Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA CIRCULAR
No. 2023-002

17 JAN 2023

SUBJECT : Guidelines on the Conduct of Regulatory Inspections for Radiation Facilities

I. BACKGROUND

The Department of Health (DOH), through the issuance of Administrative Order (AO) No. 2020-0035 or the "Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorizations," provided an updated, re-engineered, and streamlined regulatory guideline in the authorization of radiation facilities, repealing DOH AO No. 124 s. 1992 or the "Rules and Regulations Governing the Establishment, Operation and Maintenance of an X-ray Facility in the Philippines."

Among the major changes introduced in the issuance of AO No. 2020-0035, is the use of a graded or risk-based approach in the conduct of regulatory inspection of facilities commensurate with the radiation risks associated with the conduct of its activities. Such approach was utilized when the Food and Drug Administration (FDA) issued FDA Circular No. 2020-035, entitled, "Interim Guidelines for the Conduct of Licensing Inspection for Radiation Facilities" adopting measures in tackling regulatory challenges faced during the COVID-19 pandemic.

FDA Circular No. 2020-035 included provisions in the conduct of alternative arrangements and virtual inspections for continuous government service delivery while ensuring the safety of both its clients and regulatory officers. The conduct of on-line and virtual inspections are one of the risk-mitigating measures established by FDA in line with the goals of Republic Act No. 10121 or the Philippine Disaster Risk Reduction and Management Act of 2010, the Sendai Framework for Disaster Risk Reduction 2015-2030, and the ASEAN Agreement on Disaster Management and Emergency Response (AADMER), which requires the implementation of policies, actions, and measures to ensure the continuous performance of any agency's essential functions during an emergency.[1]

In view of the foregoing, the FDA aims to operationalize and supplement the provisions of DOH AO No. 2020-0035 providing for a rationalized process for the conduct of regulatory inspections for radiation facilities. This FDA Circular is issued to repeal

[1] Section II. Legal & Policy Basis of Public Service Continuity Planning. The Public Service Continuity Planning (PSCP) Guidebook. PDRF, OCD, & NDRRMC. 2020

FDA Circular No. 2020-035 and provide uniform guidelines on the conduct of regulatory inspections for radiation facilities under the jurisdiction of the FDA.

II. OBJECTIVE

This Circular aims to outline guidelines on the conduct of regulatory inspections for radiation facilities with alternative modes and approaches and using digital means to the conduct of such, in line with the graded approach established through DOH AO No. 2020-0035.

III. SCOPE

This Circular shall apply to regulatory inspections of radiation facilities to be conducted as part of the authorization process and continuous compliance of radiation facilities under the jurisdiction of the FDA. This shall also apply to the Bangsamoro Autonomous Region in Muslim Mindanao (BARMM) Region 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.

IV. DEFINITION OF TERMS

For the purpose of this Circular, the following terms shall mean and be understood as follows:

A. **Assessment Forms** – refers to the checklist of regulatory requirements that shall be used by FDA regulatory officers in the conduct of regulatory inspections, as attachment to the Inspection Report. These forms shall also be used by applicants to check their compliance with current regulatory standards.

B. **Corrective Action / Preventive Action (CAPA)** – refers to the action done by radiation facility on the noted findings during the conduct of regulatory inspections and shall require subsequent compliance within a specified timeline.

C. **Inspection Report** – refers to the form to be used by FDA regulatory officers in the conduct of regulatory inspection of radiation facilities.

D. **Regulatory Inspection** – refers to regulatory enforcement and oversight activity to ensure that radiation facilities are meeting established regulatory

standards and policies. Specifically, the types and modes of conducting regulatory inspections are:

1. **Modes of Conducting Regulatory Inspection**

    a. **On-Site Inspection** – refers to the mode of conducting regulatory inspections for radiation facilities through on-site physical evaluation, assessment, and/or verification of compliance.

    b. **Virtual Inspection** – pertains to the mode of conducting regulatory inspections through real-time interactive online electronic communication devices or conferencing services.

