## Issue History

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<th>Description of Change</th>
<th>Originator</th>
<th>Approved By</th>
<th>Effective Date</th>
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<td>1</td>
<td></td>
<td>Surur Kedir</td>
<td>Name</td>
<td>1/5/2011</td>
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### For Document Control Use Only

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PLEASE MAKE SURE THAT THIS IS THE CORRECT ISSUE BEFORE USE!
1. Purpose
This procedure is intended to establish basic/mandatory requirements required for license in Computer Tomography (CT) Scanning 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.

2. Scope
This regulatory requirement applies to Computer Tomography (CT) scanning facilities practicing diagnostic imaging application with x-ray machine for the purposes of obtaining diagnostic information of patients as prescribed by appropriate medical personnel.

3. Responsible person:
   Director /DG/ I/R/NAD

4. Definitions and Abbreviations
   4.1 Definitions
   "baseline value" means the reference value provided by the manufacturer or the value measured at acceptance testing. In the absence of these values, the values derived at the first compliance test.
   "computed tomography" means reconstructive tomography in which recording and processing is effected by a computing system.
   "computed tomography number" (CT number) means the number used to represent the mean X-ray attenuation associated with each elemental area of the computed tomography image. The CT number is normally expressed in Hounsfield units.
   "loading" means the act of supplying electrical energy to the anode of an X-ray tube.
   “Computed Tomography Kerma Index” means the Computed Tomography Kerma Index, $C_{100}$, for a single axial scan is the quotient of the integral of the air kerma along a line parallel to the axis of rotation of a CT scanner over a length of 100 mm and the product of the number of acquired tomographic sections N and the nominal section thickness T. The integration range is positioned symmetrically about the volume scanned, thus
   
   $C_{100} = \frac{1}{NT} \int_{-50}^{50} K(z) dz$

   “air kerma length product” means the air kerma-length product, $P_{KL}$, is the integral of the air kerma over a line, L, parallel to the axis of rotation of a computed tomography scanner, thus
   
   $P_{KL} = \int_{L} K(z) dz$

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For the purpose of this document the definition given in ISO 9000:2015 is used
Directorate Directors means : Directors in ERPA

4.2 Abbreviations

ERPA: Ethiopian Radiation Protection Authority
DG: Director General
I/R.NAD: Ionizing Radiation Notification and Authorization Directorate

5. Work Instruction

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<tr>
<th>I- Safety Provisions, X-Ray Premise and Safety Control System</th>
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<td>a. Lead apron, Lead aprons of 0.50 mm of lead (or lead equivalent) are indispensable for the examiner and the radiographer and other staff involved as necessary. Lead apron(s) integrity (Physical conditions for holes, cracks, etc.) shall be checked properly.</td>
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<td>b. Lead glass goggle Lead glass goggles have to be provided for protection of the eye of the patient. (Protective glass should be 0.8mm lead glass or at least 90mm plate glass).</td>
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<tr>
<td>1. Auxiliary rooms Dressing and toilet rooms that keep the privacy and safety of the patients adjacent to the exposure room shall be provided.</td>
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<td>Safety of the X-ray Premise (Radiological protection survey) The X-ray department 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 cubicle and any occupationally accessed location by radiation workers).</td>
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<tr>
<td>Lead glass window shall be provided to the control cubicle, and its thickness should have a nominal value of 2mm lead or its equivalent. The lead glass shall be fitted at proper location to provide a clear view (to the radiographer) of a patient undergoing.</td>
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General Requirements
Examination can be interrupted by operator: The operator must be able to interrupt the examination at any time.
Couch positioning accuracy: The couch positioning accuracy must not deviate by more than ±2 millimeters.
Loading indication: Loading indication must be by amber light and an audible Signal both at the control console and in the CT room.

Image Quality
The mean CT Number in center ROI ≤±4
Deviations from linearity should be < ±5 HU
Maximum différence outer/centre ROI

• License Certificate from appropriate health and trade bureaus and Certificate that assures 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 Senior Radiographer has to be available. If there is a higher workload 120 patients per week (~ 40 mA-min/week) and more than two of these practices are performed then additional Senior Radiographer has to
different sizes and shielding capacity at least for standing positions shall be made available to be used by patients and pregnant women. However, it is advisable the provision of gonad shields for lying positions (here, it is assumed that gonad shields available for standing positions will also be used for lying). Gonad shields integrity (Physical conditions for holes, cracks, etc) shall be checked properly.

c. **Lead gloves**
Glove integrity (Physical conditions for holes, cracks, etc) shall be checked properly.

d. **Personal Monitoring Service for radiation workers**
Personal monitoring service for all radiation workers (such as radiologists, radiographers and Radiation Technologist) shall be provided.

