NUCLEAR REGULATORY AUTHORITY

AUTHORISATION GUIDELINES FOR DIAGNOSTIC RADIOLOGY FACILITIES

PREAMBLE

In pursuant of the provisions of Section 1 of the Nuclear Regulatory Authority (NRA) Act 895 of 2015, the Authority has been given the mandate to ensure the protection, safety of humans and the environment in the use of radiological sources or devices and nuclear materials as well as the security of these devices in Ghana. The Authority in Sections 5 & 6 of the Act is empowered to "categorize and regulate activities involving exposure to ionizing radiation, in particular, the possession, production, processing, manufacture, purchase, sale, import, export, handling, use, transformation, transfer, trading, assignment, transport, storage and disposal of any radioactive material, nuclear material, radioactive waste, prescribed substance and any apparatus emitting ionizing radiation".

AUTHORISATION GUIDELINES

These guidelines given below are applicable to conventional radiography, dental radiography, fluoroscopy, mammography, computed tomography and other diagnostic radiation applications deemed to be under regulatory control by NRA. In order to ensure compliance of the Nuclear Regulatory Authority ACT 895 of 2015, any individual/organisation who intends to set up or operate a diagnostic radiology facility should satisfy the requirements at each stage of the authorisation process.

Step 1. Notification

Notification is required for new diagnostic radiology facilities where the individual/ organisation is to demonstrate justification of the practice. The individual/organisation should obtain the notification form (NRA Form G1) from the NRA website or in person at the NRA office, complete and submit it with the appropriate fee.

Step 2. Application for authorization

Prior to the use of the diagnostic radiology facility, specific authorisations must be granted by the NRA. The applicant must apply for authorisation by completing the application for authorisation form (NRA FORM 1A) which may be downloaded from the NRA website or requested in person at the NRA. The form must be completed in compliance with the Regulatory Requirements (Download from NRA Website) and submitted with the appropriate fee and attached documents in section *i* to *vii* as appropriate for assessment.

After the assessment of the application, a team of inspectors may be sent to the facility to verify some technical details provided in the application. An authorisation to use the device/facility may be granted or refused base on the assessment of the application. Please note that the equipment/facility can't be used for its intended purpose without obtaining authorisation from NRA.

i. Proof of Legal Status

Submit proof of business registration from the Registrar Generals' Department of Ghana. If the Applicant is a corporation, it needs to submit proof of incorporation and an official corporation profile report which sets out various information about the corporation, including corporation's legal name, corporation number, date of incorporation and registered office address. For Public Institutions, specify the name of the enabling legislation (act or instrument or equivalent) under which the institution was created. A copy of the applicant's legal status must be submitted to NRA during the application for authorisation.

ii. Approval of Radiation Shielding and Room Layout Plan

Applicants must submit two copies of room and site layout drawings showing proposed radiation shielding of the room. If there is potential occupancy above or below the radiation room, include construction details for the ceiling and floor and other necessary structural information. The copies of the drawings must be submitted to the NRA for approval and issuance of construction permit from radiation safety stand point during the application for authorisation.

Any modifications or changes to already approved structure must duly be approved by NRA. Appropriate site design approval fee and construction permit fee should accompany the application at all times before processing will commence.

iii. Import Permit Application

Importation of diagnostic radiation emitting machines into Ghana requires an import permit issued by the NRA. Import permit application form (NRA-IP) must be obtained from the NRA website or in person, completed and submitted with the appropriate fee. Applicant must enquire the technical specifications of the radiation emitting device from the supplier to aid in completing the form. A copy of the technical specifications of the radiation emitting device may be attached to your application to facilitate the process.

iv. Appointment of Radiographer/Operator

Prior to the use of a radiation emitting machine, a radiographer/operator with the required qualification and experience acceptable by NRA shall be appointed to use the device. The

experience and qualification of the individual shall be attached to the forms of the application for authorisation.

v. Procurement of Radiation Protection Accessories

In the process of procuring the radiation emitting device, required protection devices (lead apron, gonadal shield, lead goggles, staff protection screens etc.) associated with the equipment should be procured as well. These will be procured as the application of the device may require. The radiation protection device should be well kept and made available during compliance inspection by the NRA.

vi. Personnel Radiation Monitoring Services Provider

Arrangements should be made with personnel monitoring service provider authorised or recognised by the NRA to provide appropriate personnel monitoring for all the radiation workers. The service should be available during installation/use of the unit. A copy of the agreement or arrangement should be submitted to the NRA during the application for authorisation.

vii. Quality Assurance/Acceptance Test

The applicant must perform thorough quality assurance/acceptance test of the nuclear medicine facility. A copy of the acceptance/assurance test report should be submitted to the NRA during the application for authorisation. The applicant is advised to keep the original acceptance/assurance test in the facility.

Step 3. Periodic Performance/ Quality Assurance test

Quality control/performance tests on the radiation emitting device should be done periodically to check the quality of the radiation, shielding integrity of the facility, calibration of equipment etc. The test records should be maintained and made available to personnel of NRA during regulatory compliance inspection. Apart from the periodic interval, these tests are also advised to be done any time there has been maintenance on the device.

Step 4. Notification of Changes/Modification

Any intended modification or change to the approval conditions at any stage should be reported to the NRA in writing before the change is done. It is an offence to vary any approval conditions without prior knowledge of the NRA.

Approval/Permit/License Fees

The applicant should refer to the approved NRA rates, fees and charges for technical services (available on the internet or pickup in person at the office of NRA) to determine the appropriate licensing fee/charge and category. No action will be taken on applications

submitted without the proper fee. Cheque for the fees should be made payable to the Nuclear Regulatory Authority, House No 1&2, Neutron Avenue, P.O. Box AE50, Kwabenya.

NOTE: All completed forms and attachments should be sent to the contact below.

CONTACT

Director General
Nuclear Regulatory Authority
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