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QUALITY ASSURANCE IN NUCLEAR MEDICINE

REGULATORY GUIDE

PAKISTAN NUCLEAR REGULATORY AUTHORITY

For Further Details

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QUALITY ASSURANCE IN NUCLEAR MEDICINE

ABSTRACT

Pursuant to the requirements of the "Regulations on Radiation Protection-PAK-904" and "Regulations for Licensing of Radiation Facilities other than Nuclear Installation(s)-PAK/908", this document describes the parameters of quality assurance in nuclear medicine department. They should be fulfilled by the users prior to issuance of a license.

1 INTRODUCTION

This guide is prepared in support to "Regulations on Radiation protection (PAK-904)" and "Regulations for Licensing of Radiation Facilities other than Nuclear Installations (PAK-908)".

Nuclear medicine has three major concerns: efficacy, quality of life and safety. An integrated QA approach, taking into account medical, physical and radiation safety aspects, can improve nuclear medicine in achieving adequate image quality at the lowest reasonable doses to the patients.

The responsibility of QA/QC lies with the licensee/user. However, this guide provides an outline of a QA programme which encompasses the overall QA of a nuclear medicine facility. In the light of this guide, the user may develop their respective QA/QC protocols. For further reference Guidelines on Radiation Safety and Regulatory Requirements for Nuclear Medicine Facilities can be consulted.

The Authority in this guide means Pakistan Nuclear Regulatory Authority.

2 OBJECTIVE

The objective is to provide a baseline to the licensee for the establishment of a comprehensive QA programme to ensure radiation protection and safety so that all necessary procedures are developed and implemented according to Radiation Protection Regulations (PAK-904) within the country.

3 SCOPE

The scope of the guide is to address all areas in a nuclear medicine department where QA protocols are essential for ensuring radiation protection and safety. It includes not only QA of the instruments and radiopharmaceuticals but also addresses all administrative and technical parameters that are an integral part of a comprehensive QA programme.

4 GENERAL PRINCIPLES OF QUALITY ASSURANCE:

Three basic principles in a nuclear medicine department are:

i. Improvement in the quality of diagnostic information;
ii. Acquisition of desired results with minimum amount of radionuclide activity; and
iii. Appropriate use of available resources so that the facility can be upgraded to cope with the advance technology.

A QA Program should include the following parameters:

I. Physical parameters of the radiation generators, imaging devices and irradiation installation at the time of commissioning and periodically thereafter;
ii. Means for verification of the appropriate physical and clinical factors used for diagnosis and therapy;
iii. Written records of relevant procedures & results;
iv. Verification of the appropriate calibration and conditions of operation of

dosimetry and monitoring equipment; and

v. Regular and independent quality audit.

5 OPTIMIZATION OF QA

5.1 Design of the Facility

The design of the facility should take into consideration:

i. The type of work and the radionuclides and their activities intended to be used;

ii. Categorization of hazards to determine the special needs concerning ventilation, plumbing, materials used in walls, floors and work benches;

iii. The layout of a typical nuclear medicine department and building requirements is given in Annexure I.

5.2 QA Program Organization

It includes:

i. Procedures: The procedures include patient history, signs and symptoms, diagnosis, appropriateness of investigation, precautions to be taken and any contraindications, etc;

ii. Planning of procedures: This means that the facility should have appropriately defined administrative procedures, patient information system, patient preparation areas etc;

iii. Clinical procedures: It means that procedures for the purchase of equipment, radiopharmaceuticals etc are defined and only approved suppliers are listed. In addition, storage & preparation of radiopharmaceuticals, clinical environment, patient handling & preparation, equipment acquisition and performance protocols and waste disposal procedures must be available;

iv. All medical and paramedical staff in a nuclear medicine department should be qualified and have on the job training on radtiation protection.

v. Data analysis: It means that processing protocols, equipment performance, data accuracy and integrity protocols must be established;

vi. Report: QA should also be maintained while acquiring data, image review and results with further advice, etc;

vii. General outcome: It means that the general outcome of a diagnostic or therapeutic procedure should be according to the satisfaction of the physician as well as the patient; and

viii. Audit.

5.3 Facility Organization

It is advisable that the department establishes a QA group/committee that is responsible for quality assurance issues.

While defining a QA Committee, the following criteria must be kept in mind:

I. Must be chaired by the Head of the Department;

ii. Must include a nuclear medicine specialist, a medical physicist, the chief technician, a pharmacist and an engineer responsible for service and maintenance;
iii. Must be appointed and supported by senior management;
iv. Must represent many disciplines within the department;
v. Must have depth of knowledge and experience;
vi. Must have authority to exercise the powers to instigate and carry out the QA process; and
vii. Should be accessible.

The QA Committee is responsible for:

I. Establishing a comprehensive QA programme for radiation protection, safety and image quality to ensure that all necessary procedures are developed and implemented to comply with the Radiation Protection Regulations (PAK-904) within the terms and conditions of the authorization(s) of the facility;
ii. Define policies and procedures to ensure quality patient care;
iii. Provide assistance to the staff in tailoring the programme to meet the needs of the department; and
iv. Systematically reviewing and auditing the entire QA programme such as administrative routines, working procedures, procedure manuals, follow up of examinations and treatments, quality control of equipment, routine purchasing of equipment etc. This is required to determine whether the activities conducted to obtain images of good quality are consistent with the current good medical practice and are carried out in a safe manner.

6 ADMINISTRATIVE ROUTINES

An appropriate administrative routine is an important part of a QA program. This includes patient identification, patient information, type of study and justification of the request, selection of examination protocols, diagnostic reports and records. Following criteria must be followed;

I. The request of a nuclear medicine examination must be from a nuclear medicine specialist;
ii. Any request of nuclear medicine examination advised by a physician outside the facility should be justified and evaluated by the nuclear medicine specialist;
iii. Nuclear medicine specialist of the facility should communicate with the referring physician;
iv. Special consideration should be given to children and pregnant women;
v. Patient identification should follow the hospital routines. A proper system of identification will prevent examination or treatment of the wrong patient;
vi. Every request must include patient identity, information about the desired examination, any required pre-medication, any contraindications and waiting for the examination;
vii. It is recommended that a procedure manual is made available for each type of examination. This manual should have:

a. Clear and concise statements of all the policies and procedures carried out within the department;
b. The manual should be reviewed and updated annually to accommodate new techniques;
c. Administrative, clinical and radiation safety aspects need to be defined separately;
d. It should be signed by the Head of the radiation facility and head of nuclear medicine department;
e. It should incorporate opinions of all the concerned departments; and
f. It should be accessible to all.

The administrative routines in a hospital clinical practice should include the following basic information:

i. Required study;
ii. Preparation of the patient;
iii. Radiopharmaceuticals required;
iv. Route of administration;
v. Activity requested;
vi. Type of examination required;
vii. Views desired;
viii. Scanning speed;
ix. Required collimator;
x. Required window setting;
xi. Positioning of the patient for that particular test; and
xii. Presentation of results.

Efficient use of computers can increase the sensitivity and specificity of an examination. To achieve this objective, the facility administration must ensure that:

i. Software based on published and clinically tested methods are used;
ii. Well documented algorithms are used;
iii. User manuals are available; and
iv. Software phantoms are available.

It is the responsibility of the QA committee to formulate QC application protocols in order to:

i. Analyze the program code;
ii. Perform phantom studies;
iii. Do simulated examinations;
iv. Compare with the reference/normal data; and
v. Ensure clinical evaluation.

The Diagnostic Report should include

i. Patient identification;
ii. Date & type of study;
iii. Radiopharmaceuticals used and it's activity;
iv. Study results;
v. Description of findings;

vi. Diagnostic conclusions; and
vii. Recommendations.

