ANNEX D

GENERAL ASSESMENT FORM (AF) FOR DIAGNOSTIC, INTERVENTIONAL, AND DENTAL X-RAY FACILITIES

(Based on DOH AO No. 35 s. 1994, AO No. 2-A s. 1996, and AO 2022-0022)

Name of Facility	**Date Accomplished**
Facility Address	**X-ray Facility Level**

Includes administrative and operational requirements for the whole facility. Every machine applied for will need its appropriate individual AF as attachment.

I. MACHINE LIST *(please attach all individual machine AF as attachment)*

#	Machine Type[1]	Manufacturer Name / Brand		Serial Number	
		Control Console	Tube	Control Console	Tube
1					
2					
3					
4					
5					
6					
7					
8					
9					
10					

[1]Indicate if (1) Stationary/Mobile General X-ray (2) Stationary/Mobile Fluoroscopic X-ray (3) Mammography (4) Computed Tomography (5) Dental X-ray (Panoramic/Peri-apical) (6) Bone Densitometry (7) Positron Emission Tomography (PET) / Single Photon Emission Computed Tomography (SPECT)

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. 35 s. 1994, AO No. 2-A s. 1996, and AO 2022-0022)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. The head of a diagnostic x-ray facility who is the person-in-charge of the activities shall be a qualified physician as defined in DOH Administrative Order No. 35 s. 1994. a. Diplomate or fellow of the Philippine Board of Radiology or the Philippine College of Radiology. b. Refer to section 4.1.1.2 to 8 of AO 35 s. 1994 if no physician with the qualification above. c. For Dental x-ray facilities, a PRC licensed dental practitioner with appropriate training in dental x-ray work as per DOH AO no. 2-A s. 1996.		
2. A fulltime x-ray/radiologic technologist who is registered with the Professional Regulation Commission (PRC) shall be hired for each machine. a. Required only for dental x-ray machines in lieu of an available duly qualified dental x-ray practitioner.		
3. The facility shall have a Radiation Protection Officer (RPO) who is one of the following: a. Head of the facility (Refer to number 1) b. Medical Physicist c. Chief Radiologic Technologist of x-ray technologist with at least ten years working experience and attended a course on radiation protection conducted by an organization recognized by the CDRRHR. d. For dental facilities, a dental practitioner with appropriate training for dental x-ray facilities.		

III. OPERATIONAL AND ADMINISTRATIVE 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. 35 s. 1994, AO No. 2-A s. 1996, and AO 2022-0022)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. The facility shall establish a quality assurance program to ensure continuous compliance with the requirements set forth by the Department of Health under which the following policies should be included:		
a. The head of the facility shall establish a Quality Control (QC) Program/Manual for the x-ray facility under which the following *minimum* provisions should be included: ***(provide a scanned copy)***		
i. List of individuals responsible for monitoring and maintenance.		
ii. List of parameters to be monitored and frequency of monitoring. (e.g. button checks, daily output checks if applicable, etc.)		
iii. Description of standards, criteria of quality, limits of acceptability for every machine to be monitored.		
iv. Description of procedures to be done for every machine to be monitored.		
v. Records of preventive and corrective maintenance done per machine including records of daily quality checks.		
vi. Records of frequency of changing solutions for darkroom image processing. *(if applicable)*		
vii. Operation manuals and circuit diagrams including tube rating charts and cooling diagrams.		
2. The Radiation Protection Officer (RPO) shall establish and be responsible for the conduct of a Radiation Protection/Safety Program under which the following *minimum* provisions should be included: ***(provide a scanned copy)***		
a. Provisions on dose monitoring policies for radiology personnel (including interns, OJTs), patients, carers, pregnant personnel, etc.		
b. Policy on radiation protection/safety for pregnant women. (e.g. posting of notices, risk communication, etc.)		
c. Records and analysis of personnel dose monitoring. ***(provide a scanned copy of receipt/proof of purchase)*** Service Provider: _____ Subscription period: _____ Official Receipt No. _____ No. of TLD/OSL: _____		
d. Provision for records and policy on request and referral of x-ray examinations.		
e. Classification of areas as to controlled and supervised areas for occupational dose monitoring.		
f. Provision for procedures and practices to reduce dose of patients, workers, and the public applicable to the facility		
g. Guidelines of appropriate action for personnel that exceeded dose limits and for accidents / incidents involving patients. (*action plan, corrective measures, risk communication, etc.*)		
h. Process of reporting and notification in cases of exceeded doses, accidents, and incidents.		
3. All x-ray examinations should be justified by a qualified physician in which a proper request and referral policy should be established.		
4. Radiographic technique charts per x-ray machine posted near the control console. ***(provide a scanned copy)***		
5. Records and analysis of image reject/spoilage. ***(if applicable, provide picture of dedicated logbook/software to be used to record image reject)***		
6. Cleanliness and orderliness of the whole x-ray facility. ***(provide photo)***		
7. File of written results signed by qualified physician. ***(provide photo of a sample, data privacy policy applies)***		

