.

The process involves several stages, hence the processing time for each stage commences on the date/time that the applicant has satisfactorily completed the requirements for the previous stage and has submitted all the requirements for the subsequent stage being applied for.

1. Filing of Application

1.1 Filing of application whether initial, renewal, or variation shall be done online through the FDA website (*www.fda.gov.ph*).

1.2 Implementing guidelines of the step by step procedures for the online application of the authorizations shall be covered in separate issuances.

1.3 An application is deemed filed upon submission of complete requirements as required in Annexes C to G of this AO including payment of required fees and charges.

1.4 An electronically generated notice of the status of the application shall be received by the applicant.

2. Evaluation

The evaluation of all applications for authorization shall be based on the veracity of the submitted documents and compliance to the applicable requirements or appropriate standards and regulations.

3. Inspection

3.1 Inspections of facilities and activities shall be commensurate with the radiation risks associated with the facility or activity, in accordance with a graded approach.

3.2 For initial application of facilities with high risk level of radiation exposure, the FDA shall conduct Pre-Licensing inspection for compliance with existing regulatory requirements and standards prior to the issuance of LTO.

3.3 The application is recommended for approval upon compliance with all the regulatory requirements after the conduct of RPSE/FCM.

3.4 If the facility during the conduct of RPSE/FCM is found non-compliant with the licensing requirements and prescribed standards, the facility will be given a non-extendible period of 15 working days from the date of issuance of the RPSE/FCM report unless otherwise a request for extension with justifiable reason was granted, a copy of which was furnished to the applicant/requesting party, within which to submit to CDRRHR the lacking licensing requirements/rectified the noted deficiencies. Failure to submit the same within the required period of time shall warrant the issuance of Notice of Disapproval addressed to the applicant/ requesting party within the specified processing time citing the reason/s for the disapproval of its application.

3.5 In the event that a RPSE was not undertaken because of any unforeseen events or due to force majeure, and without the contributory fault negligence of the applicant/owner authorized officer, the processing time allotted for the conduct of an RPSE until the supposed schedule for the approval of the LTO shall be suspended and appropriate adjustments should be made,

affording written notification to the applicant or requesting party the reason/s for the extension of time for completion of the RPSE and final date of release of the LTO.

3.6 Any incident/accident within the facility shall be reported immediately within three (3) days from its occurrence. The conduct of post licensing/post registration inspection shall be done within seven (7) days after the facility has reported an incident/accident and/or reported violation of the appropriate AO.

3.7 All facilities with medium risk of radiation exposure, shall not require pre-licensing inspection before approval of certificate of facility registration provided that all necessary requirements are complied with and the safety assessment has been approved by the FDA. A post registration inspection may be done within the validity of the issued authorization.

3.8 Post-Licensing Inspection (PLI) or Post Registration Inspection (PRI) also known as the Facility Compliance Monitoring (FCM) shall be conducted after approval and issuance of the LTO or CFR to ensure continuous compliance with the existing regulatory requirements and standards. The manner, extent and frequency of inspections, and the areas and programs to be inspected shall be in accordance with a graded approach.

3.9 All covered facilities may be inspected at any time by FDA within the constraints of ensuring operational safety at all times and other constraints associated with the potential for harmful consequences as part of its monitoring/surveillance activities.

4. Decision on Application:

4.1. Approval

If the facility has satisfactorily complied with all the requirements upon evaluation of an application and/or inspection, the appropriate authorization shall be issued. An electronically generated notice shall be sent to the applicant/facility stating that the application has been approved and that the authorization can be downloaded for printing.

4.2. Disapproval

The application shall be disapproved:

a. If upon evaluation and/or inspection, there was no satisfactory evidence to prove compliance with the requirements.

b. If upon further evaluation, the applicant fraudulently filed or misrepresented material facts or falsified documents, or withheld any relevant data or information contrary to the provision of the law, rules and regulations or appropriate standards. Following due process, the applicant may be subjected to further investigation, appropriate changes may be filed, and penalties and sanctions may be imposed under the law.

c. If the applicant/facility failed to comply within the prescribed timeline provided by the FDA with the administrative and technical requirements found during the conduct of inspection.

d. A letter shall be sent to the applicant/facility stating the ground/s for disapproval of the application. The disapproval of application shall mean outright forfeiture of payment and the

applicant/facility shall be required to re-apply and pay the corresponding fee. The disapproval of an application is without prejudice to re-application.