Records: Maintenance of records is an integral part of QA. The records to be kept include:

i. Authorization certificate/license and documentation supporting the corresponding application;
ii. Records of any correspondence between the licensee and the Authority;
iii. Name(s) of the person(s) authorized and responsible for the radiation protection programme;
iv. Individual doses (current and prior work history);
v. Results of area surveys;
vi. Equipment and instrument QC tests and calibration;
vii. Inventory of unsealed and sealed sources;
viii. Incidents and accidents investigation reports;
ix. Audits and reviews of the radiation safety programme;
x. Installation, maintenance and repair work;
xi. Facility modification;
xii. Training provided (initial and continuing), including the following information:

- Name of the person(s) who delivered the training
- Name of the person(s) who received the training
- Date and duration of the training
- List of the topics addressed
- Copy of the certificates of the training

xiii. Evidence of health surveillance of workers;
xiv. Waste disposal;
xv. Transportation:

- Package surveys
- Package documentation
- Transfer/receipt documents
- Details of shipments dispatched

xvi. Patient records; and
xvii. Patient discharge surveys for patients receiving radionuclide therapy.

7 OCCUPATIONAL AND MEDICAL EXPOSURE

Medical and occupational exposures are affected at the following levels:

I. Receipt and storage;
ii. Preparation;
iii. Administration of radiopharmaceuticals; and
iv. Detection level.

Therefore, QA protocols should address all these issues.

The nuclear medicine physician should, therefore, consider the following

parameters in order to maintain QA in the field:

i. Choice of examination;
ii. Determination of technical parameters;
iii. Optimization of administered activity;
iv. Methods of reducing the absorbed dose;
v. QC of equipment and radiopharmaceuticals;
vi. QA of clinical procedures;
vii. Safe routines to avoid misadministration.

7.1 Radioactive Source Tracking

Radioactive sources must be tracked from receipt to transfer or disposal in order to ensure accountability, to identify when licensed material could be lost, stolen or misplaced, and to ensure that source activity limits authorized on the license are not exceeded.

7.1.1 Package Opening

The procedures for opening of packages must be maintained. They must include visual inspection of the package and monitoring of external radiation levels and removable contamination if the package is damaged, verification that the contents confirm with the packing slip and with the purchase order and monitoring of the packing material and empty package.

For further details PNRA "Guidelines on Radiation Safety and Regulatory Requirements for Nuclear Medicine Facilities" may be consulted.

7.1.2 Check of Sources

The procedures should include provision for safe handling of sources and the verification of activity.

7.1.3 Storage

Procedures should include the use of appropriate shielding, choice of an appropriate location and a check of the external dose rate to verify that it does not exceed the limits specified. Radiation level limits for various labeled packages are given in table 1.

For storage of radionuclides like I-131, the following precautions should be followed:

- It should be stored in a controlled area;
- It should always be stored in a lead container and preferably in fume hood or refrigerator to prevent evaporation; and
- In order to reach an acceptable external dose rate, 1.4 cm thick lead shield is required.

Table 1: Radiation Level Limits for Labeled Packages

TRANSPORT INDEX (TI)	MAXIMUM RADIATION LEVEL AT ANY POINT ON EXTERNAL SURFACE	CATEGORY
0[a]	Not more than 0.005mSv/h	White – I
More than 0 but not more than 1[a]	More than 0.005mSv/h but not more than 0.5mSv/h	Yellow – II
More than 1 but not more than 10	More than 0.5 mSv/h but not more than 2 mSv/h	Yellow – III
More than 10	More than 2 mSv/h but not more than 10 mSv/h	Yellow - III[b]

a = The TI shall be rounded up to the first decimal place except that a value of 0.05 or less may be considered as zero.
b = shall be transported under exclusive use.

7.1.4 Handling of Radioactive Waste

It is the responsibility of hospital management to collect, segregate and dispose off radioactive waste according to the Regulations on Radioactive Waste Management (PAK-915). For further reference, PNRA Safety Guide "Guidelines for the Management of Radioactive Waste in Hospitals/Nuclear medical Centres/Research Facilities (13002)" may be consulted.

7.1.5 Source Transport

The hospital administration/person responsible should make local rules for in-house transport of radioactive material.

If the injection is to be taken far from the dispensing room for administration to the patient, a transport container with absorbent pads need to be provided. The RPO must ensure that the container is labeled with a radiation warning sign. It must also have the following information: date, activity, name & identification number of the patient for which the injection is prepared, name of the technologist who prepared the dose and the name of the medical professional who prescribed the dose.

RPO must ensure that the most direct route is taken for transport avoiding heavily occupied areas and the time taken in the transport must be documented.

A record of all these measures must be kept.

The transportation of sources and radiopharmaceutical are subject to the Regulations for the Safe Transport of Radioactive Material Pak/916.

8 RADIOPHARMACEUTICALS

In nuclear medicine it is desirable to use relatively short-lived agents which can be delivered to hospitals & clinics from commercial sources.
The nuclear medicine department needs to have a qualified radiopharmacist or a radiochemist. The following are the responsibilities of a radiopharmacist/radiochemist:

- Elution of sterile pertechnetate from a $^{99}Mo/^{99m}Tc$ generator;

- Preparation of radiopharmaceuticals according to manufacturer's instructions;
- Performance of quality control procedures on the prepared radiopharmaceuticals.

If a radiopharmacist / radiochemist is not available, the nuclear medicine technologist is responsible to carry out these additional responsibilities.

8.1 Radionuclide Generators

The most important generator is the ^{99}Mo / ^{99m}Tc system. Commercial generator systems are autoclaved & the elution dynamics quality controlled before shipment. However, each laboratory must perform quality control steps each time the generator is eluted.

8.1.1 Radionuclide Purity

The only desired radionuclide in the $^{99}Mo/^{99m}Tc$ generator eluate is ^{99m}Tc. Any other radionuclide in the sample is considered an impurity. The amount of ^{99}Mo in the eluate is subject to limits & must be tested on each elution. The set limit is 0.15μCi of ^{99}Mo activity per 1.0 mCi of ^{99m}Tc activity in the administered dose.

8.1.2 Chemical Purity

Another routine QA step is to measure the generator eluate for the presence of Al_2O_3. For fission generators the maximum alumina concentration is10μg/ml.

8.1.3 Radiochemical Purity

The standard set for the generator eluate is that 95 % or more of ^{99m}Tc activity should be in + 7 states.

8.2 Radiopharmaceutical Behavior

The behavior of radiopharmaceuticals is dependent upon its quality, which demands high standards of radionuclide, radiochemical and chemical purity and, in case of suspensions, of particle size and uniformity. Injections have to satisfy additional standards of sterility, apyrogenicity and freedom from foreign particulate matter.

8.2.1 Radionuclide Purity

Radionuclide purity is required to avoid unnecessary radiation dose to the patient, to avoid degradation of image quality and to limit errors on measurements. Radionuclide purity depends upon the half-lives of the radionuclides involved. Contaminants with longer half-lives are potentially more hazardous.

8.2.2 Radiochemical Purity

In a nuclear medicine department, either ready-to-administer radiopharmaceutical are used or else prepared through the reconstitution of non-radioactive kits by adding a radionuclide. The manufacturing of ready-to-inject radiopharmaceuticals and of non-radioactive kits is subject to quality control.

8.2.3 Chemical Purity and Content

In general, chemical impurities in radiopharmaceuticals are objectionable only if they are toxic or if they interfere or result in the modification of the desired study.

8.2.4 pH

The pH of radiopharmaceutical injections and solutions should be within specified range.

8.2.5 Specific Activity

Control of specific activity is particularly important in exchange radio-labeling e.g., in the labeling of an iodo compound by exchange with 123I or 131I.