2. **Types of Regulatory Inspection (*DOH AO No. 2020-0035*)**

    a. **Pre-Licensing Inspection / 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.

    b. **Post-licensing Inspection (PLI) / 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 inspection made because of reported violations of the relevant rules and regulations issued by the FDA.

    c. **Post-registration Inspection (PRI) / 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.

V. GENERAL GUIDELINES

A. The conduct of regulatory inspection for radiation facilities shall be in accordance with DOH A.O. No. 2020-0035, where a graded approach is applied commensurate to the nature of hazard and level of risk associated with radiation facilities and activities.

B. On-Site and Virtual Inspections shall follow an inspection process to provide comprehensive steps for the conduct of inspection and the timely completion of the process.

C. Applicable Assessment Forms (AF) shall be accomplished by applicants for self-assessment and shall be submitted prior to the conduct of regulatory inspections for initial and major variation applications. These shall be verified by the assigned inspection team during the conduct of regulatory inspection.

D. Virtual Inspection shall be done when circumstances will not allow for the conduct of On-site Inspection, such as but not limited to, a state of public health emergency or a state of calamity.

E. If the conduct of Pre-licensing Inspection, whether on-site or virtual, was not undertaken due to *force majeure* or any unforeseen event, appropriate adjustments shall be made as prescribed by DOH A.O. No. 2020-0035.

F. Directives, findings, and violations noted by assigned inspectors shall be reflected in the Inspection Report. Compliance of inspected facilities with noted findings shall be done through the submission of a Corrective Action / Preventive Action (CAPA) Form.

G. Regulatory inspections for radiation facilities may be done *motu propio* in adherence to FDA's mandate in ensuring the compliance of regulated entities to established regulatory standards and policies.

VI. SPECIFIC GUIDELINES

A. Conduct of Regulatory Inspection

1. Radiation facilities applying for a License to Operate (LTO) or a Certificate of Compliance (COC) for facilities under the DOH One-Stop Shop Licensing System shall undergo Pre-Licensing Inspection.

2. Radiation facilities applying for a Certificate of Facility Registration (CFR) shall be subject to Post-Registration Inspection.

3. Radiation facilities applying for *major variation* shall undergo appropriate regulatory inspection prior to the issuance of authorization. For *minor variations*, regulatory inspections shall be done after the issuance of authorization.

4. All regulatory inspection done after the issuance of an authorization are unannounced. Authorized radiation facilities shall allow FDA personnel to perform regulatory inspections anytime.

5. The conduct of Post-Licensing and Post-Registration Inspections for radiation facilities shall be done by CDRRHR personnel in view of the limited availability of technical personnel.

6. In consonance with DOH A.O. No. 2020-0035 and its classification of radiation facilities and authorizations, the following schedule for the conduct of Post-Licensing and Post-Registration Inspections shall be observed:

Classification of Radiation Facility	**Level of Risk**	**Schedule of Inspection**
MEDICAL		
Diagnostic X-ray Facilities		
1. General Radiography / Fluoroscopy	High	Once in every 3 years
2. Computed Tomography	High	
3. Mammography	High	
4. Bone Densitometry	Medium	Once in every 5 years
Interventional X-ray Facilities	High	Once every year *(Due to increased complexity and use of higher doses per procedure)*
Therapeutic Radiation Facilities	High	
DENTAL		
1. Periapical	Medium	Once in every 5 years
2. Panoramic / Cephalometric	High	Once in every 3 years
3. CBCT	High	
NON-MEDICAL		
Anti-Crime		

1. Linear Accelerators for Anti-Crime Applications	High	Once in every 3 years
2. Security and Baggage Inspection System	Medium	Once in every 5 years
Education, Training, and Research	High	Once in every 3 years
Industrial		
1. Open-type Industrial Radiography	High	Once in every 3 years
2. Closed-type Industrial Radiography	Medium	Once in every 5 years
3. Linear Accelerators for Industrial Applications	High	Once in every 3 years
4. Computed Tomography for Industrial Applications	High	
5. Non-Destructive testing	High	
Veterinary	High	