5. Validity of Issued Authorizations:

5.1 All initial LTO and CFR authorizations shall have three (3) years validity.
5.2 Renewal of LTO and CFR authorizations shall have five (5) years validity.
5.3 Authorization issued for radiation facilities covered under the OSS licensing system shall respectively follow the (3) years validity for initial and (5) years validity for renewal. The validity period shall remain valid, provided that no violation has been committed in relation to existing rules and regulations which may result in sanctions such as suspension, revocation or closure of health facilities under the OSS licensing system.

6. Renewal of LTO and CFR:

6.1 Application for renewal of LTO/CFR shall be filed within three (3) months from the date of expiration. An application received after expiration of the LTO shall be subject to a surcharge or penalty equivalent to twice the renewal licensing/ registration fee and an additional ten percent (10%) per month or a fraction thereof of continuing non-submission of such application up to a maximum of one hundred twenty (120) days.

6.2 Any application for renewal of LTO/CFR filed beyond the one hundred twenty (120) days after the original expiration shall be subject to a fee equivalent to the total surcharge or penalty plus the initial license fee.

6.3 For renewal applications filed within one hundred twenty (120) days from its original expiry, the LTO/CFR shall be considered valid and existing until a decision or resolution by the FDA is rendered on the application for renewal.

6.4 Automatic renewal as provided for by the Implementing Rules and Regulations of RA No. 11032, specifically Rule VIII. Section I. *When shall Automatic Approval of an Original Application or Request be granted*, shall apply when the following conditions are met:

- The application is filed before the expiration date;
- The prescribed renewal fee is paid upon filing of the application; and
- A sworn statement is attached to the application indicating no change or variation whatsoever in the radiation facility

7. Application for Variation

7.1 Application for variation refers to post-approval applications by a radiation facility to implement a change from the previously approved and issued LTO, CFR or other related authorization.

7.2 The validity of the authorization will be from the date of approval of the variation until the original date of expiration.

7.3 No change in the previously approved circumstance of the application of the radiation facility shall be effected unless proper notification and submission of necessary documents to the FDA and approval of such changes/s has been made.

7.4 Major variations as post approval changes, may be subject to inspection as deemed necessary by the FDA.

8. Cancellation of LTO or CFR

8.1 Automatic Cancellation

Existing facilities that failed to file an application for renewal after one hundred twenty (120) days from the date of expiration shall be automatically cancelled and deleted from the list of licensed / registered facilities without prejudice to re-application.

8.2 Voluntary

The owner or legal person of a licensed / registered facility may apply for voluntary cancellation of its existing license / registration by filing a formal notification.

C. Fees and Other Charges

The FDA shall collect non-refundable application fees and other charges as may be allowed by the existing issuances on fees and charges or surcharges and any applicable amendment thereto.

VII. ENFORCEMENT ACTIONS

The Director General- FDA may execute any necessary regulatory action deemed necessary to protect and promote the health of the Filipino people. Regulatory action may include suspension, cancellation or revocation of an existing LTO, CFR and/or other related authorization, authorization of administrative violations of any other relevant laws or their implementing rules and regulations, closure of the x-ray facility, preventive measure orders, imposition of administrative fines and penalties for violation of RA 9711 and its IRR and other FDA-implemented rules and regulations.

VIII. TRANSITORY PROVISIONS

1. All new and existing facilities using ionizing radiation devices for medical and non-medical applications shall be given three (3) years from the effectivity date of this A.O. to comply with the safety assessment requirements.

2. All existing non-ionizing radiation facility using ELF and RFR radiation devices shall be given two (2) years from the effectivity date of this A.O. to comply with the designation of a Radiation Protection Officer and the submission of the facility's Radiation Safety Program as required in Administrative Order No. 175 s. 2004 (Radiation Protection Standards for Radiofrequency Radiation in the Frequency Range 3 kHz – 300 GHz) and applicable rules and regulations issued by the FDA.

IX. REPEALING CLAUSE

Provisions from the Administrative Order No. 2018-0016, 2012-0012, 2007-0021, 2008-0027, 124 s. 1992, and 175 s. 2004 that are inconsistent with this Administrative Order are hereby repealed, rescinded and modified accordingly.

