ANNEX E

GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY

(Adopted from the current FDA-CDRRHR Radiation Protection Survey and Evaluation (RPSE) Checklists; Based from DOH AO 40 s.1996, DOH AO 2022-0022, DOH AO 2020-0035)

Name of Facility	Date Accomplished
Facility Address	X-ray Facility Type[1]

[1]*Indicate whether: Industrial (choose: Irradiation facility / Food production / Semiconductor, etc.) or Anti-Crime (choose: Baggage / Packages / Freight / Cargo Inspection).*

I. MACHINE LIST *(list all machines being applied for; please attach all individual machine AF as attachment)*

Machine No.	Type of Installation[a]	Type of X-ray Machine[b]	Manufacturer / Model	Max. mA (or MeV)	Max. kVp	Machine Serial Number	Application / Use[c]	Location
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								

[a] Indicate whether: Open Installation or Enclosed Installation

[b] Indicate whether: Cabinet-type, Handheld, or Portable

[c] Indicate whether: LINAC, X-ray Gauge (choose: Thickness Gauge / Level Gauge), Radiography, Computed Tomography or Fluoroscopy (choose: Analytical / Scanning Electron Microscopy / Spectrometry / Diffractometry / Photo-ionizer / Fat Analyzer)

II. PERSONNEL REQUIREMENTS

*Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections*

REQUIREMENT *(Based on DOH AO No. 40 s. 1996 and AO 149 s. 2004)*	Self-Assessment	Verification *(FDA Use Only)*
1. The facility shall have and appoint a Radiation Protection Officer (RPO) who is an individual that undergone training in radiation protection for industrial and anti-crime facilities conducted by institutions recognized by CDRRHR. *(Attach Certificate of Completion conducted by a recognized third-party service provider)*		
2. The facility shall have operators who have completed training in radiation protection for industrial and anti-crime work conducted and/or recognized by the CDRRHR. *(Attach proof of radiation protection training)*		

III. OPERATIONAL AND ADMINISTRATIVE REQUIREMENTS

REQUIREMENT *(Based on DOH AO No. 40 s. 1996 and AO 149 s. 2004)*	Self-Assessment	Verification *(FDA Use Only)*
1. The facility shall have or make available a radiation monitoring instrument for the purpose of carrying out regular radiation monitoring surveys of x-ray units. The radiation monitoring instrument shall be calibrated at least once a year. *(Attach proof of provision of radiation monitoring instrument and its Certificate of Calibration)*		

Brand / Model: _____ Serial Number: _____ Calibration factor: _____ Due date of Calibration: _____		
2. The Radiation Protection Officer (RPO) shall establish and be responsible for the conduct of a Radiation Protection/Safety Program under which the **following policies should be included**: ***(PROVIDE A DULY SIGNED & APPROVED SCANNED COPY)***		
a. Policy on dose monitoring for operators (including interns, OJTs), pregnant personnel, etc.		
b. Policy on radiation protection/safety of pregnant women. (e.g. posting of notices, risk communication, etc.)		
c. Records and analysis of personnel dose monitoring. Service Provider: _____ Subscription period: _____ Official Receipt No. _____ No. of TLD/OSL: _____		
d. Guidelines of appropriate action for operators/personnel that exceeded dose limits. (action plan, corrective measures, risk communication, etc.)		
e. Process of reporting and notification in cases of exceeded doses and radiation accidents.		
f. Quarterly Area Survey Monitoring for scattered radiation. *(Floor plan / machine diagram showing points for measurements)*		
g. Policy on the access of operators, other personnel, and non-personnel (i.e., interns, trainees, visitors) to the site/location of the x-ray machine.		
h. Policy on monitoring of equipment for possible detection of significant leakage radiation.		
i. Policy on working procedures and protocols when operating the x-ray machine. *(Refer to Section VI of the DOH AO No. 40 s.1996 for guidance)*		
j. For open installations, policy on continuous and competent supervision of the site during the conduct of x-ray exposure.		