8.3 Preparation of Radiopharmaceuticals

The following criteria need to be fulfilled:

- Written procedures must be followed in preparation to ensure safe handling of radiopharmaceuticals;
- Transparent vial shields should be used;
- A unique code must be followed which can be able to trace the original components in the preparation;
- Labeling of vials and syringes must be ensured;
- The activity should be measured;
- Protective clothing must be available;
- Tools for remote handling of radioactive material must be available;
- Containers for radioactive waste are available;
- Dose rate monitor with alarm should be there;
- The department should have contamination monitor;
- A decontamination kit must be readily available;
- Appropriate warning signs and labels must be available;
- Records of radionuclides , kits etc must be maintained;

8.4 Dispensing Radiopharmaceuticals

The following steps must be followed:

- Check the kit & vial shield labels before dispensing;
- Draw the required volume and measure the activity;
- Dispense the radionuclide into a shielded syringe (bench top shield, vial shield, syringe shield);
- Keep the vial in fume hood and on a tray with lips, lined with plastic backed absorbent pads;
- Handle the vial with forceps or similar long handled instruments;
- Put the radionuclide in an infusion bottle;
- Line the bottle to the patient using an intravenous catheter;
- Keep the patient in bed until the bottle is empty;
- Cover the vial with lead after use;
- Check the activity;
- Remove the bottle and catheter or syringe and dispose them off as

radioactive waste;
- Document each step;

8.5 Administration of Radiopharmaceuticals

According to the "Regulations on Radiation protection (PAK – 904)", unsealed sources for nuclear medicine procedures should be calibrated in terms of activity of the radiopharmaceutical to be administered, the activity being determined and recorded at the time of administration.

The following information must be fulfilled prior to injecting radiopharmaceuticals:

- Patient name;
- Patient identification number – preferably it should include National Identity Card number as well;
- History of pregnancy and breast feeding from female patients;
- Check the request form – it should be signed by the nuclear medicine physician;
- Check the label of the syringe.

Annexure III describes safe administration of I-131 and guidance level.

9 WORK IN A CONTROLLED AREA

- Access to controlled areas must be limited;
- All regular staff of the area will be issued a personal dosimeter, worn at all times when the person enters the room;
- Occasional entry of any person without a dosimeter to a controlled area may be permitted under the supervision of an authorized member or RPO;
- Other personnel who need to enter the controlled area on occasional basis at times when they are not being supervised (works staff, contractors etc) must be issued with a permit to enter the controlled area;
- Outside normal working hours controlled areas must be locked to prevent unauthorized access.

In order to avoid skin contamination and/or accidental ingestion of radionuclides

- Laboratory coats or other suitable clothing should be worn to prevent accidental contamination of normal clothes;
- Disposable plastic gloves should be worn when working with any unsealed sources;
- Lab coats should be removed and hands washed before eating or drinking and before going home;
- Disposable handkerchiefs should be used;
- Skin cuts and abrasions should be covered before working with unsealed sources;
- If there is any risk of splashing, eyes should be protected e.g., behind the transparent lead block;
- Mouth pipettes must never be used. Always use a bulb pipette or a syringe

for measuring radioactive solutions.

- No one should eat, drink, smoke or apply cosmetics in controlled areas with the following exception:
  - Eating, drinking by a patient as part of a diagnostic procedure e.g., iodine therapy procedure;
  - Eating and drinking is allowed at the nursing station provided that no administration of radioactive substances is carried out at the time and if there is any contamination from previous administration, has been dealt with by qualified persons;
  - In the waiting area, eating and drinking is allowed as the area is not used for administration of radiopharmaceuticals.

  However, if the area gets contaminated by the vomitus or urine or any other body fluids of the patient after radiopharmaceutical administration, the area should be treated as "controlled area". No one should be allowed to eat and drink till the area is decontaminated and declared safe by RPO.

To avoid spread of contamination:

- Activity must not be splashed around e.g., do not squirt syringes or expel in the air;
- As far as practicable all operations involving unsealed sources should be carried out over a drip tray;
- Syringes containing radioactive solutions should be placed, with their shielding, in a tray before transportation;
- Any bench top which is used for the manipulation of unsealed sources e.g., blood samples, should be covered with absorbent paper which should be replaced if contamination occurs; and
- While wearing gloves which may be contaminated, unnecessary contact with all other objects should be avoided. Gloves should be removed and disposed off in the radioactive waste bin as soon as work with radioactive substances is finished.

To minimize the hazard from external radiation:

- Sources must be kept within suitable lead shielding when not in use. Vials of activity should only be removed from their lead pots when this is absolutely necessary e.g., place in the ionization chamber;
- Unshielded vials of activity should only be manipulated with long handled tongs;
- Syringes containing radioactivity should be fitted with lead syringe shields whenever possible;
- Patient doses should be kept in the shielded storage area until required. Unused doses should be returned to the radionuclide lab at the end of each session; and
- Personnel should keep as far away as possible from all sources and organize work so as to minimize the time spent in close proximity to large sources e.g., stand back while the ^{99m}Tc generator is eluting.

10 INSTRUMENTATION

The aim of the QA program for equipment used in nuclear medicine is the prediction or identification of significant changes in technical parameters that could result in a lower or otherwise unsustainable quality of diagnostic and therapeutic results. To make sure that the equipment is working correctly, the following conditions must be fulfilled:

i. Controls within the quality assurance system must be carried out with suitable frequency (some daily, others over longer time intervals);
ii. Controls must be carried out with sufficient accuracy and reproduction under a procedure according to a clearly written protocol;
iii. The results of the controls – including the conditions under which these results have been measured – must be carefully documented.
iv. As an element of the controls, it must also be described what must be done in case the measurements are not satisfactory from the point of view of the established criteria.

QA is essential not only for maintaining high standards of clinical practice but also for maintaining high performance of equipment. In each department there should be a continuous review process to monitor clinical and equipment performance in accordance with national and international standards. There should also be routines and a policy for purchasing equipment.

10.1 Equipment Purchase Rules

It is the responsibility of the hospital management to clearly define a policy for purchasing new equipment.

The facility administration should constitute a purchase group comprising of the following:

i. Nuclear Medicine Specialist;
ii. Medical Physicist;
iii. Nuclear Medicine Technologist;
iv. An Engineer;
v. A person with authority from administration.

The need to purchase new equipment depends upon:

i. Starting a new diagnostic facility;
ii. Increased workload of the patient;
iii. The technical performance is deteriorated;
iv. The equipment performance is not good enough for new techniques/methods;
v. Spare parts are not available; and
vi. Un-repairable.

Choice of equipment depends upon:

i. Type of procedures to be undertaken;
ii. Technical specifications;

iii. Manufacturer:

- Availability of spare parts;
- Service and maintenance availability;
- User and service manual;
- Education and training.

iv. Local user

- Service and maintenance;
- Education and experience of the staff;
- Siting of the instrument.

v. Ease, reliability and safety in operation; and
vi. cost

Siting of equipment:

The following factors must be looked for before the installation of the equipment:

i. The space of the room should be sufficient;
ii. Electrical power supply must be smooth without any interruptions;
iii. Environmental factors (temperature, humidity, air pollution) must be taken into consideration;
iv. Structural shielding requirements according to the specifications of the Radiation Protection Regulations (PAK-904) must be fulfilled; and
v. The level of background radiation levels must be taken into account.

Maintenance:

Regular maintenance is required for:

i. Increased availability of equipment;
ii. Increased quality by better performance;
iii. Increased safety; and
iv. Increased lifetime of equipment.

Maintenance procedures should include consideration of the following:

i. Overall management & the maintenance programme. This is provided by the medical physicist in co-operation with the RPO;
ii. Measures to prevent use of equipment during periods of maintenance;
iii. Notification of the medical physicist whenever there is a repair regardless of its importance. The physicist must assess whether any tests or measurements are to be made and whether the equipment is operating satisfactorily before it is used again;
iv. Provision of a service contract covering preventive maintenance, particularly when equipment parts & expertise are provided by the manufacturer; and
v. Maintenance of a service record during the lifetime of the equipment or for a duration specified by the Authority.

Purchase Specifications:

The following parameters must be considered prior to purchasing any equipment:

i. System overview;
ii. Contact persons;
iii. Commercial specifications;
iv. Technical specifications;
v. Data acquisition and processing;
vi. Electrical and mechanical safety parameters according to National Radiation Protection Regulations;
vii. Education and training;
viii. Documentation Service organization; and
ix. Installation and acceptance testing.