IV. GENERAL PHYSICAL PLANT REQUIREMENTS

*Please mark **check (✓)** if complied, **(X)** if not compliant, and **N/A** if not applicable). Proof/Evidence required only for virtual inspections. Refer to individual machine checklist for physical plant requirements specific to an x-ray machine*

REQUIREMENT *(Based on DOH AO No. 35 s. 1994, AO No. 2-A s. 1996, and AO 2022-0022)* ***(PROVIDE DIGITAL/SCANNED COPY OF FACILITY AS-BUILT FLOOR PLAN/LAYOUT INCLUDING PICTURES OF THE ACTUAL FACILITY AND REQUIRED EQUIPMENT)***	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. For automatic/manual processing (Dark room processing)		
a. Adequate space *(2.0 m x 1.5m)*		
b. Processing tanks (*for manual processing only*)		
c. Separate paddles for processing tanks (*for manual processing only*)		
d. Light tight		
e. Well ventilated (with exhaust fan)		
f. Tinted standard safelight *(>1.3 m from working table)*		
g. Proper storage of unprocessed films		
h. Well-maintained intensifying screens		
i. Luminous timer/digital timer (*for manual processing only*)		
j. Non-mercurial thermometer (*for manual processing only*)		
2. For digital/computed radiography processing (DR/CR)		
a. Designated area for processing/viewing machine		
3. Waiting area for patients (provision/designated area)		
4. Film storage and/or reading area *(where applicable)* a. 1 m x 2 m for level one (1) x-ray facility *b.* 3 m x 3.5 m for level two (2) and three (3) x-ray facility		

V. SPECIFIC MACHINE REQUIREMENTS

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

I hereby declare that this form has been accomplished by me, and that the foregoing information and attached documents, where applicable, 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 D - 1

SPECIFIC ASSESMENT FORM FOR GENERAL RADIOGRAPHY AND FLUOROSCOPY

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # *(Based on MACHINE LIST of Annex D)*

Applicable Type of Machines

Stationary X-ray Machine	Radio/Fluoroscopic X-ray Machine (RF)
Mobile X-ray Machine	Mobile C-arm Fluoroscopy Machine
Transportable X-ray Machine	Cardiac Catheterization Fluoroscopic Machine

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. X-ray machine properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation AND signed calibration report bearing the same serial numbers indicated in the application form for tube & console with values for kVp, mA, time, and constancy checks by the service engineer or a medical physicist; with details of test tools/radiation monitoring instruments used)***		
2. Audible and/or visible indication of x-ray production *(AO 35 s. 1994 sec. 5.1.14)*		
3. Means to set exposure factors ***(provide pictures of control console)*** *(AO 35 s. 1994 sec. 5.1.9)*		
4. Mechanically stable *(AO 2022-0022, Annex A, Part 7)*		
5. All moving parts move smoothly without obstructions to motion *(AO 2022-0022, Annex A,Part 7)*		
6. Adequate x-ray room size (for stationary x-ray & RF machines) ***(provide digital/scanned copy of detailed facility floor plan/layout)*** *(AO 35 s. 1994 sec. 6.1)* a. X-ray w/o table: 2.5 x 3 m b. X-ray w table: 3.5 x 4 m c. X-ray w titling table: 4.5 x 4.5 m d. Transportable x-ray: 2.0 m width ***(provide pictures with proof of measurement)***		
7. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 35 s. 1994 sec. 6.2)* a. At least 6 inches thick poured concrete with a density of 2.35 g/cm^3 ***(Provide picture/scanned copy of signed facility layout showing wall thickness; shielding to be confirmed during inspection)*** b. At least 1/6 in (1.5 mm) thick lead sheet glued onto and sandwich between wooden panels without any punctures during installation. ***(Provide picture/proof of purchase of lead sheets; shielding to be confirmed during inspection)***		
8. Dressing Area ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.18)*		
9. Fixed/Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. ***(provide pictures; shielding to be confirmed during inspection)*** *(AO 35 s. 1994 sec. 6.4)*		
10. If windows are present, it should be elevated to height of at least 2 m from ground. ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.6)*		
11. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.7)*		
12. With appropriate warning notice ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.8)*		
13. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.1)*		
14. Toilet with door opening directly to x-ray room **if** examinations using contrast media will be performed ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.19)*		
15. Radiological accessories ***(provide pictures or proof of purchase)*** *(AO 35 s. 1994 sec. 6.20)*		
a. Caliper		
b. Contact gonadal shields all sizes *(>1.5 mm Pb equivalent) (not needed for x-ray facilities for chest, heart, and lungs imaging only)*		
c. Upright gonadal shield *(>1.5 mm Pb equivalent)*		
d. Lead equivalent gloves *(>0.25 mm Pb equivalent) (not needed for x-ray facilities for chest, heart, and lungs imaging only)*		
e. Lead equivalent apron *(>0.25 mm Pb equivalent)*		
f. Lead equivalent goggles *(for fluoroscopic machines only) (not needed for x-ray facilities for chest, heart, and lungs imaging only)*		
g. Lead equivalent thyroid shields *(for fluoroscopic machines only) (not needed for x-ray facilities for chest, heart, and lungs imaging only)*		