7. The FDA shall reserve the right to conduct additional regulatory inspections, as deemed necessary.

B. **Regulatory Inspection Process**

1. The basic process flowchart in the conduct of regulatory inspections for radiation facilities shall follow **Annex A**. Specifically, it shall be in accordance with the following steps:

Process	**Pre-Licensing Inspection**	
	On-site	**Virtual**
Preparatory Phase	Assigned inspectors shall send a formal notice of inspection to inform the applicant of the schedule of inspection.	Assigned inspectors shall send the formal notice of inspection containing the online meeting link to be used throughout the conduct of the inspection.
	The facility to be inspected shall make available all relevant requirements such as but not limited to installed, calibrated, and functioning radiation device(s); administrative requirements; and operational requirements; among others.	
	The facility to be inspected shall accomplish and prepare the AF for the conduct of inspection.	

Survey and Evaluation Phase	An opening conference shall be conducted between the CDRRHR assigned inspectors and the facility. This shall include the introduction of parties, purpose and the scope of inspection, and flow of the inspection.	Same process with on-site but through the online meeting link provided.
	Verification of the Assessment Form (AF) accomplished by the Facility for Self-Assessment	
	Document review and actual demonstration of regular clinical practice shall also be assessed.	Same process with on-site but through the online meeting platform, video recordings, or any other applicable mode of assessment.
	Physical manifestation of requirements and documentary evidence shall be required.	Scanned copies or photos of requirements shall be prepared and uploaded for assessment.
	Inspectors shall conduct Radiation Protection Survey and Evaluation (RPSE) and machine verification tests.	RPSE and verification tests shall be done after the issuance of authorization.
	Conduct of facility tour.	Virtual facility tour subject to internet connectivity.
Reporting Phase	Inspectors shall prepare and finalize the Inspection Report.	
	An exit conference shall be conducted to discuss the findings, comments, and recommendations of the inspectors to the facility.	Same process with on-site but through the online meeting link provided.
	The Inspection Report shall be prepared and issued by the assigned inspectors to the facility. Where necessary, any findings noted shall merit the submission of CAPA by the facility pursuant to Section VI.D of this Circular.	Same process but the inspection report shall be transmitted online to the facility.

<table>
<tr><th rowspan="2">Process</th><th colspan="2">Post-Licensing / Registration Inspection</th></tr>
<tr><th>On-site</th><th>Virtual</th></tr>
<tr><td rowspan="2">Preparatory Phase</td><td rowspan="2">Inspectors shall visit assigned facilities unannounced.</td><td>Inspectors shall inform the facility of the inspection within the day through call and email. The inspectors shall provide an online meeting link to be used throughout the conduct of the inspection.</td></tr>
<tr><td>If the facility did not acknowledge the notice for virtual inspection and all efforts to contact the facility is exhausted and the facility remained unresponsive, CDRRHR shall formally send a compliance letter through physical and electronic mail to seek explanation regarding their unresponsiveness.</td></tr>
<tr><td rowspan="5">Survey and Evaluation Phase</td><td>An opening conference shall be conducted between the CDRRHR assigned inspectors and the facility. This shall include the introduction of parties, purpose and the scope of inspection, and flow of the inspection.</td><td rowspan="5">Same process with on-site but through the online meeting platform, video recordings, or any other applicable mode of assessment.</td></tr>
<tr><td>Aside from document review, actual demonstration of regular clinical practice shall also be assessed.</td></tr>
<tr><td>Physical manifestation of requirements and documentary evidence shall be required.</td></tr>
<tr><td>Inspectors may conduct Radiation Protection Survey and Evaluation (RPSE) and machine verification tests.</td></tr>
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</table>

	The inspection report shall be issued by the assigned inspectors to the facility. When necessary, any findings noted shall merit the submission of CAPA by the facility pursuant to Section VI.D of this Circular.	Same process but the Inspection Report shall be transmitted online to the facility.
	Any violation noted by inspectors, shall constitute appropriate regulatory action, remedy, or tool as specified in the Inspection Report to be given to the facility pursuant to Section VI.D of this Circular.	

