Regulatory Requirements to Practice Mammography and for Issuance of a License

I - Introduction

Background
Mammography is a specific type of imaging that uses a low-dose x-ray system to examine breasts. A mammography exam, called a mammogram, is used to aid in the early detection and diagnosis of breast diseases in women.

An x-ray (radiograph) is a noninvasive medical test that helps physicians diagnose and treat medical conditions. Imaging with x-rays involves exposing a part of the body to a small dose of ionizing radiation to produce pictures of the inside of the body. X-rays are the oldest and most frequently used form of medical imaging.

Mammography is similar to plain film radiography, but uses low operating potentials in the range of 25 to 35 kVp to maximize the contrast between the soft tissue structures of the breast. Because of the low energy, the radiation dose to the patient can be high, and strict quality control is required.

This regulatory requirement sets the minimum safety criteria for used to carry out mammography. Compliance with this requirement will assist in ensuring that patent, public and occupational exposure to radiation is minimized.

The ERPA has adapted and established the regulatory control systems from the beginning in which a continuous and an effective linked system of Notification, Authorization, Inspection and Enforcement are used for effective control of sources in the country.

Purpose
This requirement is intended to establish basic/mandatory requirements required for license in mammography and to assist inspectors to decide uniformly whether a radiological facility should be licensed, not begin or stop its services by the power vested to the ERPA by proclamation No. 571/2008. This regulatory requirement will be available and distributed to users beforehand so as to guide and inform them about the license process to get authorization to practice diagnostic radiological services.

Scope
This regulatory requirement applies to mammography facilities practicing diagnostic imaging application with x-ray machine for the purposes of obtaining diagnostic information of patients as prescribed by appropriate medical personnel.

Definitions
In this requirement –

coefficient of variation” means the ratio of the standard deviation to the mean value of a series of measurements.

“kVp” means the potential difference applied to an X-ray tube between the anode and the cathode which is expressed by its peak value in kilovolts (kVp).

“leakage radiation” means ionising radiation which has passed through the protective shielding of a radiation source as well as that which, for some types of Xray generators, has passed through the radiation aperture before and after loading (for example one containing a grid controlled X-ray tube).

“loading” means the act of supplying electrical energy to the anode of an X-ray tube. “mammography” means radiographic examination of the breast.

“mA” means the electric current of the electron beam incident on the target of an Xray tube over a particular time, which is expressed by multiplying the mean value in milliamperes by the seconds (mA).

“radiation level” means the air kerma radiation dose during a specified time.
Effective date

The provisions of this procedure shall be effective on the date of approval by the Authority.

I. Safety Provisions, X-Ray Premise and Safety Control System

A. Lead apron,

Lead aprons of 0.35mm of lead (or lead equivalent) are indispensable for the examiner and the technologist and other staff involved as necessary.

B. Personal Monitoring Service for radiation workers

Personal monitoring service for all radiation workers (such as radiologists, radiographers and Radiation Technologist).

C. Film Viewing Box

Film viewing screen with uniform light intensity and color should be available.

D. Area of the exposure room

Area of the exposure room shall not be less than 10m² for mammography.

N.B. The exposure room

F. Wall thickness

The room shall be constructed in such a way that there is no leakage radiation to the surrounding area above the public limit (1μSv/hr).

Shielding of the floor, walls, ceiling and doors on the basis of distance, maximum expected X-ray tube voltage, and workload.

G. Warning light & signs

A warning light sign coupled/synchronized with the machine power shall be provided at appropriate location(s).

Placards containing international radiation hazard sign (Trefol symbol) and notices in English and Amharic (or and other local languages) should be available and posted at suitable locations. Local rules should also be presented describing working procedures and safety rules.

H. Patient Identification System (Film Printer)

Proper patient identification system, like film printer shall be provided and routinely used.

I. Auxiliary rooms

Dressing room and toilet that keep the privacy and safety of the patients adjacent to the exposure room shall be provided.

Safety of the X-ray Premise (Radiological protection surveys)

The mammographic unit must be safe from radiological point of view at every location (maximum of 1 μSv/hr at all locations occupied by a member of public and 7.5 μSv/hr in the control cubic and any occupationally accessed location by radiation workers).There should be an adequate shield between the patient and the technologist.(mobile guards)

X-ray Machine Performance

Equipment of diagnostic radiology shall conform to applicable national or international standards such as the International Electrotechnical Commission (IEC) or International Standards Organization (ISO).

Such equipment should satisfy the technical requirements of verification of machine parameters, and Quality Assurance tests at large. Under all circumstances, the equipment should be accompanied with the necessary documents including the service and operating manuals, results of acceptance tests, and calibration certificate for the required machine parameters of the x-ray machine.

Radiation output

kVp accuracy : The kVp accuracy, starting at the lowest kVp used clinically and increasing in 1kVp steps until the maximum kVp used clinically is reached, must not be within ±5 percent of the indicated value.

Reproducibility of output: The coefficient of variation of 5 consecutive radiative dose measurements at a commonly used (manual) exposure setting, taken within a time period of 10 minutes, must not exceed 0.02.

Radiation level

Radiation level: The system must be capable of: -a) producing a minimum radiation level of 7mGy in one second when operating at 28kVp in the standard mammography (Mo/Mo) mode at any focus to film distance at which the system is designed to operate and when measured by a detector with its centre located 4.5 centimetres above the breast support surface with the compression paddle in place between the source and the detector; and (b) maintaining the 7mGy in one second output, averaged over a 3 second period.