X. MANDATORY REVIEW

This Order shall be reviewed by the FDA after three (3) years of its implementation.

XI. EFFECTIVITY

This Administrative Order shall take effect fifteen (15) days after its publication in at least two (2) national papers of general circulation and upon filing at the Office of National Administrative Register (ONAR) at the UP-Law Center, Diliman, Quezon City.

FRANCISCO T. DUQUE III, MD, MSc.
Secretary of Health

ANNEX A

Additional Definition of Terms

1. ***Anti-Crime X-ray Facility*** refers to a facility using x-ray devices for prevention, detection, and abatement or prosecution of public nuisance and crimes.

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

3. ***Dental X-ray Facility*** refers to a facility using x-ray devices for diagnosis of dental diseases.

4. ***Diagnostic Medical X-ray Facility*** refers to a facility using x-ray devices for diagnosis of human diseases and/or performing interventional medical procedures.

5. ***Education, Training and Research X-ray Facility*** refers to a facility using x-ray devices for teaching, research, training purposes and development work.

6. ***Electromagnetic Radiation*** refers to the propagation of electromagnetic energy through a medium or space in the form of electromagnetic waves.

7. ***Extremely Low Frequency (ELF) Radiation Facility/Devices*** refers to the NIR facility that uses ELF radiation devices that emits electromagnetic radiation with frequencies in the range 0 Hz (static fields) to 3 kHz, including the 50/60 Hz electric and magnetic fields associated with the domestic mains electricity supply such as in domestic electrical appliances, electricity supply substations and overhead power transmission lines.

8. ***Force Majeure*** refers to an act, unforeseen event or circumstance that is beyond the reasonable control including man-made and natural disasters.

9. ***Industrial X-ray Facility*** refers to a facility using x-ray devices for industrial applications.

10. ***Infrared (IR) Radiation Facility/Devices*** refers to the NIR device that emits electromagnetic radiation with frequency between 300 GHz to 430 THz (wavelength between 700 nm to 1 mm), which is present in sunlight and produced by artificial sources such as electric radiator heaters.

11. ***Ionizing Radiation (IR)*** refers to a type of radiation capable of producing ion pairs in biological material/s.

12. ***Magnetic Resonance Imaging Facility/Devices*** refers to the NIR facility and NIR device that uses RF radiation devices that produces (either deliberately or incidentally) radiofrequency energy during the course of their operation. It uses strong magnetic fields, magnetic field gradients and radio waves to generate images of the organs of the body for diagnosis of human diseases.

13. ***Medical Radiation Facility*** refers to a facility using radiation devices for medical application.

14. ***Microwave (MW) Radiation Facility/Devices*** refers to the NIR facility and NIR device that emits electromagnetic radiation with frequencies in the range 1 GHz to 300 GHz, which is produced by artificial sources such as in microwave ovens and by microwave communication devices.

15. ***Mobile*** refers to a type of installation where a radiation device is mounted on wheels and can be moved with reasonable ease within the facility.

16. ***Non-Ionizing Radiation (NIR)*** refers to a type of radiation incapable of producing ions directly or indirectly.

17. ***Non-Medical X-ray Facility*** refers to a facility using x-ray devices for non-medical application

18. ***Other Activities*** refer to the practices involved in the use of radiation devices.

19. ***Practice*** refers to any human activity that introduces additional sources of radiation or additional exposure pathways, so as to increase the exposure or the likelihood of exposure of people or the number of people exposed.

20. ***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 (i.e. medical physics, radiation protection, occupational health, fire safety, quality management or any relevant engineering or safety specialty).

21. ***Quality Assurance Program*** refers to a management tool which, through the development of policies and the facility of review procedures, aim to ensure that every examination or treatment is necessary, appropriate and performed according to previously accepted clinical protocols by adequately trained personnel using properly selected and functioning equipment to the satisfaction of the patient and referring physicians safely and at minimum cost.

22. ***Radiation Devices*** refers to an electrical or electronic apparatus emitting any ionizing or non-ionizing electromagnetic; or any sonic, infrasonic, or ultrasonic wave. It includes ionizing radiation emitting equipment which is not intentionally designed to produce radioactive materials.