The vendor should specify the following before the final deal of gamma camera:

Hardware:

i. Crystal size & shape;
ii. PM – Tube;
iii. Gantry dimension & weight;
iv. Gantry movements including auto contour;
v. Electrical power requirements;
vi. Imaging table;
vii. Collimators and method of change;
viii. Shielding of detector;
ix. Operating console;
x. Emergency window;
xi. Energy range;
xii. Safety features; and
xiii. Motion control

Technical performance:

i. Linearity;
ii. Uniformity (different energies, different angles);
iii. Energy resolution;
iv. Spatial resolution (intrinsic & system, planar & tomographic);
v. Count rate performance;
vi. Centre of rotation;
vii. Multiple window spatial positioning;
viii. System sensitivity (planar and tomographic); and
ix. Point source sensitivity.

Computer System:

I. Acquisition modes;
ii. Basic application programmes;
iii. Clinical application programmes;

iv. DICOM –Standards;
v. Network & communication;
vi. Printers;
vii. Storage & back-up of patient data;
viii. User lists and site visits;
ix. Reliability;
x. Service response time & follow up;
xi. Training;
xii. Service manuals;
xiii. Upgradability;
xiv. Delivery, setup & installation date;
xv. Floor loading, elevators and doors; and
xvi. Electrical requirements

After the vendor has clarified all the above requirements QC of equipment will be performed as follows:

Acceptance Tests

It is the measurement to judge whether instrumentation comply with its specification as mentioned in manual. Before the equipment is introduced to its regular use after installation, it is important to check whether its detection parameters correspond to those as specified by the manufacturer in the accompanying documentation. Acceptance tests are also important after any considerable maintenance on the equipment. The aim of the acceptance tests is:

- To compare the measured values of parameters with the values specified by the manufacturer;
- To control all parameters and features of the equipment that can influence the outcomes of measurements (especially in case of scintillation cameras); and
- To obtain a basis for performing consistency/routine tests during the use of the equipment at a workplace.

The way the acceptance test is carried out and all criteria used in the test must be declared in the contract with the manufacturer. In this regard, one of the following options can be selected:

- The supplier of the equipment himself carries out acceptance tests at the workplace where the equipment is installed in the presence of a specialist (a physician, medical physicist or a technician) of the facility;
- They are carried out by qualified persons , i.e., employees of the institution buying the equipment; and
- The supplier and the purchasing institute make an agreement that independent specialist will carry out the tests.

Routine/Consistency Tests

When the acceptance testing has been completed satisfactorily, their results will provide a baseline data for carrying out routine/consistency checks. The aim of consistency / routine tests is:

- To check whether the measured values of the parameters are within the recommended tolerance range of parameters established at the workplace during the acceptance test; and
- To estimate both short term changes in parameters and long term trends in their gradual changes.

The routine/consistency tests can be distinguished between simple and complicated tests.

a. Simple Tests

These tests utilize a low time frame and are easy to carry out in periods ranging from a few minutes to half an hour, which is very important with regard to the frequent use of the equipment especially the scintillation cameras. Another important aspect of these tests is that they do not require much technical equipment and can be carried out by commonly available equipment which is usually not very expensive. The institute itself is responsible to perform these tests by utilizing existing means.

b. Complicated Tests

The most important aspect of the complicated tests is that they require several hours for performance and much more specialized equipment is required or a combination of both. The institution may not have the capability to perform these tests itself. The institution must ask for assistance from the companies providing maintenance of medical equipment or make an agreement with a group of specialists in the field. Another alternative is that while purchasing the equipment, an agreement should be made with the supplier to include the complicated tests in the equipment warranty. However, an occasional consultation with an independent specialist in order to ensure the objectivity of such tests is nevertheless required.

Another important parameter of the QC tests is preventive maintenance of the equipment – examination, cleaning and changing of used parts; this helps to prevent sudden problems that affect the regular clinical operation.

c. Analysis of Results

The results of acceptance and routine tests must be recorded carefully and for this purpose special records must be kept for every piece of equipment.

It is important to emphasize that the licensee, when assuring the quality of the equipment technology, must strictly follow the instruction of the supplier or the manufacturer listed in the accompanying directions and documentation.

10.2 Equipment Used in Nuclear Medicine

The following equipment is listed in the QA programme:

1. Equipment measuring activity of radiopharmaceuticals (calibrators);
2. Single-detector equipment for measuring in vitro and in vivo (for unscintigraphic examination) and multiple-detector equipment for measuring in vitro;

3. Imaging equipment (scintillation planar cameras, scintillation cameras for one-photon emission tomography – SPECT);
4. Equipment for safety dosimetry (measuring equipment for input sources, surface contamination, operation dosimeters).

Control of the quality of the activity-measuring instruments (calibrators) with a well-ionizing chamber:

The consistency tests for calibrators are summarized as:

- SIMPLE
  - Background
  - Stability (short term reproducibility)
- COMPLICATED
  - Long term reproducibility
  - Calibration (measuring accuracy)
  - Linearity
  - Measuring geometry

Overview of activity tests (calibrators) with the ionizing well chamber and frequency of their application is shown in the table 2.

The licensee bears the responsibility of accuracy of radionuclide calibrator. As all calibrators show some dependence on measurement geometry that diminishes with increasing depth of the well, the nuclear medicine units will ensure that tables giving correction factors are applied in measurements on different radionuclides in syringes, vials & other containers of different sizes & types are being provided.

The records of QC tests must be maintained and provided to the Authority Inspectors on demand at the time of inspection. A full quality control report by a qualified medical physicist needs to be submitted to the Regulatory Authority annually.

TABLE 2: Activity Tests with Ionizing Well Chamber & Their Frequency

TEST	TYPE	FREQUENCY		
		ACCEPTANCE TEST	DAILY	ONCE PER YEAR
Background	Simple	x	x	
Stability (short term reproducibility)		x	x	
Long term reproducibility	Complicated	x		x
Calibration (measuring accuracy)		x		x
Linearity		x		x
Measuring geometry		x		x

Diagnostic nuclear medicine departments that use a $^{99}Mo/^{99m}Tc$ generator or

prepare their own dosages are required to determine & record the activity of each dosage before medical use by direct measurement. In this case, a dose calibrator must be employed for the activity determination and required record keeping as follows:

1. ^{99}Mo activity present in any ^{99m}Tc preparation must be determined. It must be ≤ 0.15μCi ^{99}Mo/mCi^{99m}Tc (0.15kBq ^{99}Mo/MBq^{99m}Tc). If this activity ratio is exceeded, the dosage cannot be administered.
2. ^{99}Mo concentration of the first eluate after receipt of a ^{99}Mo/^{99m}Tc generator must be measured and recorded.
3. The dose calibrator must be calibrated and the results recorded.

Personnel must be familiar with proper operation of the dose calibrator & know what actions to take in the event of a non-functional calibrator.

Quality control of detecting equipment for in vitro during experiment and in vivo in living things measuring (equipment without scintigraphy):
Table 3 enlists the recommended QC tests for a calibrator.

One-detector & two-detector equipment:

Consistency tests of equipment in vivo and in vitro can be summarized as follows:

Table 3: Test schedule for Radionuclide Calibrator.

Sr. No.	TEST	ACCEPTANCE	REFERENCE	FREQUENCY IN ROUTINE TESTING		
	Acceptance & Reference Tests			Weekly	Quarterly	½ yearly
1	Physical Inspection	x				
2	Test of precision & accuracy	x	x		x	
3	Test of linearity of activity response	x	x		x	
4	Test of background response	x	x	x		
	OPERATIONAL CHECKS					
1	Reproducibility					
2	Background response					

- ❖ SIMPLE
  - ➢ Energetic calibration

- Short term reproducibility

❖ COMPLICATED

- Long term reproducibility
- Energetic resolution capability
- Sensitivity
- Linearity of energy response
- Activity response linearity.

Overview of tests of one-detector & two-detector devices for in vitro and in vivo measuring and frequency of their performance is shown in the table 4:

Multiple-detector systems for in vitro measuring

Particularly the same parameters as for classical systems with one detector are controlled in these systems, used mainly for radio-saturation analysis. However, higher number of detectors and construction of the device leads to some peculiarities. The device is accustomed to detection of samples with very low photon radiation energy, especially 125I, emitting roentgen radiation and gamma radiation with low energy of 30keV.

