UGANDA

ATOMIC ENERGY COUNCIL

CRITERIA FOR HALTING THE AUTHORISATION PROCESS AFTER CONDUCTING PRE-AUTHORISATION INSPECTIONS IN MEDICAL RADIOLOGY FACILITIES

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Approved by

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1.0 INTRODUCTION

Pursuant to Section 8(1) of the Atomic Energy Act, Cap. 154 (AEA), Atomic Energy Council (AEC) conducts inspections to assess radiation safety and security conditions and compliance with the AEA and the Atomic Energy Regulations, 2012 (AER, 2012) and other requirements specified in the authorisation.

In this regard, AEC conducts pre-authorisation inspections to verify the information provided in the application form and the compliance of the facility with the requirements in the AEA and AER, 2012 before issuing authorisation for the intended practice. At the end of the pre-authorisation inspection, basing on the findings, the inspection team is required to identify and highlight areas of non-compliance and radiation safety gaps that need to be urgently addressed by the facility.

In line with the above, this document provides the criteria for the scenarios that lead to halting of the authorisation process after pre-authorisation inspections. These should be highlighted to facility representatives during the exit briefing as well as in the pre-authorisation inspection report.

This document will further provide guidance to Authorisation unit officers on the radiation safety gaps that should be included as issues of immediate attention after pre-authorisation inspections are conducted in facilities/activities. (In this case issues of immediate attention means those issues if not complied with, the authorisation process can't proceed).

2.0 PURPOSE OF THE DOCUMENT

To provide the criteria for halting the authorisation process after pre-authorisation inspections.

3.0 SCOPE OF THE DOCUMENT

The document applies to pre-authorisation inspections conducted in medical facilities using X-ray radiation sources for diagnostic and interventional purposes.

NB: The document may not be as exhaustive for all situations at various facilities. Thus, the officer may deviate from the phrasing of the considerations in this document in order to cater for unique situations that may arise at different facilities.

PROCESS AFTER PRE-AUTHORISATION INSPECTIONS.

The authorisation process can be halted given the following scenarios;

i. The radiation generating equipment fails the Quality control tests on specific parameters.
ii. Inadequate shielding of the X-ray imaging room.
iii. Lack of suitable and adequate personal protective equipment.
iv. Use of unqualified personnel to operate the radiation generating equipment.
v. Inadequate or inappropriate size and design of X-ray imaging room.
vi. Use of the radiation generating equipment for other practices other than the intended design purpose.
vii. Poor image quality.

4.1 The radiation generating equipment fails the Quality control tests on specific parameters.

The authorisation process should be halted if any of the results of the quality control tests for the different X-ray machines as indicated in table 1,2,3,4 and 5 are not within the permissible limits.

Note: The Quality Control tests have to be determined at clinically/commonly used settings and to identify these settings, check the patients' records where applicable. If not recorded in the patients' book, refer to the technique chart.

Table 1: Plain X-rays (Mobile and Fixed X-ray machines)

#	Parameter	Suspension limits
1.	Tube voltage accuracy	Percentage error not within ±10%
2.	Normalized dose output	Output outside range of 25 to 80 μGy/mAs at 80 kV
3.	X-ray/light beam collimation	Magnitude of deviation on any side of the axes > 2 cm
4.	X-ray/light beam alignment	Misalignment > 3°

Table 2: Fluoroscopy X-ray machines.

#	Parameter	Suspension limits
1.	Patient entrance dose rate	Normal Fluoroscopy mode > 50 mGy/mm
		High Fluoroscopy mode > 100 mGy/mm

Table 3: For Dental X-ray machines.

#	Parameter	Suspension limits
1.	Tube voltage range, Intra Oral	Outside the range 60 to 90 kVp
2.	Tube voltage range, Cephalometric and all others except CBCT	Outside the range 60 to 125 kVp
3.	Tube voltage accuracy	Percentage error not within ±10%
4.	Exposure time accuracy	Deviation from set exposure time > 20%
5.	Repeatability of radiation output	Deviation from mean measured output >20 %

Table 4: Mammography X-ray machines.

#	Parameter	Suspension limits
1.	Tube voltage accuracy	Percentage error not within ±5%
2.	Compression thickness indicator	Magnitude of deviation > 8 mm
3.	Mean Glandular Dose, MGD	MGD > 2.5 mGy at 100cm for a 45mm PMMA slab
4.	Collimation assessment	Magnitude of deviation > 5 mm

Table 5: CT X-ray machines.

#	Parameter	Suspension limits	
1.	Computed Tomography Dose Indices (CTDIvol)	Child	CTDIvol ≥ 25 mGy
		Adult Abdomen	CTDIvol ≥ 30 mGy
		Adult Head	CTDIvol ≥ 80 mGy

Note 1: For HVL values refer to Annex A of the document.
Note 2: In cases, where the X-ray machine fails on kV accuracy but with adequate filtration i.e., its HVL values are within the permissible limits and also its normalized dose rate output is in the permissible range, authourisation can proceed.