C. **Assessment Forms (AF)**

1. Applicants shall accomplish the AF for self-assessment and submit to CDRRHR assigned inspectors before the conduct of Pre-Licensing Inspections following the guidelines outlined in **Annex B**.

2. The following Annexes shall be accomplished per specific type of radiation device being applied for:

Annex C	AF for Therapeutic X-ray Facilities utilizing Medical Linear Accelerators
Annex D	General AF for Diagnostic and Dental X-ray Facilities
Annex D-1	Specific AF for General Radiography and Fluoroscopic Machines
Annex D-2	Specific AF for Computed Tomography Machines
Annex D-3	Specific AF for Mammography Machines
Annex D-4	Specific AF for Dental X-ray Machines
Annex D-5	Specific AF for Bone Densitometers
Annex E	General AF for Industrial X-ray Facilities
Annex E-1	Specific AF for Industrial Radiographic Equipment
Annex E-2	Specific AF for Industrial Fluoroscopic Equipment
Annex E-3	Specific AF for Industrial X-ray Gauges
Annex E-4	Specific AF for Industrial X-ray Analytical Equipment
Annex E-5	Specific AF for Anti-Crime Cabinet-type X-ray Device
Annex E-6	Specific AF for Non-Medical Linear Accelerator (LINAC)

3. The accomplished AF shall be verified by the CDRRHR assigned inspectors during the conduct of regulatory inspection.

D. **Compliance with Noted Findings and Violations**

1. Any of the following findings by the inspection team shall be classified as a **violation** and shall be noted in the inspection report as basis for further regulatory action:

    a. Operation of a radiation facility without a valid FDA authorization;

    b. Operation of a radiation facility without the required qualified personnel;

    c. Operation of radiation devices without a functioning collimator or appropriate beam-limiting apparatus;

    d. Operation of a radiation facility with no protective barrier; and,

    e. Non-compliance with a previous finding for compliance or non-submission of required CAPA form within specified compliance deadline.

2. Aside from the outlined above, any other findings noted by the inspection team during the conduct of regulatory inspections shall merit the requirement of a CAPA.

3. The applicant shall provide complete compliance documents or evidence on or before the deadline. Incomplete or late submissions shall be considered as grounds for legal action, or any other penalties prescribed by law.

4. For facilities with noted violations, CDRRHR shall forward a Report of Violation (ROV) to the Legal Services Support Center (LSSC) of FDA for appropriate action pursuant to the Implementing Rules and Regulations (IRR) of RA 9711. The radiation facility shall coordinate and comply with any administrative or legal proceedings following existing FDA guidelines and processes.

VII. PENALTY CLAUSE

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

VIII. SEPARABILITY CLAUSE

In case any section or provision of this Circular or any part thereof, or the application of such section, provision or portion shall be declared invalid, the validity of the remaining provisions of this Circular shall not in any way be affected or impaired thereby.

IX. REPEALING CLAUSE

The FDA Circular No. 2020-035 or the "Interim Guidelines for the Conduct of Licensing Inspection for Radiation Facilities," BHDT Bureau Order No. 46 s. 2003 entitled "Revision of Bureau Order No. 90 s. 2002," and CDRRHR Center Order No. 2015-071 or "Policies in Reporting the Violations Noted by the Health Physics Team in the Regular Conduct of RPSE and FCM" are hereby repealed and superseded. Any other FDA issuances that are inconsistent with the provisions of this Circular are hereby modified or repealed accordingly.

X. EFFECTIVITY

This Circular shall take effect fifteen (15) days after its publication in the Official Gazette or in any newspaper of general circulation and upon filing with the University of the Philippines Law Center Office of the National Administrative Register.

DR. SAMUEL A. ZACATE
Director General