TABLE 4: Tests for One-Detector/Two-Detector Devices & their Frequency

Test	Type	Frequency				
		Acceptance Test	Daily/Weekly	Monthly	Semi Annual	Yearly
Energetic calibration	Simple		X*			
Stability (Short term reproducibility)		X		X		
Long term reproducibility	Complicated					X
Energetic resolution		X			X	
Sensitivity		X				X
Linearity of energy response		X				X
Activity response linearity		X				X

** Daily for in vivo equipment, once a week for in vitro equipment.*

Manufacturers of multiple-detector systems also provide the software programmes for quality control, instruction for carrying out these controls and evaluation of the measured results.

If the user does not proceed appropriately according to programmes included in the software (QC test, standardization, setting the high voltage i.e., autocalibration & others), when setting and controlling the equipment, the system indicates such an error.

The system further indicates that the difference in particular parameters have exceeded the allowed value determined by the manufacturer. In such cases it is necessary to repeat the test with special attention to proceed exactly according to the manufacturer's instructions. When the test results repeatedly fail to be satisfactory, the maintenance service must be contacted.

10.3 Quality Control of Imaging Systems – Scintillation Cameras

The scintillation camera QC has two purposes:

- It verifies whether the equipment produces images adequately corresponding to the distribution of radiopharmaceuticals in the patient; and
- It contributes towards achieving the requirements of maximal diagnostic information gained under the lowest possible radiation exposure to patients and staff.

Gamma camera has now been developed into a very sophisticated series of imaging devices that permit dynamic & tomographic imaging, as well as, conventional static planer imaging. In order to attain high standards of efficiency & reliability, an appropriate quality assurance programme is mandatory.

The licensee is responsible to ensure that:

- Site is appropriate for the installation of the camera;
- Once received & installed, the licensee will perform a series of acceptance tests to confirm whether its initial performance confirms with the manufacturer's specifications. At the same time, reference tests are carried out to provide data against which its subsequent performance can be assessed by routine testing weekly, monthly, quarterly, yearly etc;
- Full technical specifications are obtained from the manufacturer, covering all options of the instrument including power supply;
- Operational checks & servicing facilities are taken into account;
- The Authority is informed before the operation of the gamma camera to evaluate the radiation protection requirements;
- Operational & service manuals, fully updated, accompany every instrument; and
- Records of all such procedures & tests are kept and produced at the time of regulatory inspection.

A summary of a general gamma camera QC is placed at table 5.

The table 6 indicates the duties of the personnel responsible for QC of gamma camera in a nuclear medicine department.

SPECT Parameters

The recommended QC tests fall broadly into three categories:

i. "Good Practice": easy steps requiring only vigilance on the part of the technologist. Very important for good SPECT quality.
ii. "Daily Tests": the core of the QC programme.

iii. "Less Frequent Tests": tests to be performed on some regular schedule other than daily.

Table 7 indicates tests for SPECT QC.

TABLE 5: General Gamma Camera QC

PARAMETERS	COMMENTS
DAILY	
Uniformity Check	Flood field; intrinsic(without collimator) or extrinsic(with collimator)
Window setting	Confirm energy window setting relative to photopeak for each radionuclide used.
WEEKLY	
Spatial Resolution	Requires "resolution" phantom (PLES, four quadrants bar, orthogonal hole) & standardized protocol.
Linearity Check	Qualitative assessment of bar pattern linearity
PERIODICALLY (Biannually or when a problem is suspected)	
Collimator Performance	High count flood with each collimator.
Energy Registration	For cameras with capability of imaging multiple energy windows simultaneously.
Count Rate Performance & Count Rate Linearity	More important in cameras with "count skimming" or "count addition" correction circuitry.
Energy Resolution	Easiest in cameras with built-in multichannel analyzer
Sensitivity	Count rate performance per unit of activity.

TABLE 6: Duties of the Personnel for QC of Gamma Camera

TEST	ACCEPTANCE	DAILY	WEEKLY	YEARLY
Uniformity	P* & T**	T	P	
Uniformity, tomography	P		P	
Spectrum display	P & T	T	P	
Energy resolution	P		P	
Sensitivity	P	T	P	
Pixel size	P	T	P	
Centre of rotation	P	T	P	
Linearity	P		P	
Resolution	P		P	
Count losses	P		P	
Multiple window pos	P		P	
Total performance phantom	P		P	

*P: Physicist

**T: Technician/radiographer

GOOD PRACTICE TESTS

I. Visual Check of Energy Spectrum: Look at peak position, peak width or presence of other activity (peaks of other radionuclides);

ii. Background Activity Check: Performed with the collimator on or off;

iii. Cine Review of SPECT Data: After acquisition & before reconstruction cine review will show up patient motion along the axis of rotation, background activity in the field of view, variations in camera performance with view angle & gross COR errors; and

iv. Sinogram Review of Data: It will give similar information as cine review of planar images, but with greater sensitivity for lateral patient motion & less for vertical shifts.

DAILY QC TESTS

i. Low Count Extrinsic or Intrinsic Flood: A low count extrinsic or intrinsic flood should be performed daily on all camera heads for visual assessment of camera uniformity. For clinical radionuclides other than ^{99m}Tc, it is important to verify intrinsic uniformity with the appropriate corrections on a regular schedule, the frequency of which will depend on the variety of radionuclides used with a particular system; and

ii. Visual Inspection of Collimators: A visual inspection of collimators should be performed daily & whenever collimators are changed. Signs of denting, scratches, or stains should be followed with an extrinsic flood test & a background check before a suspect collimator is used for patient imaging.

LESS FREQUENT TESTS

i. Resolution Phantoms: Using a four quadrant bar pattern or some other repetitive pattern, such as holes, resolution & linearity of the entire surface of the camera can be judged. Compare the results with the reference image identically acquired at the time of known performance. Loss of resolution may indicate electronic noise or degradation of crystal or interface;

ii. Center of Rotation (COR) Test: COR testing should be performed as per recommended schedule of the manufacturer. It is recommended that COR testing be performed routinely on all collimators used for SPECT. Variable angle cameras should be checked for both the 90 & 180 degree positions, unless otherwise stated by the manufacturer. It is a good practice to look at per-view deviations from expected source positions which can indicate problems with mechanical alignment. It is desirable to rotate collimators systematically for the purpose of this test, so that a different collimator (or collimator set) is used for performing the test until all SPECT collimators have been tested;

TABLE 7: Tests for SPECT QC

VARIABLES	DAILY:5M COUNT FLOOD	PEAK SPECTRUM	CINE RVIEW	SINOGRAM REVIEW	4 QUADRANT (RESOLUTION) PHANTOM	CENTER OF ROTATION	HIGH COUNT INTRINSIC UNIFORMITY	SPECT PHANTOM	BACKGROUND CHECK	HEAD TILT CHECK	RECONSTRUCTED POINT SOURCE	RECONSTRUCTED UNIFORMITY FLOOD
Collimator Damage	+	-	-	-	-	-	-	0	-	-	-	+
PMT Drift	+	-	-	-	+	-	+	0	-	-	-	+
Energy Peak Drift	0	+	-	-	-	-	+	0	-	-	-	+
Mechanical COR	-	-	0	+	-	+	-	+	-	+	+	-
Electronic Noise	-	0	-	-	+	-	-	+	0	-	+	0
Crystal Damage/Coupling Dry	0	0	-	-	+	-	+	0	-	-	-	+
Contamination/Spills	-	0	-	0	-	-	+	-	+	-	-	+
Magnetic Fields	0	0	0	0	-	-	0	+	-	-	+	+
Power Fluctuations	0	0	-	-	0	-	0	0	-	-	0	+
Background	-	0	+	0	-	-	+	-	+	-	-	-
Temperature Fluctuations	+	0	-	-	-	-	+	0	-	-	-	+
Any Variable As a Function of Angle	0	-	+	+	-	+	-	+	-	-	0	+