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

24. ***Radiation Protection Officer (RPO)*** refers to an individual technically competent in radiation protection matters relevant for a given type of practice who is designated by the company or authorized officer.

25. ***Radiation Worker*** refers to a person who by reason of his profession, trade, or occupation uses any radiation device or is directly involved in any activity or operation in which a radiation device is used and who may be exposed to radiation as a result of being directly involved in such activity or operation.

26. ***Radiofrequency (RF) Radiation Facility/Devices*** refers to the NIR facility that uses RF radiation devices that produces (either deliberately or incidentally) radiofrequency energy during the course of their operation. It is a NIR that emits electromagnetic radiation with frequencies in the range 3 kHz to 300 GHz, which is produced by artificial sources such as visual display units, mobile phones and its base station.

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

28. ***Stationary*** refers to a type of installation where a radiation device is fixed and used only within the designated room.

29. ***Therapeutic X-ray Facility*** refers to an x-ray facility utilizing Linear Accelerator (LINAC), Tomotherapy, Intraoperative Radiation Therapy or any other radiation devices that are used for treatment of cancer diseases.

30. ***Transportable*** refers to a type of installation where a radiation device is fixed inside a vehicle that can be transported and properly shielded to ensure protection of workers, patients and members of the public from the hazards of x-rays.

31. ***Ultraviolet (UV) Radiation Facility/Devices*** refers to NIR that emits electromagnetic radiation frequency between 770 THz to 3000 THz with wavelengths between 100 nm and 400 nm, which is present in sunlight as well as produced by artificial sources such as arc welding and sterilization lamps.

32. ***Ultrasound Facility/Devices*** refers to NIR in the form of a high frequency sound, exceeding the upper limit of human hearing – 20.000 cycles per second (20 KHz).

33. ***Veterinary X-ray Facility*** refers to a facility using x-ray devices for diagnosis of animal diseases.

34. ***Visible Light Facility/Devices*** refers to NIR that emits electromagnetic radiation with frequency between 430 THz to 770 THz (wavelengths between 400 nm (blue) and 700 nm (red)), which is present in sunlight and produced by numerous artificial sources, including lasers.

ANNEX B

CLASSIFICATION OF RADIATION FACILITIES AND AUTHORIZATION ISSUED ACCORDING TO TYPE OF RADIATION, LEVEL OF RISK, MAGNITUDE OF EXPOSURE, PRACTICE COMPLEXITY OR USE, INSTALLATION AND APPLICATION.

Classification of Radiation Facility	Level of Risk	Authorization Issued			
		License to Operate (LTO)	Certificate of Facility Registration (CFR)	Notification	Certificate of Safety Evaluation (CSE)
IONIZING RADIATION					
MEDICAL					
Diagnostic Radiology					
1. General Radiography / Fluoroscopy	High	x			
2. Computed Tomography	High	x			
3. Mammography	High	x			
4. Bone Densitometry (DEXA)	Medium		x		
5. Interventional	High	x			
Therapeutic	High	x			
NON-MEDICAL					
1. Anti-crime					
a. Linear Accelerator for Anti-crime Applications	High	x			
b. Security and Baggage Inspection System	Medium		x		
2. Education, training and research	High	x			
3. Industrial					
a. Open-type industrial radiography	High	x			
b. Closed-type industrial radiography	Medium		x		
c. Linear Accelerator for Industrial Application	High	x			
d. Computed Tomography for Industrial Application	High	x			
e. Non-destructive Testing	High	x			
4. Dental					
a. Periapical	Medium		x		
b. Panoramic/Cephalometric	High	x			
c. CBCT	High	x			
5. Veterinary	High	x			
NON-IONIZING RADIATION					
Extremely Low Frequency (ELF) Radiation Facility	Medium				x
Radiofrequency (RF) Radiation Facility	Medium				x
Magnetic Resonance Imaging Facility	High	x			
Microwave (MW) Radiation Facility	Medium				x
Infrared (IR) Radiation Facility	Low			x	
Visible Light Facility	Low			x	
Ultraviolet (UV) Radiation Facility	Low			x	
Ultrasound Facility	Medium-High	x	x		