IV. SITE REQUIREMENTS *(Attach detailed floorplan indicating the wall thickness, distances, and points of measurements for scattered radiation)*

REQUIREMENT *(Based on DOH AO No. 40 s. 1996 and AO 149 s. 2004)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Enclosed Installations		
a. All walls and doors shall be made of materials which will reduce radiation level to 2.5 μSv per hour (0.25 mR/hr).		
b. There shall be functioning interlocks installed either in the machine or on the door leading to the room. *(Upload a video as proof of functioning interlocks)*		
c. There shall be a warning visual boundary (floor markings) at least 1.0 m perimeter from the machine. *(Upload photo/s)*		
2. **Open Installation**		
a. The boundaries of an open field shall be clearly defined by some appropriate means such as ropes, perimeter cords, or fences. *(Attach photo of the actual field/area)*		

b. Dose equivalent rate outside the boundary shall not exceed 25 μSv per hour (2.5 mR/hr)		
c. For **industrial radiographic equipment using manual image acquisition (x-ray film)**, there shall be a darkroom designed and equipped with following: *(Attach photos)*		
i. Light tight room (no light leaks)		
ii. Well ventilated (installed light-tight exhaust fan)		
iii. Processing tanks (with two insert tanks)		
iv. Separate paddles for the developer and fixer solutions		
v. Adequate supply of fresh water		
vi. Amber or red-tinted safelight installed not lower than 4 feet from the working table		
vii. Proper storage for unprocessed films		

V. SPECIFIC MACHINE REQUIREMENTS

Accomplish and attach applicable individual machine checklist as per machine list (Annex E-1 to 5)

I hereby declare that this application has been accomplished by me, and that the foregoing information and attached documents required for the authorization are true and correct.

PREPARED AND ACCOMPLISHED BY:		
Name & Signature:	**Designation/Position:**	**Date:**
ATTESTED BY (FACILITY HEAD/MANAGER):		
Name & Signature:	**Designation/Position:**	**Date:**
VERIFIED BY (FDA USE ONLY):		
Name & Signature:	**Designation/Position:**	**Date:**
Name & Signature:	**Designation/Position:**	

ANNEX E - 1

SPECIFIC ASSESSMENT FORM FOR INDUSTRIAL RADIOGRAPHIC EQUIPMENT

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine No.
(Based on MACHINE LIST of Annex E)

Applicable Type of Machines

Industrial Radiographic Equipment	X-ray equipment used in taking radiographs of test items and specimens

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation. ***(Upload a video as proof of functioning audible and visual warning signs)***		
2. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**CAUTION – X-RAY EMITTING APPARATUS.**" The warning notice shall be on a 180 mm x 270 mm white background. ***(Attach a photo of the posted standard warning notice)***		
3. The radiographic equipment shall be enclosed in a housing such that the leakage radiation measured at a distance of 1.0 m from the focus does not exceed 1 mSv/hr. ***(attach a duly signed leakage radiation survey report using the facility's survey meter)***		
4. The radiographic equipment shall be provided with diaphragms, cones, or adjustable collimator to limit the area of the useful beam.		
5. The radiographic equipment shall be provided with an automatic timer which will terminate the exposure by de-energizing the x-ray tube after the pre-set time has elapsed.		
6. Safety devices such as warning lights and interlocks shall be tested periodically to ensure their proper operation. *(Attach proof of provision of preventive maintenance service/s).*		

(Accomplished per machine as an attachment to the GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY)

ANNEX E - 2

SPECIFIC ASSESMENT FORM FOR INDUSTRIAL FLUOROSCOPIC EQUIPMENT

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine No.
(Based on MACHINE LIST of Annex E)

Applicable Type of Machines

Industrial Fluoroscopic Equipment	X-ray equipment used for test items or specimens for fluoroscopic inspection.