Key

- *Signifies that the test is unlikely to show sensitivity for the designated variable*
- *0 Signifies some sensitivity for the designated variable*
- \+ *Signifies high sensitivity for the designated variable*

iii. High Count Intrinsic Uniformity Flood: High count density intrinsic floods should initially be acquired weekly; afterwards the frequency of the test is adjusted according to the camera's stability. Departments using multiple radionuclides should rotate radionuclides used for this test & compare images to the baseline acquired with the same radionuclide;

iv. Tilt Angle of the Camera Head(s): For best results in SPECT, the detector head must be parallel to the axis of rotation (level). For manually positioned systems this must be verified at every acquisition; but even systems with motorized tilt angles need to be checked periodically. Verify that a level detector corresponds to a tilt indication of zero, at different radii of rotation. A change in indicated value will be indicative of mechanical problems;

v. Reconstructed Point Source Resolution: Features to look for in the

reconstructed image are: width in all three dimensions, shape & presence of streaking or other artifacts. This test can conveniently be carried out at the same time as a COR test (using the same point source). An offset point source will provide more information about camera performance than a source on axis, but when combining this test with the COR test, follow manufacturers recommendations;

vi. Reconstructed Cylindrical Phantom Uniformity: A frequency of once a month is recommended. This test will uncover any angular variations in camera performance that have not been picked up by other tests;

vii. SPECT Resolution & Uniformity Phantom Test: This test is recommended for QC purposes. When performed using the recommended phantom, and when acquired correctly, the analysis of the results of this test provides information on the complete SPECT imaging system, both hardware & software. This test may not specifically indicate the source of an error but when used routinely it provides a valuable trend analysis of total system performance. It is recommended that this phantom test be acquired initially at system acceptance and then quarterly thereafter. Results of all subsequent acquisitions should be compared to the baseline acceptance study; and

viii. Pixel Size: Pixel size is another parameter that affects SPECT image quality & quantization. This should be monitored more frequently in older SPECT systems. The newer digital cameras should be tested initially upon acceptance & then every six months thereafter following manufacturers' instructions.

Table No: 8 outlines a summary of recommended SPECT QC Tests. The tests outlined are not performance tests; rather, the outcome of these tests is expected to change as the system performance changes. It is, therefore, important to establish a baseline as an indication of system degradation. Acquisition parameters as well as acceptable deviations will be based on individual manufacturer's recommendations.

10.3.1 QA of Equipment for Safety Dosimetry

10.3.1.1 Dose and Dose Rate Measuring Device

Response control test: It is the value shown on the equipment when measuring the dose and the dose rate of a known value in the photon radiation field (gamma & roentgen radiation). The measured value of the dose must not differ by 20% from the standard value.

This test should be done during the acceptance test and then once a year.

TABLE 8: Summary of SPECT QC Tests

GOOD PRACTICE	DAILY	ONE – TWO WEEKS	QUARTERLY
Visual check of energy spectrum	Extrinsic (intrinsic) Low count flood	High count-density Intrinsic flood	Point source Reconstructed resolution
Cine review of projection & optionally sonogram data		Intrinsic/Extrinsic resolution check with bar or hole pattern	Reconstructed SPECT Phantom
Background Check			Pixel size check
Visual inspection of collimators for damage		Center of rotation (rotating collimators)	Tilt angle check

10.3.1.2 *Surface contamination measurement device:*

Response control test: It is the value shown on the equipment when measuring the surface contamination of a known value expressed in $Bq*cm^{-2}$.

The equipment's response to the surface source of a given radionuclide must not differ by more than 10% from its detected surface activity.

This test should be done during the acceptance test and then once a year.

11 EDUCATION AND TRAINING

It is the responsibility of the licensee to ensure that:

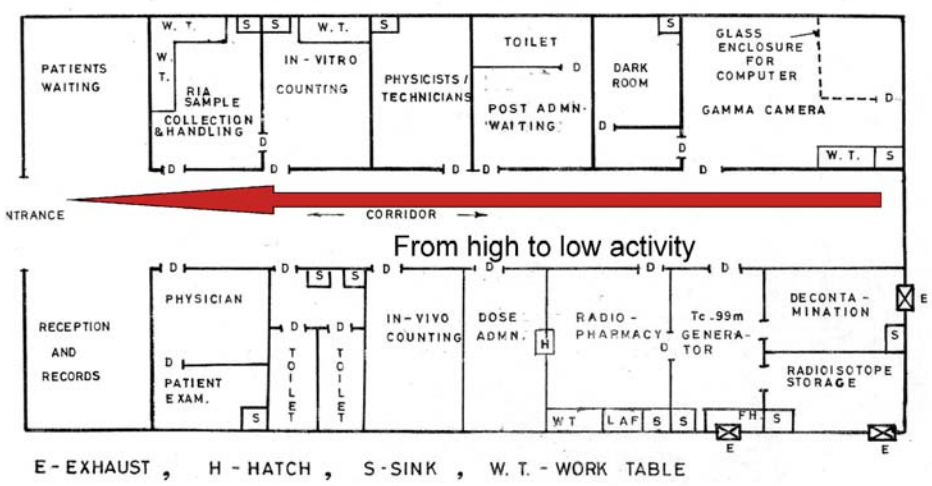
- All persons responsible for protection and safety are appropriately trained and qualified so that they understand their responsibilities and perform their duties with appropriate judgement and according to defined procedures, especially physicians, medical physicist, nuclear medicine technician, RPO;
- Outside contractors on whom radiation protection may depend (e.g., service engineers) are appropriately trained and qualified;
- RPO should give instructions to:
    - Nurses in wards with radioactive patients;
    - Staff who do not belong to the nuclear medicine practice but need to enter controlled areas;
    - Staff who transport radioactive patients.
- Basic and continuing training is received by the persons who have the responsibility for the operation of the equipment or for preparation of radiopharmaceuticals;
- Advanced training for physicians, physicists and radiopharmacists is available;
- All staff have regular updates on radiation protection aspects; and
- Education and training records are maintained, with the following information:

- Name of the person who received the education/training;
- Name of the person who delivered the education/training;
- Date and duration of the programme;
- Syllabus of the training;
- Copy of the certificates of the training.

Annexure IV is the checklist for the inspectors of inspection of a nuclear medicine department.

ANNEXURE I

LAYOUT OF A NUCLEAR MEDICINE DEPARTMENT



- All new facilities should be constructed according to this plan, low activity area must always be located near the entrance and high activity area is restricted and placed far beyond the patient waiting area.
- Preexisting facilities should make alterations accordingly.
- For convenience, the categorization of the areas can be done according to the following criteria:

WEIGHTED ACTIVITY	CATEGORY
<50MBq	Low Hazard
50 – 50000MBq	Medium Hazard
>50000MBq	High Hazard

BUILDING REQUIREMENTS

CATAGORY OF HAZARD	STRUCTURAL SHIELDING	FLOORS	WORKTOP SURFACES-WALLS, CEILING
LOW	NO	CLEANABLE	CLEANABLE
MEDIUM	NO	CONTINUOUS SHEET	CLEANABLE
HIGH	POSSIBLY	CONTINUOUS ONE SHEET FOLDED TO WALLS	CLEANABLE

NOTE: What the room is used for should be taken into account e.g., waiting room

BUILDING REQUIREMENTS

CATEGORY OF HAZARD	FUME HOOD	VENTILATION	PLUMBING	FIRST AID
LOW	NO	NORMAL	STANDARD	WASHING
MEDIUM	YES	GOOD	STANDARD	WASHING & DECONTAMINATION FACILITIES
HIGH	YES	MAY NEED SPECIAL FORCED VENTILATION FACILITIES	MAY NEED SPECIAL PLUMBING FACILITIES	WASHING & DECONTAMINATION FACILITIES

ANNEXURE II

SAFE ADMINISTRATION OF I-131

GUIDANCE LEVEL FOR MAXIMUM ACTIVITY FOR PATIENTS IN THERAPY ON DISCHARGE FROM HOSPITAL

RADIONUCLIDE	ACTIVITY (MBq)
Iodine – 131	1100[a]

In some countries a level of 400 MBq is used

Activity of I-131 administered (MBq)				
Behaviour Restriction	30-200	200-400	400-600	600-800
	Period Restriction (d)			
Stay at least 1 meter away from all members of the household except for very brief periods (a few minutes every day)	5	9	12	14
Restrict dose contact "cuddling" with all members of the household to less than 15 minutes per day, and sleep separately from them	15	21	25	27
Sleep separately from "comforters and cares"	--	--	4	8
Avoid prolonged dose contact (more than 3 hours at <1 meter) with other adults	--	--	---	1

NOTE THAT

The restriction times in the first two rows run concurrently e.g. for 30-200 MBq category, a child should only be cuddled for brief periods for 5 days, then cuddling must be restricted to 15 minutes per day for a further 10 days.

