Regulatory Inspection of Radiotherapy Facility

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Highlights

- Definition
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INSPECTION

- **Definition**: An examination, observation, measurement or test undertaken by the Regulatory Authority to assess structures, systems, components and materials, as well as operational activities, processes, procedures and personnel competence

Legal Basis

- Section 37(1) of the Act: The Authority shall appoint Inspectors to inspect practices and installations licensed or proposed to be licensed by the Authority

Legal Basis

Section 37(1) of the Act: An Inspector may for the purpose of the execution of this Act:

a) Enter without hindrance at any time during the normal working hours of the establishment concerned or as may be determined by the Authority upon any premises, vehicle, ship or aircraft to which this Section applies, with such equipment as he requires for the performance of his duty as specified under this Act

Legal Basis

(b) Inspect any plans, drawings, records, register or documents pertaining to :

- the design, siting, construction, testing, development, operation, decommissioning or abandonment of an installation
- the health and safety, security or environmental aspect of any activity covered by this Act
- Any matter relevant to the enforcement of this Act

(c) Carry out test and take samples, measurements and photographs of the installation

(d) Ask the operator of any vehicle, ship or aircraft or any person who has duties on or in connection with any premises, vehicle, ship or aircraft to provide him with such information relating to the vehicle, ship or aircraft as he may require

INSPECTION - Objectives

Objectives of inspection:

To satisfy the Authority that the:

- Licensee complies with the legislation, regulations and any imposed conditions
- facilities, equipment, and work performance comply with requirements e.g. safety and security requirements
- persons employed by the Operator, the contractors inclusive possess the necessary competence
- deficiencies and deviations are identified and corrected without undue delay

INSPECTION - Methodologies

- **Inspection Methodologies**
  - General observations of work practices and facilities
  - Examination of records
  - Examination of written guidance on working procedures
  - Interview with management and workers
  - Independent measurements of radiation and contamination levels
  - Routine checks of safety control systems

Authorization

- (a) Through discussions and review of records, the Inspector shall verify Licensee's compliance with radiation safety requirements for the following stages of radiotherapy practice (Regulation 4(4) of Radiotherapy):
- design and construction
- acceptance, commissioning, operation and maintenance
- modifications
- decommissioning

Authorization 2

- (b). Inspectors shall also verify Licensee's compliance with Regulation 7 and confirm that authorizations have been obtained from NNRA and that Licensees have contracted the following to enterprises accredited by the NNRA:
- import, distribution, sale or distribution of radioactive sources
- installation, maintenance of radiotherapy equipment, including source change and decommissioning
- disposal of radioactive sources

Inventory of Ionizing radiation sources/Equipment

- Inspectors shall verify the following:
- -Inventory of ionizing radiation sources and equipment
- -For gamma units - radionuclides, model no., and initial activity of source + date of manufacture, maximum design activity and total activity installed
- -For Brachtherapy - Manufacturer, Model Number, Radionuclide, type of loading (Manual or Remote), Dose rate type (High or Low), Number of channels, maximum activity, physical dimensions and shape

Inventory of Ionizing radiation sources/Equipment 2

- For external beam therapy unit design - type (Gamma or Accelerator), Name of manufacturer, model-name and no., country and year of manufacture, type of gantry (stationary or rotary), Output Gy/min at isocenter,
- For accelerators - maximum energy, maximum current

Inventory of Ionizing radiation sources/Equipment 3

- -Availability of the required compliments of equipment for the particular radiotherapy practice e.g. LINAC + Fluoroscopy/CT Scan + TPS; Co-60 + Simulator + TPS + Orthovoltage; Brachtherapy + CT + TPS, etc.

Equipment standards

- The Inspectors shall verify by sighting and obtaining relevant records to confirm compliance with Reg. 21 (2) of Radiotherapy Regulations which requires
- -that the equipment conform to applicable standards of the International Electrotechnical Commission (IEC) and the ISO or equivalent national standards

Equipment standards 2

- The IEC standards applicable to radiotherapy are:
- -IEC 601-2-1, for medical electron accelerators;
- -IEC 60601-2-11, for external beam radiotherapy;
- -IEC 60601-2-17, for remote afterloading brachytherapy;
- -IEC 601-2-8, for superficial therapy with X rays;
- -IEC 60601-2-29, for therapy simulators;
- -IEC 62C/62083, for treatment planning systems (TPSs);
- -IEC 60601-1-4, for computer controlled or programmable medical systems.

