Development of Inspection Procedure for Nuclear Medicine Facility in Zambia: A Regulatory Agencies Guide

Anthony Siamulonga[a*], Dae Soo Shin[b]

[a] Korea Advanced Institute of Science and Technology, 291 Daehak-ro, Yuseong, Daejeon, Republic of Korea, 34141

[b] Korea Institute of Nuclear Safety, 62 Gwahak-ro, Yuseong, Daejeon, Republic of Korea, 34142

[*] Corresponding author: asiamulonga@kaist.ac.kr

1. Introduction

Nuclear medicine facilities have become essential in modern healthcare, utilizing radioactive materials for diagnosis and treatment of various conditions. Because ionizing radiation can cause harm to the body of those exposed, a systematic approach must be applied to ensure that there is a balance between exploiting the benefits of medical uses of radiation and minimizing the risks of radiation effects to patients, radiation workers, and the public [1].

One of the key functions of regulatory agencies is inspection for monitoring compliance with regulatory requirements and, in the event of non-compliance, taking enforcement action to bring about compliance [2]. This article outlines the development of an inspection procedure for nuclear medicine facilities, focusing on key aspects that ensure comprehensive evaluation and enforcement of regulatory standards for Zambia.

2. Problem Statement

Nuclear medicine facilities in Zambia face challenges in maintaining regulatory compliance. Despite the establishment of a legal framework and the Radiation Protection Authority (RPA) overseeing practices utilizing ionizing radiation, the country struggles with inadequate enforcement regulations, specialized personnel, and insufficient infrastructure. These challenges are compounded by the outdated or non-functional equipment, limited funding, and the lack of comprehensive inspection and monitoring procedures. These challenges pose risks to patient safety, hinder the effective delivery of nuclear medicine services, and impede Zambia's progress towards achieving sustainable healthcare development.

3. Establishment of Regulatory Framework

The primary step in developing an inspection procedure is the establishment of a regulatory framework anchored on both national and international standards. The International Atomic Energy Agency (IAEA) and the International Commission on Radiological Protection (ICRP) standards provide a foundation for safety protocols, radiation protection measures, and operational procedures. The Radiation Protection Authority (RPA), Zambia's nuclear and radiation regulatory agency, must also consider local regulations and guidelines specific to its jurisdiction.

4. Defining Inspection Objectives

An establishment of clear achievable objectives is key in developing a robust inspection procedure and ensuring a focused approach. In this article, the key objectives include:

- The radiation protection system for radiation workers, the public, and patients is checked to ensure that it is maintained as authorized.
- The radioactive waste is handled, stored, and disposed of according to authorized procedures.
- The licensee is inspected to ensure that it is complying with radiation safety regulations.
- The facility's emergency preparedness and response plan are evaluated.
- The training and qualifications of workers handling radioactive materials are reviewed.

5. Inspection Priorities and Frequency

One of the key components of a successful inspection is establishment of inspection priorities and frequency. The priorities of an inspection programme are established first and requires analysis of inspection data for the different types of radiation practices and sources, while frequency is subject to the regulatory body's available resources. Priorities must be given to medical facilities using radiotherapy and nuclear medicine sources, as well as those using Computer Tomography Scanners.

IAEA recommends a graded approach to inspection frequency for medical facilities based on the type of facility and associated risk levels. A general summary of the IAEAs recommended inspection frequencies are shown in the Table 1 below [3].

Table 1: IAEA Recommended Inspection Frequencies for Medical Facilities

No.	Practise	Frequency
1.	Dental radiography	Every 5 years
2.	Nuclear medicine	Every 1 to 2 years
3.	Radiotherapy	At least once per year

4.	Diagnostic radiology (e.g. computed tomography, interventional radiology, fluoroscopy, mammography)	Every 2 to 3 years
5.	Diagnostic radiology - conventional X ray equipment only	Every 3 to 5 years

The Inspection frequencies may vary based on the facility's workload, complexity, and compliance history. Additional inspections may be conducted following incidents, modifications, or upon receiving complaints. National regulations and policies can influence specific inspection schedules.

6. Development of Inspection Procedure

In this section some elements of developing an inspection procedure are described.