The dose constraint for third row is 5 mSv

The fourth row only covers on single event whereas the other categories assume daily contact.

RESTRICTION FOR PATIENT WITH I-131

Activity (MBq)	Public travel allowed per day		Off work (d)	Sleep apart from partner		Restricted close contact with children		
	1st week (h)	2nd week (h)		Pregnant (d)	No (d)	<2 y (d)	2-5 y (d)	5-11 y (d)
200	3.5	24	0	15	1	15	11	5
400	1.5	14	3	20	8	21	16	11
600	1	9	6	24	11	25	20	14
800	0.5	7	8	26	13	27	22	16

TABLE: HOSPITALIZATION PARAMETERS FOR THERAPY PATIENTS WITH I-131

ACTIVITY	ADMIT OR DISCHARGE
1100MBq	Stay in hospital or discharge: individual restriction
600MBq	Discharge with individual restrictions
150MBq	Discharge with general restrictions

INSTRUCTIONS TO OUT-PATIENTS

- No eating and drinking during the first hour after treatment.
- During the following two days drink more than usual.
- Use only a WC and flush 2-3 times. Keep the toilet and the floor clean.
- Wash your hands frequently and take a shower every day.
- Avoid close contact with members of the family, children and pregnant women according to the time table attached.
- Avoid solid waste.
- Contact the nuclear medicine department in case of problems or questions.

AVOIDING SOLID WASTE

- Do not use paper plates or disposable cups or flatware.
- Use regular dishes, glasses and utensils. Wash them in the sink or dishwasher.
- Tissues and paper napkins should go in the toilet, not in the garbage.
- Food residues should be avoided during the first week (apple cores, chicken bones etc).
- Articles contaminated with body fluids that cannot be washed clean or disposed off in the toilet should be stored for decay.

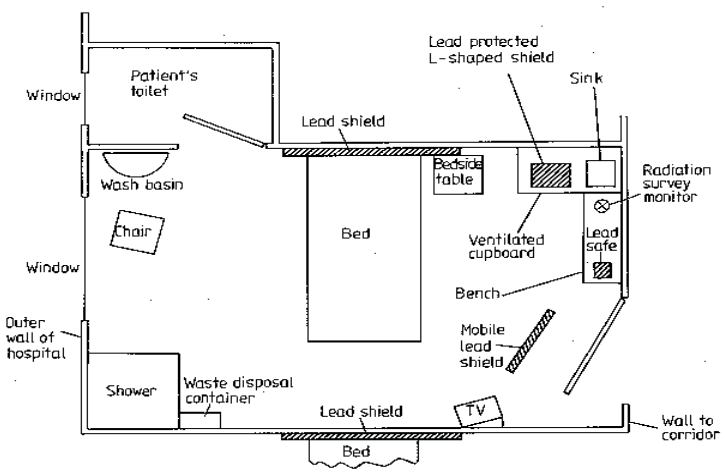
HOSPITALIZATION OF PATIENTS WITH I-131

The following instructions should be fulfilled:

- Room for Iodine therapy is a controlled area;
- Only one patient should be in the room;
- The room should have easily cleanable surfaces and utensils;
- Extra lead shields should be used;
- The door should be kept locked;
- Radiation warning signs should be posted on the door;
- Visitors should be restricted;
- Decontamination equipment should be easily available;
- The medical physicist should monitor the activity levels before the patient is

being discharged.

A SKETCH OF A ROOM FOR PATIENTS ADMITTED



PATIENT INSTRUCTIONS

- Stay in the room.
- Drink as much as possible.
- Eat lemon slices.
- Use only the private toilet and flush 3 times. (Men should sit down to avoid splashing.)
- Wash hands well in soapy water after using toilet.
- Wear footwear when leaving the bed.
- In event of vomiting or incontinence notify the nurse immediately.

INSTRUCTIONS TO NURSING STAFF

- Reduce time spent with patient by planning ahead and working efficiently.
- Work as far from patient as possible.
- Practice preventative measures against contamination.
  - wear impermeable protection gloves
  - wear shoe covers
  - wear a protective gown
- Remove protection clothing before leaving the room.

INSTRUCTIONS FOR VISITORS

The nursing staff should be given the following recommendations:

- Visitors are discouraged for a 48 hour period after the patient receives the treatment.
- Pregnant women and children under the age of 18 are not permitted to visit.
- Visit time should be very short (<30 min).
- A reasonable distance (e.g. 2 m) away from the patient must in any case be maintained.
- Do not eat, drink or smoke in the patient's room.
- Do not touch the toilet or sink in the patient's room

If there is any question in the mind of visitors the nursing staff should answer it or guide them to the treating physician.

ANNEXURE III

CHECKLIST FOR THE INSPECTION OF A NUCLEAR MEDICINE DEPARTMENT

I – AUTHORIZATION APPLICATION FOR USE OF UNSEALED RADIOACTIVE SOURCES IN MEDICINE

I.I – TYPE OF AUTRHORIZATION:

- New application
- Amendment
- Renewal

I.II – PURPOSE OF APPLICAION:

- Construction
- Import/purchase
- Use/beginning of operation

I.III – GENERAL INFORMATION:

1 – NAME & ADDRESS OF ORGANIZATION

MAIN ADDRESS	MAILING ADDRESS, IF DIFFERENT	ADDRESS OF USE, IF DIFFERENT

2 – NAME & QUALIFICATION OF:

SPECIALITY	NAME	DEGREE / CERTIFICATION	EXPERIENCE	CONTACT NO.
Nuclear Physician				
Radiation Protection Officer				
Medical Physicist				
Nuclear Medicine technologist				

3– NAME OF THE RESPONSIBLE PERSON/ADMINISTRATOR:

Name:
Title:
Telephone number:
Fax number:
Mailing address:
E-mail address:

4 – PROPOSED DATE OF INSTALLATION &/OR COMMISSIONING OF FACILITY & EQUIPMENT:

II – SOURCES

II.I– DETAILS OF RADIONUCLIDES INVOLVED:

RADIONUCLIDE/ PHARMACEUTICAL (e.g., ^{99m}Tc Generator)	Maximum activity at one time (Bq) e.g., 37GBq	Physical/Chemical form (e.g., Sodium pertechnetate)	Use/Application (e.g., Diagnostic Imaging)

II.II – CONTAINMENT OF THE RADIONUCLIDES:

- Initial containment;
- Any special features e.g., whether the container is pressurized or incorporate shielding.

II.III– WORK PATTERN:

Frequency of consignments of radionuclides:

II.IV – WORK LOCATIONS

Will the work be carried out at any address other than those given in I.C (1)	Do not know	Yes	No

List all other known addresses.