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<th>different sizes and shielding capacity at least for standing positions shall be made available to be used by patients and pregnant women.</th>
<th>radiological examination. The wall of the CT-Scan room (exposure room) should be thick enough to attenuate leakage of radiation. The wall thickness is generally suggested to be 17 cm of concrete (pure) or equivalent, as an alternative to the description on the layout of the X-ray premise. All doors adjacent to the exposure room shall be properly shielded/lead-lined with lead of 2mm or its equivalent material. Lead overlap shall be made to avoid radiation leakage at edges, hinges and connections.</th>
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<tr>
<td><strong>Slice thickness</strong> ≤±2 mm for all slices</td>
<td><strong>Position movement discrepancy</strong> ≤±0.5mm of selected.</td>
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<td><strong>Reproducibility of position</strong> ≤±1mm</td>
<td><strong>Distance of light/Slice centre</strong> ≤±min slice width)</td>
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<td>(The difference in the CT number between a peripheral and a central region of a homogeneous test object should be &lt; 8HU)</td>
<td><strong>Image noise</strong> The SD of CT numbers in the central 500 mm² ROI for a water or tissue equivalent phantom should not deviate more than 20% from the baseline.</td>
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<td><strong>CT number values</strong> The deviation in the CT number values for water or tissue equivalent material and materials of different densities should be ±20 HU or 5%</td>
<td><strong>CT number</strong> be provided.</td>
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**Justification** Since CT procedures contribute up to 40% of the collective dose from diagnostic radiology, it should be justifiable. CT scan is one of the practices/procedures with significant dose to patients. Therefore, sufficient justification shall be made to prescribe CT scan by qualified physicians based on valid clinical indication.

**Ultrasound and MRI** offer alternatives to CT in many areas of applications.

It is also highly recommended that errors (such as exposure to wrong patient, wrong organ, etc) 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.
E. **Film Viewing Box**
Film viewing screen with uniform light intensity and color should be available.

F. **Area of the exposure room**
Area of the exposure room shall not be less than 28 $m^2$ for CT scan.

N.B. The exposure room shall have sufficient ventilation (such as a ventilation window with a height above 2m from outside ground level and position in such a way that backscatter radiation will not fall on windows of opposite building, verandah, etc)

G. **Wall thickness**
Wall thickness of at least 17cm concrete or its equivalent (with no radiation leakage to the surroundings, i.e. maximum of 1µSv/hr at all locations occupied by a member of the public and 7.5µSv/hr to the control cubicle and any occupationally accessed location by radiation workers)

### Equipment Requirements

- **Uniformity**
  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.

  1. **Deviation of kVp Accuracy**
     $\leq \pm 10\%$

  2. **Deviation of the X-ray timer**
     $\leq \pm 10\%$

  3. **Output inconsistency**
     $\leq 5\%$

  4. **The first half value layer in the X-ray beam incident to the Patient must be greater than or equal to:**
     a) 3.8 millimeters of aluminum at 120kVp; or
     b) 4.2 millimeters of aluminum at 130kVp.

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

- Machine specifications (with manufacturer’s information, maximum and minimum parameters that could be set, date of manufacture, etc) and shipping certificate as basic.
- Floor layout of the facility,
- Copies of educational qualifications of workers,
- Properly signed and

### Computed tomography dose index (CTDI)
The CTDI for a single slice for each available beam shaping filter and for each available slice thickness should not deviate more than $\pm 20\%$ from the baseline.

### Irradiated slice thickness
The FWHM of the dose profile should not differ more than $\pm 20\%$ from baseline.

### High contrast resolution (spatial resolution)
The FWHM of the point spread function of a pin, or the edge response function of an edge should not differ more than $\pm 20\%$ from baseline.

### Low contrast resolution
Polystyrene pins of 0.35 cm diameter inserted in a uniform body water phantom should be visible in the image.

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### 11. Warning light & signs
Warning red light coupled/synchronized with the machine power shall be provided at appropriate location(s). Placards containing international radiation hazard sign (Trefoil 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.

### 6. List of Forms
- Ionizing Radiation Sources/Generators Notification APNT-01 form OF/ERPA/099
- Application form to use diagnostic x-ray equipment and facility APDR-01 form OF/ERPA/099

### 7. Reference Document
- ERPA Quality manual

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