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation. ***(Upload a video as proof of functioning audible and visual warning signs)***		
2. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**CAUTION – X-RAY EMITTING APPARATUS.**" The warning notice shall be on a 180 mm x 270 mm white background. ***(Attach a photo of the posted standard warning notice)***		
3. The x-ray tube shall be enclosed in a tube housing with an aperture that is covered by a shutter or a completely shielded enclosure which include interlocks so that opening one entrance automatically deenergizes the x-ray tube.		
4. Radiation level at any accessible point 5 cm from the surface of the x-ray tube housing and any enclosure attached to it shall not exceed 25 µSv (2.5 mR) per hour when the x-ray tube is operated at any of the permissible ratings specified by the manufacturer of the equipment.		
5. Radiation level at any accessible point 5 cm from the external surface of the equipment shall not exceed 5 µSv (0.5 mR) per hour when averaged over an area of 100 cm^2 when the tube is operated at any of the permissible rating specified by the manufacturer.		
6. Fluoroscopic screens should be viewed indirectly by the use of mirrors or remotely by TV/Digital screens/monitors. (*Attach a photo*)		

(Accomplished per machine as an attachment to the GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY)

ANNEX E - 3

SPECIFIC ASSESMENT FORM FOR INDUSTRIAL X-RAY GAUGES

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine No. *(Based on MACHINE LIST of Annex E)*

Applicable Type of Machines

Industrial X-ray Gauges	X-ray device that uses the detection of an x-ray beam transmitted through or scattered by a material of interest to measure a parameter associated with the material.

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation. ***(Upload a video as proof of functioning audible and visual warning signs)***		
2. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words **"CAUTION – X-RAY EMITTING APPARATUS."** The warning notice shall be on a 180 mm x 270 mm white background. ***(Attach a photo of the posted standard warning notice)***		
3. The x-ray tube shall be enclosed in a tube housing with an aperture that is covered by a shutter or a completely shielded enclosure which include interlocked so that opening one entrance automatically deenergizes the x-ray tube.		
4. Radiation level at any accessible point 5 cm from the external surface of the equipment shall not exceed 5 μSv (0.5 mR) per hour when averaged over an area of 100 cm^2 when the tube is operated at any of the permissible rating specified by the manufacturer.		
5. The equipment shall be housed, shielded, and installed so as to prevent unauthorized access to these devices.		

(Accomplished per machine as an attachment to the GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY)

ANNEX E - 4

SPECIFIC ASSESMENT FORM FOR INDUSTRIAL X-RAY ANALYTICAL EQUIPMENT

Name of Facility	
Facility Address	

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine No.
(Based on MACHINE LIST of Annex E)

Applicable Type of Machines

Industrial X-ray Analytical Equipment	X-ray device which is used to determine properties and composition of materials using x-ray fluorescence or x-ray diffraction techniques.

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation. ***(Upload a video as proof of functioning audible and visual warning signs)***		
2. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**CAUTION – X-RAY EMITTING APPARATUS.**" The warning notice shall be on a 180 mm x 270 mm white background. ***(Attach a photo of the posted standard warning notice)***		
3. The high-tension generator supplying the x-ray tube shall have an independent and easily detachable cable connection or line switch.		
4. An interlocking device should prevent entry of any part of the body into the beam path or cause the beam to be shut off upon such entry into its path.		
5. The x-ray camera or other recording devices shall be provided with a protective screen that effectively absorbs radiation.		

(Accomplished per machine as an attachment to the GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY)

ANNEX E - 5

SPECIFIC ASSESMENT FORM FOR ANTI-CRIME CABINET-TYPE X-RAY DEVICE

Name of Facility	
Facility Address	

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine No.
(Based on MACHINE LIST of Annex E)

Applicable Type of Machines

Anti-Crime Cabinet-Type X-ray Devices	X-ray unit used for inspection of mails, packages, baggage, freight, and other articles for security purposes.