ANNEX C

LTO DOCUMENTARY REQUIREMENTS

1. Accomplished on-line application form
2. Proof of Payment
3. Scanned copy of the following documentary requirements

C.1 MEDICAL X-RAY FACILITY

C.1.1 GENERAL RADIOGRAPHY / FLUOROSCOPY AND INTERVENTIONAL

Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s
4. Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s
5. Certificate of training on radiation protection of the radiation protection officer (RPO)
6. If transportable, copy of valid vehicle LTO registration (OR/CR)
7. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years
2. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

3. Valid professional regulation commission (PRC) license of new radiologist/s and/or radiologic/x-ray technologist/s
4. Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of new Radiologist/s
5. Certificate of training on radiation protection of the new radiation protection officer (RPO)

C.1.2 COMPUTED TOMOGRAPHY / MAMMOGRAPHY

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit);
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s
4. Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s
5. Certificate of training on radiation protection of the radiation protection officer (RPO)
6. Performance test report from FDA-Laboratory Support Division /Department of Trade Industry-Philippine Accreditation Bureau accredited testing body
7. If transportable, copy of valid vehicle LTO registration (OR/CR)
8. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years
2. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

3. Valid professional regulation commission (PRC) license of new radiologist/s and/or radiologic/x-ray technologist/s
4. Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of new Radiologist/s
5. Certificate of training on radiation protection of the new radiation protection officer (RPO)

C.1.3 THERAPEUTIC (Utilizing LINAC)

Pre-Operational Permit (POP)

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Design of the medical linear accelerator facility indicating shielding details duly evaluated, verified, and signed by a board-certified ROMP.
3. Technical description/specifications of the following equipment:
   a. Therapeutic X-ray Machine
   b. Treatment planning system
   c. Patient data management software if available
   d. Radiotherapy simulator or computed tomography simulator,
   e. All other equipment listed in Appendix V of AO 2013-0031 or as revised
4. Certification issued by the equipment manufacturer
   a. That the Therapeutic X-ray machine in its present condition is compliant with the performance and safety requirements of the International Atomic Energy Agency (IAEA) and the International Organization for Standardization / International Electrotechnical Commission (ISO/IEC)
   b. On the availability of spare parts, maintenance, and repair services.
5. Personnel requirements: notarized contract of employment between the facility and:
   a. The radiation oncologist/s
   b. The certified radiation oncology medical physicist
   c. The radiation oncology medical physicist
   6. Radiation Protection and Safety Program
7. Emergency procedures during testing, commissioning, internal, and external quality audit, and during clinical operation, including a system of reporting a radiological accident/incident
8. Emergency preparedness and response plan in the event of radiological emergencies such as:
   a. Accident medical exposure of a patient
   b. Accident exposure of a worker
   c. Accident exposure of a member of a public.

Initial Application

1. Pre-operational Permit (POP)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years;
3. Updated PROS or PBR-RO certificate/s and valid professional regulation commission (PRC) license/s of all the radiation oncologist/s working in the therapeutic x-ray facility;
4. Updated PRC board certificates and valid PRC licenses of all the radiotherapy technologists and their certificates of training as prescribed in Section VI-A-4.3 of the A.O. No. 0031 series of 2013 or as revised;
5. Updated Philippine Board of Medical Physics certificate/s of all the Radiation Oncology Medical Physicist (ROMP). For non-board ROMPs, documentary evidence satisfying the provisions stated in Section XV-C-2 of the A.O. No. 0031 series of 2013.
6. Updated and valid notarized contract of employment between the facility and the radiation oncologist/s, radiation oncology medical physicist/s, and radiotherapy technologists;
7. Notarized appointment of the Radiation Protection Officer (RPO) and Assistant RPO; and
8. Where applicable, proof of qualification/recognition as a Qualified Expert

9. Acceptance Test Certificate signed by the technical representative of the equipment manufacturer/supplier and board-certified ROMP (if available upon filing of application);
10. Commissioning report of the equipment duly signed by the facility's certified ROMP; and
11. Conformance testing report of the x-ray unit/s in the therapeutic x-ray facility.
12. LINAC output calibration report of the DOH-SSDL or of a third-party board Certified ROMP.
13. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years;
2. Updated and valid professional regulation commission (PRC) licenses of all the radiation oncologist/s and radiotherapy technologist/s;
3. Valid notarized contract of employment between the facility and the radiation oncologist/s, radiation oncology medical physicist/s, and radiotherapy technologists; and
4. Annual report indicating the workload of the facility and the radiotherapy procedures/techniques done in the therapeutic x-ray facility.
5. Updated safety assessment;

