NUCLEAR REGULATORY AUTHORITY

AUTHORISATION GUIDELINES FOR RADIOTHERAPY 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 radiotherapy facilities. In order to ensure compliance of the Nuclear Regulatory Authority (NRA) ACT 895 of 2015, any individual/organisation who intends to set up or operate a radiotherapy facility should satisfy the requirements at each stage of the authorisation process.

Step 1. Notification

Notification is required for new radiotherapy facility/device 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 radiotherapy facility/device, 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 *xi* 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 radiotherapy devices into Ghana require 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 radiotherapy device from the supplier to aid in completing the form. A copy of the technical specifications of the radiotherapy device may be attached to your application to facilitate the process.

iv. Road Transport Approval

The applicant is required to obtain a radiation source transport permit from NRA (NRA Act 895, section 51) for transporting the radioactive source from the airport/port to the site of installation by completing the transport permission form.

v. Sources Receipt Notification

Notify the NRA in writing upon receipt of the radiation sources (includes Accelerator and Simulator) within 15 days.

vi. Procurement of Measuring and Monitoring Instruments

The applicant is required to procure appropriate measuring instruments for measurement of output and other dosimetric parameters. Additionally, procure appropriate monitoring instruments for area monitoring. It may be noted that gamma zone monitor for remote afterloading brachytherapy unit should be of auto-reset type, whereas, that for manual brachytherapy must have manual-reset button.

vii. Other Associated equipment/Accessories

One of the main accessories of brachytherapy includes simulator / Computed Tomography (CT) - simulator for simulating the patient prior to radiation therapy. The layout plan of simulator installation also requires approval by NRA (see requirements for diagnostic facilities). The other associated equipment/accessories includes Treatment Planning System (TPS), beam modifiers, patient immobilisation devices such as moulds, quality assurance test tools etc.

viii. Appointment of Radiation Therapy Staff

Adequate number of full time staff should be appointed and they include; Radiation Oncologists, Medical Physicists and Radiation Therapy Technologists as per the qualification and experiences acceptable by NRA. The appointed Medical Physicists and Radiation Protection Officer (RPO) must be made known to the NRA in writing for approval.

ix. 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.

x. Installation and Loading of the source/switching on device

Install the teletherapy/brachytherapy unit as per the approved plan and carryout the mechanical and electrical tests thoroughly prior to source loading. Loading of teletherapy sources shall only be done in the presence of a Qualified Expert (QE) and RPO. After loading the source or switching on the radiation generation equipment, the RPO and the QE shall carryout radiation protection survey of the installation prior to any other radiation

tests. In case the radiation levels around the installation are not within the limit, all other tests must be suspended and NRA shall be informed promptly with the recorded survey data.

xi. 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. 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.

Step 4. Decommissioning

Applicants should provide to the NRA with the policies and procedures for decommissioning of a radiotherapy facility. Licensees must obtain a decommissioning license prior to decommissioning a radiotherapy facility. A Copy of agreement to transfer the source(s) to the supplier or to an authorised waste disposal facility at the end of the useful life should be sent to NRA during the application for authorisation stage.

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
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