INTERNAL PROCEDURE

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NNRA MINIMUM REQUIREMENTS FOR ACCREDITATION TO SALE AND SUPPLY IONIZING RADIATION GENERATING EQUIPMENT – DIAGNOSTIC RADILOGY FOR MEDICAL APPLICATIONS

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NIGERIAN NUCLEAR REGULATORY AUTHORITY (NNRA)

NNRA MINIMUM REQUIREMENTS FOR ACCREDITATION TO SALE AND SUPPLY IONIZING RADIATION GENERATING EQUIPMENT – RADIOTHERAPY/DIAGNOSTIC RADILOGY FOR MEDICAL APPLICATIONS

Find below the minimum requirements for accreditation to sale and supply ionizing radiation generating equipment - Diagnostic Radiology for medical applications. This requirement should be applied in additions to the:

- i. Nigerian Radiation Safety in Diagnostic and Interventional Radiology Regulations 2006,
- ii. Nigerian Radiation Safety in Radiotherapy Regulations 2006
- iii. Nigerian Radiation Safety in Nuclear Medicine Regulations 2006

Note that this minimum requirement is not exhaustive and does not in any way preclude other decision by the NNRA.

a) Administrative Requirements

- i. Nature of practice in Nigeria
- ii. Name of the Legal Persons of the company including the Chief Executive Officer
- iii. Provision of a certified copies of Memorandum and Article of Association and Certificate of Incorporation from CAC and Particulars of your First Directors (Form C02 & C05)
- iv. Certificate of Registration with Federal Ministry of Health and other relevant Medical registration bodies
- v. Name of the Legal Persons of the company including the Chief Executive Officer
- vi. Payment of applicable authorization fees in accordance with section 47(c) of Nuclear Safety and Radiation Protection Act 19 of 1995:
- vii. Tax clearance Certificate from the Nigerian Federal Inland Revenue Services (FIRS)
- viii. Enlisting the services of an NNRA accredited Radiation Safety Adviser (RSA) to assist you in attaining NNRA requirements
- ix. Designation of an officer as Radiation Safety officer (RSO) who shall develop skills in basic radiation safety and understand the regulatory requirements for practices involving radioactive materials and ionizing radiation

b) Personnel/Training

- i. Evidence of having adequate staff that are trained in the area of handling of ionizing radiation generating equipment for medical applications including installation and conducting acceptance tests;
- ii. Provision of training and retraining programs
- iii. Provision of copies of CVs, academic and professional of all staff

c) Equipment

- i. Evidence of having adequate and function radiation survey meters with valid calibration certificates
- ii. Evidence of having equipment and all instruments necessary for the installation and conduction of acceptance tests
- iii. Evidence of having operation manual with details of overall safety systems including design features, Defense in depth and prevention of unauthorized access to equipment when activated

d) Storage Facility

- i. Name, Addresses and locations of all storage facilities and offices in Nigeria
- ii. Provision of detailed diagram of the layout of the storage facility and security arrangement
- iii. If facility will be used for testing of imported X-ray Machines, shielding assessment of the facility and demarcation of the control and supervised areas.

e) Transportation

- i. Procedures for transportation of imported equipment locally and role of the driver as well as the certification of the driver with respect to radiation protection.
- ii. Transportation and Security arrangement for imported machines movement from the port to storage facility.

f) Radiation Protection Programme

- i. Adequate programs for radiation protection, safety and security in the handling and transportation ionizing radiation generating equipment for medical applications
- ii. Evidence of engagement with an NNRA accredited Dosimetry Service Provider (DSP) who shall be responsible for monitoring staff that will be involved in installations and acceptance testing of machines
- iii. Emergency contact numbers including that of NNRA contact numbers to be included emergency programme
- iv. Description of policies for assigning monitoring badges to workers, review of individual doses including reference levels and actions to be taken when values are exceeded
- iii. Establishment of local rules in written form which should describe how the use of X-ray Machines will be carried out in compliance with the requirements of Nigerian Radiation Safety in Diagnostic Radiology 2006

g) Workshop

- i. Name, addresses and location of all workshops and offices in Nigeria
- Layout, shielding assessment of the workshop and evidence of demarcating control and supervised areas if repairs and maintenance will be carried out in the licensee's workshop