C.2. NON-MEDICAL X-RAY FACILITIES

C.2.1 ANTI-CRIME (Utilizing LINAC)

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Certificate of training of the radiation protection officer (RPO) conducted by an organization recognized by the CDRRHR
4. Provision of radiation survey meter
5. Valid Radiation Survey Meter Calibration Certificate
6. If transportable, copy of valid vehicle LTO registration (OR/CR)
7. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years
2. Copy of periodic workplace area monitoring results within the validity period of the expired license
3. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

4. Certificate of training of the new radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR;

C.2.2 EDUCATION, TRAINING AND RESEARCH

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR
4. Valid professional regulation commission (PRC) license of the RPO and all radiologic/x-ray technologist/s;
5. If transportable, copy of valid vehicle LTO registration (OR/CR)

6. Safety Assessment

Renewal Application
1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years 2. Updated Safety Assessment If there are changes in the personnel from the previous issuance: 3. Certificate of training of the new radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR 4. Valid professional regulation commission (PRC) license of the new RPO and/or new radiologic/x-ray technologist/s

C.2.3 INDUSTRIAL (OPEN-TYPE INDUSTRIAL RADIOGRAPHY, NON-DESTRUCTIVE TESTING and APPLICATIONS UTILIZING LINAC and COMPUTED TOMOGRAPHY)

Initial Application
1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit) 2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years 3. Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR 4. Provision of radiation survey meter 5. Valid Radiation Survey Meter Calibration Certificate 6. If transportable, copy of valid vehicle LTO registration (OR/CR) 7. Safety Assessment

Renewal Application
1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years; 2. Copy of periodic workplace area monitoring results within the validity period of the expired license 3. Updated Safety Assessment If there are changes in the personnel from the previous issuance: 4. Certificate of training of the new radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR;

C.2.4 DENTAL (PANORAMIC/CEPHALOMETRIC AND CBCT)

Initial Application
1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit) 2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years 3. Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s 4. Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR 5. If transportable, copy of valid vehicle LTO registration (OR/CR) 6. Safety Assessment

Renewal Application
1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years;

2. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

3. Valid professional regulation commission (PRC) license of new dentist/s and/or radiologic/x-ray technologist/s
4. Certificate of training on radiation protection of the new radiation protection officer (RPO);

C.2.5 VETERINARY

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Valid professional regulation commission (PRC) license of all veterinarian/s and radiologic/x-ray technologist/s
4. Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of veterinary x-ray facilities conducted by an organization recognized by CDRRHR
5. If transportable, copy of valid vehicle LTO registration (OR/CR)
6. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years
2. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

3. Valid professional regulation commission (PRC) license of new veterinarian/s and/or radiologic/x-ray technologist/s
4. Certificate of training on radiation protection of the new radiation protection officer (RPO)

C.3 MAGNETIC RESONANCE IMAGING

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s;
3. Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of all Radiologist/s
4. Certificate of training on radiation protection of the radiation protection officer (RPO)
5. Radiofrequency /Magnetic field map
6. If transportable, copy of valid vehicle LTO registration (OR/CR)
7. Safety Assessment

Renewal Application

1. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

2. Valid professional regulation commission (PRC) license of new radiologist/s and/or radiologic/x-ray technologist/s
3. Certificate for being a fellow of the Philippine College of Radiology (FPCR) or diplomate of the Philippine Board of Radiology (DPBR) of new Radiologist/s
4. Certificate of training on radiation protection of the new radiation protection officer (RPO)

ANNEX D

FACILITY REGISTRATION DOCUMENTARY REQUIREMENTS

1. Accomplished on-line application form
2. Proof of Payment
3. Scanned copy of the following documentary requirements

D.1 MEDICAL X-RAY FACILITY (BONE DENSITOMETRY)

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Valid professional regulation commission (PRC) license of all radiologist/s and radiologic/x-ray technologist/s
4. Certificate of training on radiation protection of the radiation protection officer (RPO)
5. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years
2. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