Equipment standards 3

- The Inspector should also confirm that:
- -manuals for performance specifications, operating and maintenance instructions, including protection and safety instructions, have been provided in English and are in compliance with the relevant IEC or ISO standards
- the operating procedures and values are displayed on the operating consoles in English

Equipment

- The Inspectors shall confirm by observation and sighting records Licensee's compliance with Regulation 21(6):
  - radiation generators and irradiation installations include provisions for selection, reliable indication and confirmation of operational parameters such as type of radiation, indication of energy, beam modifiers (such as filters), treatment distance, field size, beam orientation and either treatment time or preset dose
  - irradiation installations using radioactive sources be fail-safe in the sense that the source will be automatically shielded in the event of an interruption of power and will remain shielded until the beam control mechanism is reactivated from the control panel
  - Resuming irradiation shall only be possible from the control panel
  - the equipment have at least two independent `fail to safety' systems for terminating the irradiation

Equipment 2

- the equipment is provided with safety interlocks or other means designed to prevent the clinical use of the machine in conditions other than those selected at the control panel
- The Inspectors shall confirm Licensee's compliance with Regulation 21(7) - Teletherapy equipment containing radioactive sources shall be provided with a device to return sources manually to the shielded position in case of emergency

Design requirements

- As a general rule, the design of a radiotherapy facility needs to make provisions for safety systems or devices associated with the equipment and treatment room. This includes electrical wiring related to emergency switches, safety interlocks and warning signals.
- The Inspector must request for the design diagram or layout of the facility

Design requirements 2

- The Inspector shall confirm the following by obtaining drawings, records and making observations

For external beam therapy equipments

- - The primary beam shall be only directed towards primary barriers with sufficient shielding
- - It shall be stable in any position and it shall be possible to fix it in any desired position
- - Couch and table top movements (vertical, longitudinal, lateral, angular) shall facilitate patient positioning and set-up and shall be fixed by adequate brakes
- - Shielding calculation was carried out prior to construction of the facility; independent radiation measurement shall be used to confirm adequacy of shielding

Design requirements 3

- - Access control in relation to the location of therapy treatment room and/or source storage area
- - Has prior risk assessment been conducted in compliance with Regulation 12 of NiBIRR 2003?

For manual brachtherapy, Inspectors shall confirm the availability of the following:

- - Source storage and preparation laboratory,
- - Operating room
- - Treatment planning room
- - Nursing station

Design requirements 4

- The Inspectors shall further confirm the availability and operability of the following:
  - Fire detection and protection in the radiation and source storage area;
  - Adequate ventilation in the radiation and source storage area;
  - Fixed area radiation monitors
  - Mechanical door interlocks
  - Means of preventing unauthorized personnel from entering the treatment room
  - Means of communication between the control console and treatment room
  - Exposure signals at the entrance of treatment room; and
  - Warning signs and notices (in relevant local languages) posted within supervised and controlled areas
  - Redundant and independent means of patient observation e.g. closed circuit television or lead glass windows

Acceptance tests and Commissioning

- Inspectors shall verify by obtaining records that Licensee have conducted or have available arrangement with Supplier to conduct acceptance tests; and with Qualified Experts for commissioning tests for radiation emitting equipment or sources as well as any system that has implications on safety, such as treatment planning systems (TPS).

Personnel

- (i) The Inspectors shall through observation and suitable records confirm Licensee's compliance with Regulations 16 and 6 of the Radiotherapy Regulations that the facility has the required compliments of the individuals needed to carry our responsibilities with regard to protection and safety and that they have been appropriately trained and qualified. These individuals are:
- - medical practitioners working in radiotherapy (radiotherapists, radiation oncologists);
- - qualified experts in radiotherapy physics (medical physicists) and dosimetrists or physics assistants;

Personnel 2

- - other health professionals operating radiotherapy equipment or handling radioactive sources (radiotherapy technologists/ Radiographers);
- - Radiation Safety Officer;
- - staff for maintenance of radiotherapy equipment; and
- - staff performing special tasks (type tests, long term stability checks, etc.)
- (3). These individuals shall provide evidence of education and training relevant to their duties related to the use of radiation sources.

