CHECKLIST FOR COMMISSIONING AND REGULAR INSPECTION OF DIAGNOSTIC X RAY INSTALLATIONS

Prepare a visit agenda to review the operating program with details contained in the application for authorization, the authorization certificate, prior programme review/inspection reports and their implementation, relevant correspondence, and other relevant documentation such as dosimetry reports.

Check the following for compliance with the authorization and with the regulatory authority requirements.

I-IDENTIFYING INFORMATION

I-1. Name of the institution: _____
_____

I-2. Address of facility: _____
_____
_____

I-3. Telephone/facsimile/e-mail: Voice: _____ Fax: _____
e-mail: _____

I-4. Authorization number: _____

I-5 Staff working in X-Ray:

Name	Position	Authorisation No.

II-VERIFICATION OF SAFETY

II-1. Radiation generating equipment

Type of X ray equipment	Manufacturer:	Model no:	Number of X ray tubes	Maximum voltage	Maximum current	Exposure time per week	Weekly work-load

Describe any differences between equipment in use and that approved by the regulatory authority and any features outside the parameters considered in the original safety assessment (i.e. higher energy or output.)

_____
_____
_____
_____
_____

II-2. Shielding design

Describe any differences or modifications from those approved by the regulatory authority and/or considered in the safety assessment (e.g. shielding design, building materials and controls, etc.):

_____
_____
_____
_____

a)	Was a safety assessment by a qualified expert performed prior to any modifications?	Yes	No
b)	Is the thickness and type of shielding appropriate for the types and intensity of radiation produced by X ray devices?	Yes	No
c)	Are the areas of installation adequate?	Yes	No
d)	Is operator protection adequate?	Yes	No
e)	Are appropriate accessories available? (Mobile protective barrier/Lead rubber apron/lead rubber gloves/Lead rubber flaps/Red goggles/Fluoroscopic chair/Gondola shield)	Yes	No

II-3. Safety control and equipment design

a)	Radiology		
	i) Light beam diaphragm available:	Yes	No
	ii) Diaphragm opening symmetrical:	Yes	No
	iii) Grid movement satisfactory:	Yes	No
	iv) Chest stand lead backing satisfactory?	Yes	No
v)	Diaphragm/Cone available:	Yes	No
b)	Fluoroscopy		
	i) Fluoroscopic screen brightness satisfactory?	Yes	No
	ii) Tube to screen alignment satisfactory?	Yes	No

iii) Beam confinement to screen at maximum fields size and table to screen distance satisfactory?		Yes	No
iv) Shutter movements satisfactory?		Yes	No
v) Foot switch	Provided? Used?	Yes Yes	No No
vi) Diaphragm control knobs shielded?		Yes	No
vii) Red light provided inside the room?		Yes	No
viii) Room darkening adequate?		Yes	No

II-4. Warning systems:

a)	Exposure signals and posted explanation (e.g. illuminated signs written signs, posters)	provided? working?	Yes Yes	No No
b)	Warning notices (In local language?)	provided? working? legible? local language?	Yes Yes Yes Yes	No No No No

II-5. Safety operations — management

a)	Is management knowledgeable of the certificate of authorization and its restrictions and requirements?	Yes	No
b)	Does management provide adequate staffing levels?	Yes	No
c)	Has management provided the radiation protection officer authority to stop unsafe operations?	Yes	No
d)	Does management provide adequate resources for personnel training (time and money)?	Yes	No
e)	Does management provide adequate equipment?	Yes	No
f)	Does management provide for periodic program reviews and recommendations?	Yes	No

i) Date of the last program review: _____

ii) Status of recommendations:_____

_____

_____

_____

II-6. Safety operations — technical

a)	Does the radiation protection officer (RPO) have adequate knowledge and expertise?	Yes	No
b)	Does the RPO have qualified experts available?	Yes	No
c)	Is the RPO knowledgeable about the requirements of the regulatory authority and the provisions of the certificate of authorization?	Yes	No
d)	Is the RPO given sufficient time and resources to do the job (e.g. not kept too busy with other assignments or given insufficient technical and secretarial help)?	Yes	No
e)	Does RPO maintains knowledge of activities of workers using radiation sources?	Yes	No
f)	Does the RPO conduct initial and periodic training of workers?	Yes	No
g)	Does the RPO maintain adequate records to demonstrate worker and public protection?	Yes	No

II-7. Investigations and quality assurance

a)	Were there any incidents or accidents?		Yes	No
b)	If so, were incident and accident investigation reports prepared?		Yes	No
c)	Were safety assessments reviewed or made based on lessons learned from any accident or accidents at similar facilities?		Yes	No
d)	Is there a written quality assurance program?	Procedure? Performed?	Yes Yes/	No No

e)	Is maintenance and repair work in accordance with manufacturer's recommendations?	Scheduled? Performed?	Yes Yes/	No No
f)	Are repair/maintenance procedures?	Developed? Followed?	Yes Yes/	No No