(Accomplished per machine as an attachment to the AF of DIAGNOSTIC, INTERVENTIONAL, AND DENTAL X-RAY FACILITIES)

ANNEX D - 2

SPECIFIC ASSESMENT FORM FOR COMPUTED TOMOGRAPHY

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # [ ]

(Based on MACHINE LIST of Annex D)

Applicable Type of Machines

Computed Tomography Machines	CT Simulator Machine for Radiation Therapy
PET CT Machines	
SPECT Machines	

REQUIREMENTS. *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. CT unit assembly properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation)***		
2. Undergone and passed performance testing conducted by PLSD-CSL or by DTI-PAB accredited testing laboratory ***(attach SIGNED report of service provider)*** *(BO 220 s. 2002)*		
3. Adequate x-ray room size (*manufacturers specifications*) *(AO 35 s. 1994 sec. 6.1.4)*		
4. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 35 s. 1994 sec. 6.2)* a. At least 6 inches thick poured concrete with a density of 2.35 g/cm^3 ***(Provide picture/scanned copy of signed facility layout showing wall thickness; shielding to be confirmed during inspection)*** b. At least 1/6 in (1.5 mm) thick lead sheet glued onto and sandwich between wooden panels without any punctures during installation. ***(Provide picture/proof of purchase of lead sheets; shielding to be confirmed during inspection)***		
5. Fixed/ Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. *(AO 35 s. 1994 sec. 6.4)* ***(provide pictures; shielding to be confirmed during inspection)***		
6. If windows are present, it should be elevated to height of at least 2 m from ground. ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.6)*		
7. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.7)*		
8. Dressing Area ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.18)*		
9. With appropriate warning notice outside x-ray examination room door. It 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 "**X-RAY ROOM: DO NOT ENTER WHEN THE RED LIGHT IS ON**". The Warning notice shall be on a 180 mm x 270 mm white background. ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.8)*		
10. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.1)*		
11. Toilet with door opening directly to x-ray room **if** examinations using contrast media will be performed ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.19)*		
12. Radiological accessories ***(provide pictures or proof of purchase)*** *(AO 35 s. 1994 sec. 6.20)*		
a. Lead equivalent gloves *(>0.25 mm Pb equivalent)*		
b. Lead equivalent apron *(>0.25 mm Pb equivalent)*		
c. Quality control phantom *(AO 35 s. 1994 sec. 5.7.9)*		

(Accomplished per machine as an attachment to the AF of DIAGNOSTIC, INTERVENTIONAL, AND DENTAL X-RAY FACILITIES)

ANNEX D - 3

SPECIFIC ASSESMENT FORM FOR MAMMOGRAPHY

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # [ ]

(Based on MACHINE LIST of Annex D)

Applicable Type of Machines

Analog Mammography Machines
Digital Mammography Machines
3D Mammography Machines

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Mammographic unit assembly properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation)***		
2. Undergone and passed performance testing conducted by PLSD-CSL or by DTI-PAB accredited testing laboratory ***(attach SIGNED report of service provider)*** *(BO 220 s. 2002)*		
3. Adequate x-ray room size (*manufacturers specifications*) *(AO 35 s. 1994 sec. 6.1.4)*		
4. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 35 s. 1994 sec. 6.2)* a. At least 6 inches thick poured concrete with a density of 2.35 g/cm^3 ***(Provide picture/scanned copy of signed facility layout showing wall thickness; shielding to be confirmed during inspection)*** b. At least 1/6 in (1.5 mm) thick lead sheet glued onto and sandwich between wooden panels without any punctures during installation. ***(Provide picture/proof of purchase of lead sheets; shielding to be confirmed during inspection)***		
5. Fixed/ Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements. ***(provide pictures; shielding to be confirmed during inspection)*** *(AO 35 s. 1994 sec. 6.4)*		
6. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.7)*		
7. With appropriate warning notice outside x-ray examination room door. It 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 "**X-RAY ROOM: DO NOT ENTER WHEN THE RED LIGHT IS ON**". The Warning notice shall be on a 180 mm x 270 mm white background. ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.8)*		
8. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.1)*		
9. Dressing Area ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.18)*		