4.2 Inadequate shielding of the imaging room.

Dose rates at any location behind the containments are greater than 10 μSV/hr.
NB: (All measurements are taken at 30 cm away from the barrier)

4.3 Lack of suitable and adequate personal protective equipment.

If there are no personal protective equipment at the facility based on the practices below;

i) For Plain radiology:

At least one (01);

b. thyroid shield of Lead equivalent ≥ 0.25mm Pb
c. Lead gonad shield of Lead equivalent ≥ 0.25mm Pb

ii) For Computed Tomography

At least one (01);

a. Lead apron of Lead equivalent ≥ 0.25mm Pb
b. pair of Bismuth eye shields
c. thin Bismuth breast shields
d. thyroid shield of Lead equivalent ≥ 0.25mm Pb
e. Lead gonad shield of Lead equivalent ≥ 0.25 mm Pb

iii) For Dental radiology

At least one (01);

a. Lead apron of Lead equivalent ≥ 0.25mmPb
b. thyroid shield of Lead equivalent ≥ 0.25mm Pb
c. pair of Lead Goggles of Lead equivalent ≥0.5mm Pb for Handheld Portable Dental X-ray machines

iv) For Interventional radiology (Fluoroscopy, C-arm, Cathlab)

At least;

a. Lead aprons with closed back designs of Lead equivalent ≥ 0.35mmPb (sufficient number for all the workers and interventionists)
b. Thyroid shields of Lead equivalent ≥ 0.25mm Pb (sufficient number for all the workers and interventionists)
c. Lead gonad shields of Lead equivalent ≥0.25mm Pb of; Large size (Adult), Medium size (Child), Small size (Infant),
d. Protective accessories such as ceiling suspended shielding, or Protective curtains
e. Pairs of lead gloves (sufficient number) alternatively, forceps and/or needle holders should be in place for interventionists)
f. Pairs of eye wear/lead glass spectacles of lead equivalent ≥0.5mm Pb. (sufficient number for all the workers and interventionists)

v) For Bone densitometry

At least one (01);

a. thyroid shield of Lead equivalent ≥ 0.25mm Pb

b. Lead gonad shield of Lead equivalent ≥0.25mm Pb
c. Lead apron of Lead equivalent ≥ 0.25mm Pb

vi) For Mammography

At least one (01);

a. Lead skirt of Lead equivalent ≥ 0.25mm Pb
b. Lead apron of Lead equivalent ≥0.25mm Pb (for the worker).

4.4 Use of unqualified personnel to operate the radiation generating equipment.

If the facility does not have qualified personnel e.g. radiographer to undertake the practice.

Note: A valid practicing license or extract from main register issued by the relevant professional body (Allied Health Professional Council (AHPC), Uganda Medical and Dental Practitioner Council (UMDPC)) is required from each of the radiation workers at the facility.

4.5 Inadequate size or inappropriate design of X-ray imaging room.

i. No lead glass installed in the viewing window.
ii. No safe method to continuously observe the patient during exposure.
iii. Ground area of the X-ray imaging room is less than the recommended size i.e., less than 16.0 m^2 excluding the control cubicle or 21 m^2 including the control cubicle for plain radiography, 9 m^2 excluding the control cubicle and 12.0 m^2 including the control cubicle for dental and Mammography X-ray machines, and 25.0 m^2 excluding the control cubicle for Computed Tomography and interventional radiology practice respectively.

4.6 Use of the radiation generating equipment for other practices other than the intended design purpose.

If the facility is using or intends to use the radiation generating equipment for other purposes other than the intended design purpose for example, using a dental X-ray machine for general radiography.

If the X-ray machine fails on any of the image quality tests i.e., image uniformity and artefacts test (exclusive of interventional radiography X-ray machines), low contrast detectability test and limiting spatial resolution test by analyzing the radiographs/displayed images on the screen.

The suspension limits for image quality for both plain and interventional radiology are as indicated in table 6 and 7 respectively.

Table 6: For plain radiology

#	Test	Suspension limits
1.	Image uniformity and artefacts	Visibility of any artefact
2.	Low contrast detectability	Number of visible objects (discs < 10) or less than the previous obtained value.
3.	Limiting spatial resolution	Number of visible group of line pairs that are distinct < 10 or less than the previous obtained value.

Table 7: For interventional radiology

#	Test	Suspension limits
1.	Low contrast detectability	Number of visible objects (discs ≤ 10) or less than the previous obtained value.
2.	Limiting spatial resolution	Number of visible group of line pairs that are distinct; < 5 for field sizes > 25 cm < 7 for field sizes ≤ 25 cm or less than the previous obtained value.