X-ray source assembly: The leakage radiation level must not be able to exceed 1mGy per hour at 1 meter from the housing.

Radiation dose

Mean Granular Dose: The mean glandular radiation dose must not exce 3mGy for a 5 centimetre breast phantom of 50 percent adipose tissue, 50 percent glandular tissue.

Control panel

Exposure switch: Each loading must be initiated and maintained by means of a control requiring continuous actuation by the operator.

Loading indication: Loading must be indicated by an amber light and an audible Signal.

Beam limiting device

Light field intensity: The luminescence of the light beam indicator measured at the level of the breast support (maximum achievable distance) must be greater than or equal to 100 lux.

X-ray field/light beam: The extent of misalignment between any boundary of the light beam and the equivalent boundary of the X-ray beam in the plane of the image receptor must not exceed 1 percent of the focus to film distance.

X-ray field/image receptor alignment: The X-ray field must: (a) extend to the edge of the patient support that is designed to be adjacent to the chest wall of the patient and must not extend beyond this edge by more than 5 millimeters; and (b) not extend, by more than 2 percent of the perpendicular distance from the image receptor plane to the position of the focal spot, beyond all edges of the image receptor area.

Automatic exposure control

Documentation Requirements

Full documentation shall be presented with the application for Authorization to the Authority such as:

- Machine specifications (including manufacturer’s information, maximum and minimum parameters that could be set, date of manufacture, etc) and shipping certificate as necessary.
- Floor layout of the facility.
- Copies of educational qualifications of workers.
- Properly signed and sealed completed notification & application protocols AP-NT-01 and AP-DR-01.
- License Certificate from appropriate health and trade bureaus, and Certificate that assures that the institution is the registrant of TIN number shall be submitted to ERPA.

Personnel Requirements

A Radiation Safety Officer (RSO) has to be officially assigned by the organization applying for Authorization.

At least one formally trained Radiologist and a Senior Radiographer has to be available.

Justification

Mammography is similar to plain film radiography, but uses...
The following darkroom accessories shall be provided:

1. Safelight (A safe light with a correct height shall be provided)
2. Film hopper (Light tight) (A film hopper with a pull-back or shutter has to be provided and the film hopper shall be light tight.)
3. Film dryer (that could provide uniform drying of radiographs)
4. Film processor (with all necessary items, such as alarm timer, temperature control mechanism/heater and thermometer)
5. Hatch box with an interlock system
(A hatch box with an interlock system, and internal dimensions that could accommodate the largest size film cassettes in sufficient number, must be available. Besides, if one side of the hatch box is along the exposure room it shall be properly shielded (lead-lined) to avoid radiation exposure of the films placed in the box).
6. Light tight film cassettes with intensifying screen adequate to the diagnostic radiological practice.
7. Radiation level in the darkroom shall be very small and usually in the level of background to ensure the quality of films.
8. sufficient ventilation to the dark room

Selection indication: There must be an indication on the control panel that the automatic exposure control function has been selected.

Backup timer operation: The backup timer must limit the mAs to no more than 600mAs per irradiation. A preset exposure of less than 600mAs also constitutes a backup timer.

Backup timer indication: A visible indication at the control panel must be provided whenever a loading has been terminated by the backup timer.

Backup timer manual reset: When the exposure has been stopped by the backup timer it must not be possible to initiate another exposure without first operating a manual reset.

Reproducibility: The coefficient of variation of the radiation dose from 5 consecutive, phototimed exposures of an acrylic phantom, or similar, taken within a time period of 10 minutes, must be less than or equal to 0.05.

Compression
Compression (a) The compression device must not be able to apply a force exceeding 300 newtons; and (b) for power driven compression, the compression device must be able to apply a force of at least 150 newtons, and must be unable to apply a force exceeding 200 newtons; and (c) the inner lip of the chest wall side of the compression device must be aligned just beyond the chest wall edge of the image receptor by a distance not exceeding 1 percent of the focus to film distance.

kVp compensation, thickness compensation: For phototimed images of 2, 4 and 6 centimetres of perspex using clinically relevant kVps and target/filter combinations (for both contact and magnification imaging), the film optical density must be within ±0.15 of the mean optical density.

Mean optical density
Mean optical density: The mean optical density must be greater than or equal to 1.2 of the optical density.

Image quality
System resolution: Using a line pair phantom 4.5 centimetres above the breast support: (a) measurements made with the bars parallel to the anode-cathode axis must resolve at least 13 line pairs per millimetre; and (b) measurements with the bars perpendicular to the anode-cathode axis must resolve at least 11 line pairs per millimetre. These limits apply for both contact and magnification modes.

Object visualization: It must be possible to visualize: 4 of 6 fibers, 3 of 5 specks and 3 of 5 masses. The optical density difference due to the 4 millimetre thick acrylic disc must be greater than or equal to 0.40.

Protective screen
Protective screen: The protective screen (a) must not prevent the operator from observing the patient during mammography; and (b) must extend from not more than 15 centimetres above the floor to a height of not less than 185 centimetres; and (c) must not be narrower than 60 centimetres; and (d) must be able to attenuate 35kVp radiation to an extent greater than or equal to 0.08 millimetres of lead.

low energy x-rays (about 25 kVp) to maximise the contrast between the soft tissue structures of the breast. Because of the low energy, the radiation dose to the patient can be high, and strict quality control and justification is required. It is also highly recommended that errors (such as exposure to wrong patient) shall be avoided/minimized by defense-in-depth procedures to confirm the right patient and target organ, as a result proper working procedures and local safety rules shall be established and implemented.