Personnel 3

- Typical documentary evidence applicable with regards to these Qualified Experts consist of:
- - university degree or academic qualification relevant to the profession, issued by universities, colleges of health technology, polytechnics and colleges of technology and other accredited federal institutions;
- - accreditation to exercise the profession granted by the relevant competent authorities or other professional or academic bodies recognized by the Authority;
- - attendance at and passing of required examinations on a course on radiation protection for which the contents, the methodology and the teaching institution are accredited by the Authority or by other professional bodies recognized by the Authority. This course may be integrated in the curricula of the professional education under (a) and (b), and;
- - on-the-job training supervised by professionals with accreditation by the Authority or other appropriate competent authorities

Personnel 4

- The documentary evidence for an individual to perform maintenance of radiotherapy equipment should consist of:
- - certification by the manufacturer of his or her having completed a training programme on the type of authorized equipment (the certification should indicate the type of equipment and the parts of the equipment that the engineer or technician has been trained to repair or adjust, or the scope of the maintenance he/she is enable to perform); and
- - a course on radiation protection for which contents, methodology and teaching institution are approved by the Authority.

Personnel 5

- The Inspectors shall also verify that the professional education and the training mentioned above have been completed before commencement of duties and these continued subsequently as part of their professional development (Regulations 17(3) of Radiotherapy Regulations)
- (iii) The Inspectors shall obtain records showing initial and periodic training instructions of personnel

Management Commitment

- The Inspectors shall carry out observations, interviews and sight relevant records to assess the involvement of management and their commitment to radiation protection and safety (Regulation 12). The following areas are important:
- - fostering and maintaining safety culture
- - written policy statement that clearly assigns prime importance to protection and safety in radiotherapy
- - appropriate resources made available to support commitment to protection and safety
- - assigning clear responsibilities to personnel, Reg 13 (3)
- - determining the need for qualified personnel and appointing same on either full or part time basis, Reg 13(4)

Management Commitment 2

- - establishment of a comprehensive radiation safety programme and providing necessary resources to implement the programme, Reg 14(1)
- - appointment of a Radiation Safety Officer with sufficient authority and is able to communicate with the management regarding compliance with Regulations and terms and conditions of the licence (Reg 14(2)
- - establishment of a Radiation Safety Committee for radiotherapy institutions that handle Categories 1 and 2 sources to co-ordinate and review the radiation safety and protection programme and quality assurance procedures

Quality Assurance

- Inspectors shall confirm that a comprehensive quality assurance program (Regulation 15) which covers all aspects of the work in a radiotherapy facility is available in written form and is being implemented by the Licensee:
- a. Safety associated with operation, Regulation 28 of Radiotherapy Regulations
- (i) operating the equipment in accordance with technical documents and operating manuals provided by the Manufacturer
- (ii) subjecting sealed sources to leak test prior to first use and at regular intervals thereafter
- (iii) establishing quality control protocols and carrying out quality control periodically, after the source was installed or replaced or after repairs or maintenance work that has potential to alter the radiation output
- (iv) carrying out independent audit of the calibration of the sources before starting clinical use, e.g. IAEA/WHO TLD badge postal system

Quality Assurance 2

- b. Maintenance, Regulation 29
- (i) availability of written maintenance programme covering preventive and corrective maintenance
- (ii) availability of written procedure and records for daily, weekly, monthly and yearly preventive maintenance
- (iii) availability of service agreement with accredited maintenance engineering company
- (iv) provisions for ensuring that where maintenance of the therapy equipment or treatment planning equipment may affect the accuracy of the physical or clinical dosimetry or the safe operation of the equipment, a qualified expert in radiotherapy physics must carry out relevant tests or measurements to confirm that equipment is operating satisfactorily before it is used to treat patients