1. Valid professional regulation commission (PRC) license of new radiologist/s and/or radiologic/x-ray technologist/s
2. Certificate of training on radiation protection of the new radiation protection officer (RPO)

D.2 NON-MEDICAL X-RAY FACILITY

D.2.1 ANTI-CRIME (SECURITY AND BAGGAGE INSPECTION SYSTEM)

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor's Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR
4. Safety Assessment

Renewal Application

1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years
2. Updated Safety Assessment

If there are changes in the personnel from the previous issuance:

1. Certificate of training on radiation protection of the new radiation protection officer (RPO)

D.2.2 INDUSTRIAL (CLOSED-TYPE INDUSTRIAL RADIOGRAPHY)

Initial Application

1. Proof of Business Name (SEC or DTI Registration or Mayor' Business Permit)
2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years
3. Certificate of training of the radiation protection officer (RPO) in an appropriate radiation protection training course conducted by an organization recognized by the CDRRHR
4. Safety Assessment

Renewal Application
1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years 2. Updated Safety Assessment If there are changes in the personnel from the previous issuance: 1. Certificate of training on radiation protection of the new radiation protection officer (RPO)

D.2.3 DENTAL (PERIAPICAL)

Initial Application
1. Proof of Business Name (SEC or DTI Registration or Mayor' Business Permit); 2. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for three (3) years 3. Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s 4. Certificate of training of the radiation protection officer (RPO) on radiation protection for radiation safety officers of dental x-ray facilities conducted by an organization recognized by CDRRHR 5. Safety Assessment

Renewal Application
1. Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider valid for five (5) years 2. Updated Safety Assessment If there are changes in the personnel from the previous issuance: 1. Valid professional regulation commission (PRC) license of all dentist/s and radiologic/x-ray technologist/s; 2. Certificate of training on radiation protection of the new radiation protection officer (RPO)

ANNEX E

CERTIFICATE OF SAFETY EVALUATION DOCUMENTARY REQUIREMENTS

1. Accomplished on-line application form
2. Proof of Payment
3. Scanned copy of the conceptual/elevation drawing for outdoor antennas or floor plan for indoor antennas

ANNEX F

NOTIFICATION DOCUMENTARY REQUIREMENTS

1. Accomplished on-line application form
2. Proof of Payment
3. Scanned copy of the following documentary requirements
    a. Notification Letter
    b. Technical Specifications of radiation device (model and serial number, power, generator type, etc.)
    c. Brochure/Literature of the equipment/device

ANNEX G

LIST OF REQUIREMENTS FOR VARIATION APPLICATIONS FOR RADIATION FACILITIES

1. Accomplished on-line application form
2. Proof of Payment
3. Scanned copy of the following documentary requirements

Documentary Requirements
For Major Variation related to:
1. Physical transfer of the radiation facility • Updated DTI/SEC registration. 2. Change of location of the machine within the facility • Notarized letter request stating the changes of location of the machine from one room to another. 3. Change of machine or inclusion of additional machine/s • Notarized letter request stating the changes of the machine and/or inclusion of additional machine.
For Minor Variation related to:
3. Change of Business Name of the Radiation Facility • Updated DTI/SEC registration. 4. Change of Management or Ownership • Deed of Sale/Transfer/Donation; and • DTI/SEC registration under the name of the new owner/management. 5. Change of Authorized Personnel • Proof of subscription to personal dose monitor (TLD or OSL) from authorized personal dosimetry service provider where applicable; • Proof of qualification of the new personnel as required in the application form checklist of requirements; and • Notarized contract of employment of the new personnel. 6. Removal of Machine • Notarized letter of request stating the reason/s for the removal of the machine; 7. Change in the radiation facility service category • Notarized letter of request stating the change in the radiation facility service category.

For LTO/CFR:

Major Variation refers to:
1. Physical transfer of the radiation facility (and may entail changes in the previously approved address); 2. Change of location of the machine within the facility (includes the transfer of stationary machine from one room to another or from one area or another); 3. Change of machine or inclusion of additional machine/s (includes replacement of x-ray tube assembly, x-ray generator and/or control console); and

Minor Variation refers to:
1. Change of business name of the radiation facility;

2. Change of management or ownership;
3. Change of authorized personnel;
4. Removal of non-functional machine; and
5. Change in the radiation facility service category (includes the upgrading of service/s).