NB: The expiry of the films and processing chemicals (where applicable) may be put into consideration before making a final conclusion on these tests.

Annex A: The suspension levels for minimum HVL for X-Ray generators used in medical radiology facilities.

Table 1: Suspension levels for minimum HVL for equipment manufactured after 2012

X-ray Tube Voltage (kV)	Minimum permissible first HVL (mm Al)
50	1.80
51	1.84
52	1.88
53	1.92
54	1.96
55	2.00
56	2.04
57	2.08
58	2.12
59	2.16
60	2.20
61	2.23
62	2.26
63	2.29
64	2.32
65	2.35
66	2.38
67	2.41
68	2.44
69	2.47
70	2.50
71	2.54
72	2.58
73	2.62
74	2.66
75	2.70
76	2.74
77	2.78
78	2.82
79	2.86
80	2.90
81	2.93
82	2.96
83	2.99
84	3.02
85	3.05
86	3.08
87	3.11
88	3.14
89	3.17
90	3.20
91	3.24
92	3.28
93	3.32
94	3.36
95	3.40
96	3.44
97	3.48
98	3.52
99	3.56
100	3.60
101	3.63
102	3.66
103	3.69
104	3.72
105	3.75
106	3.78
107	3.81
108	3.84
109	3.87
110	3.90
111	3.94
112	3.98
113	4.02
114	4.06
115	4.10
116	4.14
117	4.18
118	4.22
119	4.26
120	4.30
121	4.34
122	4.38
123	4.42
124	4.46
125	4.50
126	4.54
127	4.58
128	4.62
129	4.66
130	4.70
131	4.73
132	4.76
133	4.79
134	4.82
135	4.85
136	4.88
137	4.91
138	4.94
139	4.97
140	5.00
141	5.04
142	5.08
143	5.12
144	5.16
145	5.20
146	5.24
147	5.28
148	5.32
149	5.36
150	5.40

X-ray Tube Voltage (kV)	Minimum Permissible HVL (mm Al)
50	1.50
51	1.53
52	1.56
53	1.59
54	1.62
55	1.65
56	1.68
57	1.71
58	1.74
59	1.77
60	1.80
61	1.83
62	1.86
63	1.89
64	1.92
65	1.95
66	1.98
67	2.01
68	2.04
69	2.07
70	2.10
71	2.12
72	2.14
73	2.16
74	2.18
75	2.20
76	2.22
77	2.24
78	2.26
79	2.28
80	2.30
81	2.32
82	2.34
83	2.36
84	2.38
85	2.40
86	2.42
87	2.44
88	2.46
89	2.48
90	2.50

X-ray Tube Voltage (kV)	Minimum Permissible HVL (mm Al)
91	2.52
92	2.54
93	2.56
94	2.58
95	2.60
96	2.62
97	2.64
98	2.66
99	2.68
100	2.70
101	2.73
102	2.76
103	2.79
104	2.82
105	2.85
106	2.88
107	2.91
108	2.94
109	2.97
110	3.00
111	3.02
112	3.04
113	3.06
114	3.08
115	3.10
116	3.12
117	3.14
118	3.16
119	3.18
120	3.20
121	3.23
122	3.26
123	3.29
124	3.32
125	3.35
126	3.38
127	3.41
128	3.44
129	3.47
130	3.50
131	3.53

X-ray Tube Voltage (kV)	Minimum Permissible HVL (mm Al)
132	3.56
133	3.59
134	3.62
135	3.65
136	3.68
137	3.71
138	3.74
139	3.77
140	3.80
141	3.83
142	3.86
143	3.89
144	3.92
145	3.95
146	3.98
147	4.01
148	4.04
149	4.07
150	4.10

Table 3: Suspension levels for minimum HVL for Dental X-ray machines

kV	HVL (mm Al)	
	Intra-oral	Ceph/OPG
60	1.5	1.8
70	1.5	2.1
80	2.3	2.3
90	2.5	2.5

Table 4: Suspension levels for minimum HVL for Mammography X-ray machines

Tube Voltage (kV)	Minimum recommended HVL for different target-filter combination (mm Al)			
	HVL for Mo/Mo	HVL for Mo/Rh	HVL for Rh/Rh	HVL for W/Rh
24	0.317	0.381	0.369	0.507
25	0.326	0.389	0.382	0.516
26	0.336	0.397	0.394	0.525
27	0.345	0.405	0.407	0.534
28	0.355	0.413	0.419	0.543
29	0.365	0.422	0.432	0.552
30	0.374	0.430	0.444	0.561
31	0.384	0.438	0.457	0.571
32	0.394	0.446	0.469	0.580