Quality Assurance 3

- c. Calibration, Regulation 51
- (i) that the radiotherapy centre has the required compliment of dosimetry equipment (including phantoms) for calibration of radiation sources used for medical exposure and they are traceable to a standards dosimetry laboratory
- (ii) the dosimetry equipment have valid calibration certificates
- (iii) that calibration are carried out at the time of commissioning, after any maintenance which may affect the dosimetry and at intervals approved by the Authority
- (iv) that there is written protocol for calibration of radiation sources used for radiotherapy and this is being implemented
- (v) all teletherapy equipment outputs are compared at least once every two years in a national, regional or international programme for independent dose verification, such as the TLD postal service established by the IAEA/WHO
- (vi) Calibration is done independently by at least two different qualified experts in radiotherapy physics and preferably using different dosimetry systems. The results are being compared after the completion of both measurements

Quality Assurance 4

- d. Clinical dosimetry, Regulation 52
- (i) records of absorbed doses to relevant organs
- (ii) for patient treated with external beam radiotherapy, records of the maximum and minimum absorbed doses to the planning target volume together with the absorbed dose to a relevant point such as the centre of the planning target volume, plus the dose to other relevant points selected by the medical practitioner prescribing the treatment
- (iii) for brachytherapeutic treatments performed with sealed sources, records of the absorbed doses at selected relevant points in each patient

Quality Assurance 5

- e. Quality assurance for medical exposures, Regulation 53
- Inspectors shall conduct interviews and obtain relevant records with regard to Licensee's conduct of:
- (i) regular and independent quality audit reviews of the quality assurance programme for radiotherapy procedures
- (ii) treatment conferencing for each patient by all qualified experts in radiotherapy to assess and review the treatment
- (iii) in vivo" dosimetry for verification of the treatment, estimating the total dose to the tumor and comparing with prescribed dose

Quality Assurance 6

- f. Investigation of accident medical exposure, Regulations 55
- Inspectors shall confirm through observations, interviews and sighting of appropriate records that Licensee has procedure for detecting, notification of the NNRA and prompt investigation of the following and that procedure for informing the patient and his or her doctor about the incident is in place:
- (i) any therapeutic treatment delivered to either the wrong patient or the wrong tissue, or using the wrong pharmaceutical, or with a dose or dose fractionation differing substantially from the values prescribed by the medical practitioner
- (ii) any equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended

Classification of areas Regulation 39

- Inspectors shall observe and confirm that Licensee has designated the following and ensured that a diagram or sketch indicating this designation is obtained:
- (i) controlled areas designated in accordance with Regulation 32 of NiBIRR 2003, demarcated by physical boundaries, marked and identified with “radiation area” signs
- (ii) supervised areas designated in accordance with Regulation 33 of NiBIRR 2003

Local rules, Regulation 40

- (i) Inspectors shall confirm that local rules and procedures have been established in writing and that it is sufficient to ensure adequate levels of protection and safety for workers and other persons
- (ii) Inspectors shall also confirm that the local rules and procedures have been posted and brought to the attention of all concerned
- (iii) Inspectors shall on site review the Local rules and observe that the following provisions are included:
- - Values of any relevant investigation levels or authorized level and procedure to be followed when such value is exceeded
- - Protective measures and safety provisions

Local rules, Regulation 40

- - Adequate supervision of occupationally exposed workers
- - Sufficient information on health risks due to their occupational exposure, adequate instruction and training on protection and safety, adequate information on the significance for protection and safety of their actions
- - Appropriate information to females who may enter controlled and supervised areas on risk to foetus due to exposure of a pregnant woman, importance of a female notifying her employer as soon as she suspects that she is pregnant
- - Instruction and training on emergency plan
- - Keeping records of training provided to personnel

Individual Exposure monitoring, Regulations 42

- Inspectors should note and confirm that the Licensee:
- -has developed a program for the individual monitoring
- -has written agreement with a service provider on the provision of dosimetry service
- -occupationally exposed staff are correctly wearing their TLD badges
- -the exchange of dosimeters in a radiotherapy department and receipt of the dose reports does not exceed a period of one month
- -has procedure on notification of the licensee on lost of individual's dosimeter and on evaluation of the dose the individual received
- Is keeping personnel monitoring records