III-VERIFICATION OF WORKER PROTECTION

III-1. Classification of areas

a)	Are controlled areas demarcated?		Yes	No
b)	Are approved signs at access points?	provided? legible? local language?	Yes Yes Yes	No No No
c)	Are supervised areas demarcated?		Yes	No
d)	Are approved signs at access points?	needed? provided? legible? local language?	Yes Yes Yes Yes	No No o No

III-2. Local rules and supervision

a)	Are rules established in writing?	Yes	No
b)	Do rules include investigation levels and authorised levels and the procedure to be followed when a level is exceeded?	Yes	No
c)	Are workers (including nurses attending patients) instructed in the implementing procedures?	Yes	No
d)	Do workers have adequate supervision to ensure rules, procedures, protective measures and safety provisions are followed?	Yes	No

III-3. Monitoring

a)	Does the authorised organisation provide personal dosimeters?	Yes	No
b)	Are the dosimeters:		
	i) Worn properly?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Exchanged at required frequency?	Yes	No
c)	Are personnel exposures within limits?	Yes	No
d)	Area and portable survey instruments		
	i) Appropriate?	Yes	No
	ii) Calibrated?	Yes	No
	iii) Operational?	Yes	No
	iv) Operational check performed before use?	Yes	No
e)	Do the authorised organisation's surveys indicate that the radiation room shielding is adequate and the dose rates around the room meet authorised radiation levels?	Yes	No
Record independent measurements made during the inspection:			
_____ _____ _____ _____ _____			
Type/model no. of survey meter:			
Date last calibrated:			
Do the inspector's independent surveys agree with the survey results of the authorised organisation?		Yes	No

Document any significant differences and any agreed upon plan to resolve the different results: _____ _____ _____

IV-VERIFICATION OF PUBLIC PROTECTION

IV-1. Control of visitors

a)	Are visitors permitted in controlled areas?		Yes	No
b)	Is adequate information provided to visitors entering controlled areas?		Yes	No
c)	Are there adequate controls over entries into controlled and supervised areas and appropriate postings?	provided? legible? local language?	Yes Yes Yes	No No No

IV-2. Sources of exposure

a)	Are the shielding and other protective measures optimised for restricting public exposure to external sources of radiation?	Yes	No
b)	Are the floor plans and arrangement of equipment appropriate considering public areas adjacent to the installation?	Yes	No

IV-3. Monitoring of public exposure

a)	Are routine periodic measurements of exposure rates in areas adjacent to treatment and storage made by the staff or qualified expert?	Yes	No
b)	Record independent measurements made during the inspection:		
	_____ _____ _____		
	Type/model no. of survey meter:		
	Date last calibrated:		
	Are the inspector's independent measurements in agreement with the organisations routine measurements?	Yes	No
	Do surveys shows that the shielding is adequate and the dose rates outside the controlled and supervised areas meet authorised radiation levels?	Yes	No

V-EMERGENCY PREPAREDNESS

V-1. Emergency plan

a)	Is there a written plan?	Yes	No
b)	Is the plan periodically reviewed and updated?	Yes	No
c)	Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No
d)	Have workers involved in implementing the plan received training?	Yes	No

VI-MEDICAL EXPOSURE

VI-1. Responsibilities

a)	No patient treated unless the exposure is prescribed by a medical practitioner?	procedures? followed?	Yes Yes	No No
b)	Are there an adequate number of trained medical and paramedical personnel to discharge assigned tasks?		Yes	No
c)	Are diagnostic imaging and quality assurance requirements fulfilled with the advice of a qualified expert in radiodiagnostic physics?		Yes	No

VI-2. Justification

a)	Are diagnostic medical exposures justified by taking into account the benefits and risks of alternate techniques that do not involve medical exposure?	Yes	No
b)	Are there procedures to ensure that exposure of humans for medical research is in accordance with the Helsinki Declaration and follows the guidelines for its application prepared by the Council for International Organizations of Medical Sciences and the World Health Organization?	Yes	No
c)	Is each exposure of humans for medical research subject to the advice of an Ethical Review Committee or other similar institutional body?	Yes	No
d)	Are standards available and followed for radiological examinations for screening of large populations or for occupational, legal, or health insurance purposes.	Yes	No