(Accomplished per machine as an attachment to the AF of DIAGNOSTIC, INTERVENTIONAL, AND DENTAL X-RAY FACILITIES)

ANNEX D - 4

SPECIFIC ASSESMENT FORM FOR DENTAL X-RAY

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # ☐

(Based on MACHINE LIST of Annex D)

Applicable Type of Machines

Panoramic/Cephalometric
Dental CT/CBCT
Dental Intraoral/Periapical

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. Dental x-ray unit assembly properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation AND signed machine calibration report with values for kVp, mA, time, and constancy checks from the service engineer; with details of test tools/radiation monitoring devices used)*** *(AO 2-A s. 1996 sec. 5)*		
2. With effective electrical grounding ***(provide pictures)*** *(AO 2-A s. 1996 sec. 5.3)*		
3. Stability and quality of mechanical parts *(AO 2-A s. 1996 sec. 5.14)*		
4. Adequate x-ray room size (*manufacturer's specifications, not required for*) *(AO 2-A s. 1996 sec. 6)*		
5. Adequate shielding for the x-ray room (doors, walls, etc.) *(AO 2-A s. 1996 sec. 6)* a. Homogeneous concrete with a density of 2.35 g/cm^3 ***(Provide picture/scanned copy of signed facility layout showing wall thickness; shielding to be confirmed during inspection)*** b. Lead sheet glued onto and sandwich between wooden panels without any punctures during installation. ***(Provide picture/proof of purchase of lead sheets; shielding to be confirmed during inspection)***		
6. Fixed/ Movable Protective barrier with means of viewing patient (glass/acrylic with 1.5 mm lead equivalence) and with adequate shielding from x-rays similar to room shielding requirements for panoramic dental x-ray units ***(provide pictures; shielding to be confirmed during inspection)*** *(AO 2-A s. 1996 sec. 6.9 and 10)*		
7. With red warning light bulb ***(provide pictures)***		
8. With appropriate warning notice outside x-ray examination room door. It 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 "**X-RAY ROOM: DO NOT ENTER WHEN THE RED LIGHT IS ON**". The Warning notice shall be on a 180 mm x 270 mm white background. ***(provide pictures)*** *(AO 2-A s. 1996 sec. 7.3.1)*		
9. With adequate ventilation ***(provide pictures)*** *(AO 2-A s. 1996 sec. 6.2)*		
10. Radiological accessories ***(provide pictures/proof of purchase)***		
a. Thyroid shields (1/8 in lead equivalent) *(AO 2-A s. 1996 sec. 7.1.8)*		
b. Lead rubber apron, with lead equivalence of 0.25 mm *(AO 2-A s. 1996 sec. 7.1.8)*		
c. Film holders for periapical & bitewing examinations *(if applicable)*		

(Accomplished per machine as an attachment to the AF of DIAGNOSTIC, INTERVENTIONAL, AND DENTAL X-RAY FACILITIES)

ANNEX D - 5

SPECIFIC ASSESMENT FORM FOR BONE DENSITOMETERS

Name of Facility
Facility Address

X-RAY MACHINE REQUIREMENTS

(use additional sheets if necessary)

Machine # *(Based on MACHINE LIST of Annex D)* [ ]

Applicable Type of Machines
Bone Densitometer / DEXA

REQUIREMENT *(please check "yes" if complied, "no" if not complied, and N/A if not applicable)*	**Self-Assessment**	**Verification** *(FDA Use Only)*
1. X-ray machine properly installed, operational, and duly accepted by the licensee with appropriate documents signed by installer/supplier and received by licensee representative/owner. ***(provide pictures/proof of installation AND signed calibration report bearing the same serial numbers indicated in the application form for tube & console with values for kVp, mA, time, and constancy checks by the service engineer)*** *(AO 35 s. 1994 sec. 5.8.10)*		
2. Audible and/or visible indication of x-ray production *(AO 35 s. 1994 sec. 5.8.8)*		
3. Means to set exposure factors ***(provide pictures of control console)*** *(AO 35 s. 1994 sec. 5.8.3)*		
4. Mechanically stable *(AO 2022-0022, Annex A, Part 7)*		
5. All moving parts move smoothly without obstructions to motion *(AO 2022-0022, Annex A, Part 7)*		
6. With red warning light bulb ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.7)*		
7. With appropriate warning notice ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.8)*		
8. With adequate ventilation ***(provide pictures)*** *(AO 35 s. 1994 sec. 6.1)*		

(Accomplished per machine as an attachment to the AF of DIAGNOSTIC, INTERVENTIONAL, AND DENTAL X-RAY FACILITIES)