Workplace monitoring, Regulations 44

- (i) The Inspector shall on the basis of observations of activities, discussions with staff, and as appropriate, a review of selected records and procedures determine that Licensee has developed a written programme for workplace monitoring and that the programme has provisions for
- the quantities to be measured;
- where and when the measurements are to be made and at what frequency;
- the most appropriate measurement methods and procedures; and
- reference levels and the actions to be taken if they are exceeded.
- calibration of survey meters used for workplace monitoring and its traceability to a standard dosimetry laboratory

Workplace monitoring, Regulations 44

- (ii) The Inspectors should also confirm that the following records are being kept additionally:
  - monitoring conducted immediately after the installation of new radiotherapy equipment and after the replacement of teletherapy sources and remote-controlled brachytherapy sources
  - monitoring of packages containing radioactive sources, upon receipt by the licensee
  - survey of exposure rates in the vicinity of the patient and the transport container, source storage and handling areas before and after brachytherapy procedures

Health surveillance, Regulation 46

- Inspectors shall determine that Licensee
- -has a written health surveillance programme to assess the initial and continuing fitness of employees for their intended tasks, Regulation 46 of Radiotherapy Regulations 2006
- -has ensured that each of his employees is under adequate medical surveillance by an appointed doctor, Regulation 54(2) of NiBiRR 2003
- -health records of the employees are made and maintained in accordance with Seventh schedule of NiBiRR 2003

Safety and security of radiotherapy sources, Regulations 34, 56 and 57 of Radiotherapy regulations

- Inspectors shall verify that Licensee is implementing requirements for safety and security of radioactive sources especially as regards
- procedures for controlling public exposures and control of access of members of the public to radiotherapy source room and provision of adequate information and instruction to public before they enter a controlled area,
- procedure for accounting for radioactive sources including periodic inventory and on preventing loss of control

Monitoring of Public exposure, Regulation 59 of Radiotherapy Regulation

- Inspectors shall also verify that the programme for monitoring public exposure from radiotherapy is in place, it is being implemented and relevant records are being maintained.
- This includes dose assessment in the surrounding of irradiation rooms for external beam therapy, of brachytherapy - wards and source storage, preparation room and waiting rooms

Emergency Plans, Regulation 62 of Radiotherapy Regulation

- Inspectors shall determine that the
- - licensee has in place written mitigation measures embodied in a set of emergency procedures.
- - the relevant staff have been trained in the mitigation measures,
- - emergency procedures is being periodically rehearsed
- - lessons learned from the rehearsals is being used to review and update the emergency plans.

Discharge of Patients, Regulation 54

- For Brachytherapy, the Inspector should determine if a licensee is knowledgeable about patient release criteria and that a process exists to establish that a patient that undergo therapeutic procedure with sealed or unsealed radionuclide is releasable from control. The Inspector should note that the patient release criteria permit licensees to release individuals from control if the TEDE to any other individual is not likely to exceed 5 mSv.
- The inspector should verify that the licensee is familiar with the requirements to provide instructions to released individuals if the dose to any other individual is likely to exceed 1 mSv

Other areas

- Transportation of radioactive sources
- Plans for disposal of spent/disused radioactive sources
- Decommissioning

CONCLUSION

- The Inspector should conduct the inspection in a manner that will allow him/her to draw conclusions about licensee's performance with regard to the implementation of the requirements as laid down in the Act, Regulations and licence conditions

References

- Nuclear Safety and Radiation Protection Act 19, 1995
- Nigeria Basic Ionizing Radiation Regulations, 2003
- Nigerian Radiation Safety in Radiotherapy Regulations, 2006
- Nigerian Safety and Security of Radioactive sources Regulations, 2006
- Checklist for Commissioning and regular Inspection of Radiotherapy
- NRC Inspection Manual IMNS/RGB, Inspection Procedure 87133, Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs
- NRC Inspection Manual IMNS/RGB, Inspection Procedure 87134, Medical Broad-Scope Program
- NRC Inspection Manual IMNS/RGB, Inspection Procedure 87132, Brachytherapy Programs