VI-3. Optimisation

a)	Does newly acquired equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or to equivalent national standards?	Yes	No
b)	Are performance specifications and operating and maintenance instructions provided in a major world language understandable to the users and in compliance with the relevant IEC or ISO standards with regard to "accompanying documents"?	Yes	No
c)	The operating terminology (or its abbreviations) and operating values be displayed on operating consoles in a major world language acceptable to the user; where practicable?	Yes	No

VI-4. Operational considerations

a)	Do medical practitioners ensure that appropriate equipment is used, that the exposure of patients is the minimum necessary to achieve the diagnostic objective, and take into account relevant information from previous examinations to avoid unnecessary additional exposure?	Yes	No
b)	Do the medical practitioner, the technologists or other imaging staff select the parameters such that their combination produces the minimum patient exposure consistent with acceptable image quality and the clinical purpose of the examination?	Yes	No
c)	Are radiological examinations causing exposure of the abdomen or pelvis of women who are pregnant avoided unless there are strong clinical reasons for such examinations?	Yes	No
d)	Are diagnostic examinations causing exposure of the abdomen or pelvis of women of reproductive capacity planned to deliver the minimum dose to any embryo or foetus?	Yes	No

VI-5. Calibration

a)	Is the calibration of X ray equipment used for medical exposure traceable to a Standards dosimetry laboratory?	Yes	No
b)	Are calibrations carried out at commissioning of a unit, after maintenance that could affect dosimetry and at periodic intervals?	Yes	No

VI-6 Clinical dosimetry

Are representative values for typical sized adult patients of entrance surface doses, dose-area products, dose rates and exposure times, or organ doses determined and documented?	Yes	No

VI-7. Quality assurance

a)	Does the medical quality assurance program include:			
	i) measurements and verification of physical parameters at the time of commissioning and periodically thereafter?	procedures? followed?	Yes Yes	No No
	ii) written records of relevant procedures and results?		Yes	No
	iii) verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment?	procedures? followed?	Yes Yes	No No
	iv) verification of patient identity?	procedures? followed?	Yes Yes	No No
	v) regular and independent quality audit reviews?	procedures? followed?	Yes Yes	No No
b)	Darkroom procedures:			
	i) Dark room light-proof		Yes	No
	ii) Film storage satisfactory?		Yes	No
	iii) Cassette pass box available?		Yes	No
	iv) Timer available?		Yes	No
	v) Temperature control in the dark room adequate?		Yes	No
c)	Processing of films:			
	i) Type of film used:			
	ii) Films developed/week:			
	iii) Type of developer:			
	iv) Developing time:			
	v) Frequency of change of processing solutions:			

VI-8. Dose constraints

a)	Does an Ethical Review Committee or other institutional body specify dose constraints to be applied on a case by case basis in the optimisation of protection for persons exposed for medical research purposes if such medical exposure does not produce direct benefit to the exposed individual?	Yes	No
b)	Have dose constraints been established for individuals knowingly exposed while voluntarily helping in the care or comfort of patients under going medical treatment?	Yes	No
c)	Have dose constraints been established for individuals knowingly exposed while voluntarily visiting patients under going medical treatment?	Yes	No

VI-9. Investigations of accidental medical exposures

a)	Did the registrant or licensee promptly investigate any or all instances where:		
	i) A diagnostic exposure was substantially greater than intended or resulting in doses repeatedly and substantially exceeding guidance levels?	Yes	No
	ii) An equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?	Yes	No
b)	With respect to any incidents investigated, did the registrant or licensee:		
	i) Calculate or estimate the doses received and their distribution within the patient?	Yes	No
	ii) Indicate the corrective measures required to prevent recurrence of such an incident?	Yes	No
	iii) Implement all corrective measures that were under their control?	Yes	No
	iv) Submit to the regulatory authority, as soon as possible after the investigation or as otherwise specified by the regulatory authority, a written report which stated the cause of the accident and included the information specified in “i” to “iii”, as relevant?	Yes	No
v)	Inform the patient and his or her doctor about the incident?	Yes	No

VII-RECORDS

Note: Records will be needed as part of the assessments and verifications outlined in the prior sections of the checklist. This list is a reminder of the type of records that may be helpful. The appearance of the list at the end of the checklist does not indicate that records review is the last item to be done. Rather, an inspection may begin with an entrance interview and facility tour followed by an initial review of some of the records listed below.

a) Copy of authorization certificate
b) System of records management
c) Dosimetry
    i) current
    ii) prior work history
d) Area surveys
e) Instrument tests and calibrations
f) Audits and reviews of radiation safety programme
g) Incident and accident investigation reports
h) Maintenance and repair work
i) Facility modifications
j) Training provided
    i) initial
    ii) refresher
k) Evidence of health surveillance

Clinical dosimetry records