6.1 Inspection Checklist

An inspection checklist is a crucial instrument that inspectors use to methodically evaluate every facet of the license's operations. It identifies the key features of a radiation practice that are to be checked by an inspector to determine regulatory compliance and are developed from the regulatory body's code of practice or regulatory guide [3]. The checklist covers the following safety target areas items in Table 2:

Table 2: Checklist target area

No.	Target Area	Description
1.	Facility Layout and Shielding	Facility Layout and Shielding Inspect facility maintenance to minimize radiation exposure to radiation workers, patients, and the public.
2.	Radiation Safety Program	Verify implementation of the facility's radiation safety program, including radiation protection policies, monitoring protocols, and dosimetry records.
3.	Handling of Radioactive Materials	Verify compliance with safety standards by examining procedures for receiving, storing, and disposing of radioactive materials.
4.	Instrumentation and Equipment	Verify the calibration and maintenance of radiation detection and measurement instruments.
5.	Personnel Competency and Training Program	Verify that radiation workers have completed training on radiation safety and emergency procedures, and evaluate the adequacy of the training program.
6	Emergency Response and Preparedness	Evaluate the facility's emergency response plan, including drills and availability of emergency equipment.

6.2 Conducting Pre-Inspection activities

Pre-inspection activities are essential for a successful inspection and must be conducted prior to visiting the licences facility. Inspectors should [3]:

- Review previous inspection reports and compliance history.
- Collect and review relevant documentation, such as licenses, permits, and radiation safety reports.
- Arrange and verify that the necessary tools and equipment are in operational order.
- Communicate with the facility to schedule the inspection and provide an overview of the process.

6.3 On-Site Inspection Procedures

During the onsite inspection, inspectors should [4]:

- Conduct an opening meeting with facility management to outline the inspection scope and objectives.
- identify specific areas within a facility to be seen and arrange for appropriate personnel to be present were necessary.
- Observe operations and interview staff to assess their understanding and adherence to safety protocols.
- Inspect storage areas, treatment rooms, and waste disposal sites.
- Review records and documentation, including radiation dose logs, maintenance records, and training certificates.
- Perform independent measurements and tests, if necessary, to verify compliance with radiation limits.

6.4 Post-Inspection Activities

After conducting the inspection, the inspection team meets to review the facts relating to the scope of the inspection to ensure information is adequately recorded. The team should then [4]:

- Conduct a closing meeting to discuss preliminary findings with facility management.
- Prepare a detailed inspection report, outlining findings, areas of non-compliance, and recommendations for corrective actions.
- Provide the facility with a timeline for addressing any identified deficiencies.

- Follow up to ensure that corrective actions are implemented and verified.

7. Continuous Improvement

It is recommended that the regulator conduct periodic reviews and updates of inspection procedures to ensure they align with evolving regulations, technology improvements, and insights gained from past inspections. Continuous training for inspectors is essential to maintain high standards of competence and effectiveness [3].

8. Conclusion

Developing a comprehensive inspection procedure for nuclear medicine facilities is vital to ensuring the safe and effective use of radioactive materials in healthcare. By establishing a clear regulatory framework, defining inspection objectives, utilizing detailed checklists, and conducting thorough pre- and post-inspection activities, regulatory agencies can effectively monitor and enforce compliance, thereby protecting public health and safety. Continuous improvement of the inspection process will further enhance the oversight and safety of nuclear medicine practices.

REFERENCES

[1] IAEA, "Radiation protection and safety in medical uses of ionizing radiation," Specific Safety Guide SSG-46, IAEA, Vienna, pp.1, 2018.

[2] IAEA, Regulatory Inspection of Nuclear Facilities and Enforcement by the Regulatory Body, Vienna: INTERNATIONAL ATOMIC ENERGY AGENCY, pp.1, 2002.

[3] IAEA, Inspection of Radiation Sources and Regulatory Enforcement, Vienna: INTERNATIONAL ATOMIC ENERGY AGENCY, pp.13-27 2007.

[4] Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), "NSPECTION MANUAL: Guide for regulatory officers on the management & implementation of ARPANSA's inspection program," pp.19-20 2021.