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation. ***(Upload a video as proof of functioning audible and visual warning signs)***		
2. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words "**CAUTION – X-RAY EMITTING APPARATUS.**" The warning notice shall be on a 180 mm x 270 mm white background. ***(Attach a photo of the posted standard warning notice)***		
3. Devices used for baggage inspection shall be arranged that the operator stays in a position where all ports and doors can be readily observed during exposure.		
4. A key operated control console shall be designed such that x-rays cannot be produced when the key is removed.		
5. Exposure switch shall be of a dead man type.		
6. Radiation level at any accessible point 5 cm from the external surface of the equipment shall not exceed 5 μSv (0.5 mR) per hour when averaged over an area of 100 cm^2 when the tube is operated at any of the permissible rating specified by the manufacturer.		
7. Anti-crime x-ray device may not be located in a separate room, provided that access shall be limited to personnel authorized to work in the area.		

(Accomplished per machine as an attachment to the GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY)

ANNEX E - 6

SPECIFIC ASSESMENT FORM FOR NON-MEDICAL LINEAR ACCELERATOR (LINAC)

Name of Facility
Facility Address

REQUIREMENTS
(use additional sheets if necessary)

Machine No. *(Based on MACHINE LIST of Annex E)*

Applicable Type of Machines

Non-Medical LINAC	X-ray equipment used either for irradiation to treat an object for variety of purposes or inspection of cargo shipments for security purposes.

1. ADDITIONAL OPERATIONAL REQUIREMENTS

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Machine commissioning report duly signed by the authorized Service Engineer of the manufacturer *(Attach document)*		
2. Installation report duly signed by the authorized service engineer of the manufacturer *(Attach document)*		

2. MACHINE REQUIREMENTS

REQUIREMENT *(Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Audible and visual warning signs shall be provided within the perimeter where the machine is installed or will be operated. The audible and visual warning signs shall be actuated before the irradiation and shall remain actuated until completion of the irradiation. ***(Upload a video as proof of functioning audible and visual warning signs)***		
2. Warning notices shall be posted along defined boundaries and shall be made up of a solid yellow equilateral triangle 180 mm long on each side. At the center of the triangle is a black tre-foil sign for radiation. Under the triangle are the words **"CAUTION – X-RAY EMITTING APPARATUS."** The warning notice shall be on a 180 mm x 270 mm white background. ***(Attach a photo of the posted standard warning notice)***		
3. Safety devices such as warning lights and mechanical door interlocks shall be provided and tested periodically to ensure their proper operation. *(Attach proof of provision of preventive maintenance service).*		
4. The equipment shall be provided with an automatic timer which will terminate the exposure by de-energizing the x-ray tube after the pre-set time has elapsed.		

(Accomplished per machine as an attachment to the GENERAL ASSESMENT FORM (AF) FOR INDUSTRIAL /ANTI-CRIME X-RAY FACILITY)

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

MEMORANDUM

FOR: **DR. SAMUEL A. ZACATE**
Director General

FROM: **MARIA CECILIA C. MATIENZO**
Director IV
Center for Device Regulation, Radiation Health, and Research

SUBJECT: **PROPOSED FDA CIRCULAR OUTLINING THE GUIDELINES ON THE CONDUCT OF REGULATORY INSPECTIONS FOR RADIATION FACILITIES**

DATE: December 12, 2022

DTN: **20220222133555**

BACKGROUND

1. References:

    a. DOH Administrative Order No. 2020-0035 – Rules and Regulations on the Licensing and Registration of Radiation Facilities Involved in the Use of Radiation Devices and Issuance of Other Related Authorizations
    b. FDA Circular No. 2020-035 - Interim Guidelines for the Conduct of Licensing Inspection for Radiation Facilities
    c. BHDT Bureau Order No. 46 s. 2003 - Revision of Bureau Order No. 90 s. 2002
    d. CDRRHR Center Order No. 2015-071 - Policies in Reporting the Violations Noted by the Health Physics Team in the Regular Conduct of RPSE and FCM

DISCUSSION

2. Currently, the conduct of regulatory inspections for radiation facilities are based on established Quality Work Procedures (QWP) of the Center for Device Regulation, Radiation Health, and Research (CDRRHR) pursuant to BHDT Bureau Order No. 46 s. 2003, Center Order No. 2015-071, and regulatory requirements