II.V– RADIOACTIVE WASTE:

Indicate whether the work involved is likely to generate radioactive waste. If YES then provide an assessment of the different forms:

Radionuclide (e.g., I-125, ^{99M}TC	Waste form (liquid, used syringes)	Maximum activity 10KBq 2MBq	Proposed disposal route · To drain · Decay in storage

III – FACILITIES AND EQUIPMENT

III.I – FACILITY SPECIFICATIONS

- Detailed description of the location
- Layout of the laboratory, clearly indicating storage areas of radioisotopes, ^{99m}TC generator & radiopharmaceuticals, dose administration, counting and imaging rooms and wards for thyroid cancer patients.
- Layout of the drainage ducts systems such as sinks, wash basins, toilets etc should be connected directly to the sanitary sewage system.
- Drawing of the facilities or a detailed sketch including wall & ceiling materials & thicknesses.
- Any specific features designated to limit the spread of surface or airborne contamination.
- Proposed category of the facility.

III.II – EQUIPMENT SPECIFICATIONS:

- Manufacturer's specifications for any imaging equipment to be used
- Manufacturer's specifications and type approval certificate for radiopharmaceuticals dose measuring or calibrating equipment
- Proposed arrangements for restricting exposure, including:

    - o Shielding provided to minimize external doses, including vial & syringe shields
    - o Forms of extract ventilation to minimize the risk of internal doses to staff
    - o Readily available/accessible decontamination facilities
    - o Personal protective equipment provided
    - o Description of any remote handling equipment.

IV – VERIFICATION OF SAFETY

IV.I– DESCRIPTION OF RADIONUCLIDES INVOLVED:

Radionuclide/ pharmaceuticaL (e.g., ^{99m}Tc Generator)	Maximum activity at one time (Bq) e.g., 37GBq	Physical/Chemical form (e.g., Sodium pertechnetate)	Use/Application (e.g., Diagnostic Imaging)

IV.II – DESCRIPTION OF MEASURING & HANDLING EQUIPMENT:

TYPE OF EQUIPMENT	MANUFACTURER	MODEL NO.	NUMBER	COMMENTS
Radionuclide activity calibrator				
Imaging equipment				
Syringe shield				
L-Block				
Tongs				
Forceps				
Lead blocks				
Well counter				
^{99}Mo Generator				
Fume hood				
Xenon trap				

IV.III – FACILITY DESIGN:

Describe any differences or modifications from those approved by PNRA &/or considered in the safety assessment (e.g., shielding design, building materials, floor plan): --- ---		
a). Was a safety assessment by a qualified expert performed prior to any modification?	Yes	No
b). Is the thickness & type of shielding appropriate for the types & intensity of radiation produced by radioisotopes in use?	Yes	No

IV.IV – SAFETY CONTROL & EQUIPMENT DESIGN:

a). Are an adequate number of lead containers, lead blocks and portable or fixed shields available for shielding in storage and handling rooms?	Provided? Used?	Yes Yes	No No
b). Is remote handling equipment such as tongs, forceps etc available?	Provided? Used?	Yes Yes	No No
c). Are ventilated fume hoods for handling large doses of I-131 & for carrying out MEK (methyl ethyl ketone (2-butanone)) extraction of ^{99m}Tc available?	Provided? Used?	Yes Yes	No No
d). Are the drainage ducts in the laboratory (sinks, wash basins, toilets etc) connected directly to the sanitary sewage system?		Yes	No
e). Is adequate provision made for storage of wastes before disposal?		Yes	No

IV.V – WARNING SYSTEMS:

Are warning signs/notices	Provided? Working? Legible? In local language?	Yes Yes Yes Yes	No No No No

IV.VI – SAFETY OPERATIONS – MANAGEMENT:

a). Is management familiar with the certificate of authorization & its restrictions & requirements?		Yes	No
b). Does management provide adequate staffing levels?		Yes	No
c). Has management invested the RPO with PNRA to stop unsafe operations?		Yes	No
d). Does management provide adequate resources for personnel training?		Yes	No
e). Does management provide adequate equipment?		Yes	No
f). Does management provide for periodic programme reviews & recommendations?	Scheduled? Performed?	Yes Yes	No No
i). Date of the last programme review: ii). Status of recommendations:			

IV.VII – SAFETY OPERATIONS – TECHNICAL:

a). Does the RPO has adequate knowledge & expertise?		Yes	No
b). Does the RPO has qualified experts available?		Yes	No
c). Is the RPO familiar with the requirements of PNRA & the provisions of the certificate of authorization?		Yes	No
d). Is the RPO given sufficient time & resources to do the job e.g., kept too busy in other assignments or not given sufficient technical/secretarial help?		Yes	No
e). Is the RPO kept informed of activities of workers using radiation sources?		Yes	No
f). Does the RPO conduct initial & periodic training of workers?		Yes	No
g). Does the RPO maintain adequate records to demonstrate worker & public protection?		Yes	No
h). Are there provisions for inventory of sources & accountability?	Procedures? Performed?	Yes Yes	No No
I). Are there provisions for audits and reviews of radiation safety programme?	Procedures? Performed?	Yes Yes	No No

IV.VIII – INVESTIGATION & QA:

a). Were there any incidents or accidents?		Yes	No
b). If so, were incident and accident investigation reports prepared?		Yes	No
c). Were safety assessments reviewed or made on the basis of lessons learned from any incident or accident at similar facilities?		Yes	No
d). Is there a written QA programme?	Procedures? Performed?	Yes Yes	No No
e). Is maintenance & repair work of measuring equipment, imaging devices, ventilation systems etc in accordance with manufacturer's recommendations?	Scheduled? Performed?	Yes Yes	No No
f). Are repair/maintenance procedures	Developed? Followed?	Yes Yes	No No

V – VERIFICATION OF WORKER PROTECTION

V.I – CLASSIFICATION OF AREAS:

a). Are controlled areas demarcated?		Yes	No
b). Are approved signs at access points	provided? legible? In local language?	Yes Yes Yes	No No No
c). Is radioactive material storage (including waste) at physically defined locations?		Yes	No
i). Is there a locked/secured location with key control?		Yes	No
ii). Are radiation warning signs/notices	provided? legible? In local language?	Yes Yes Yes	No No No
iii). Is there proper shielding (e.g., individual containers, enclosures)?		Yes	No
iv). Are the storage locations reserved only for radioactive material?		Yes	No
d). Are supervised areas demarcated?		Yes	No
e). Are approved signs at access points	needed? provided? legible? in local language?	Yes Yes Yes Yes	No No No No

V.II – LOCAL RULES AND SUPERVISION:

a). Are rules established in writing?		Yes	No
b). Do rules include investigation levels and authorized levels and the procedure to be followed when a level is exceeded?		Yes	No
c). Are workers instructed in the implementing procedures?		Yes	No
d). Do workers have adequate supervision to ensure rules, procedures, protective measures & safety provisions are followed?		Yes	No
e).Specifically, are operating & working procedures for:			
i). Nurses attending patients	provided? adequate? followed?	Yes Yes Yes	No No No
ii). Diagnostic examination	provided? adequate? followed?	Yes Yes Yes	No No No
iii). Therapy administration	provided? adequate? followed?	Yes Yes Yes	No No No
iv). Repairing and maintaining safety systems	provided? adequate? followed?	Yes Yes Yes	No No No
v). Making surveys	provided? adequate? followed?	Yes Yes Yes	No No No

V.III – MONITORING:

a). Does the authorized organization provide personal dosimeters?	Yes	No
b). Are the dosimeters: i). Worn properly? ii). Calibrated? iii). Exchanged at required frequency?	Yes Yes Yes	No No No
c). Are personnel exposure within limits?	Yes	No
d). Are area and portable survey instruments: i). appropriate? ii). calibrated? iii). operational? iv). checked before use? v). supplied with spare batteries?	Yes Yes Yes Yes Yes	No No No No No
e). Do the authorized organization's surveys indicate that the shielding is adequate and the dose rates around storage and patient treatment rooms meet authorized radiation levels?	Yes	No
f). Does the authorized organization make periodic tests for leakage of radioactive materials from any sealed sources (e.g., calibration sources)?	Yes	No
g). Is the instrumentation: i). appropriate? ii). calibrated? iii). operational?	Yes Yes Yes	No No No
Record independent measurements made during the inspection: ----------		
Type/model number of survey meter:		
Date last calibrated:		
Do the inspector's independent surveys confirm the survey results of the authorized organization?	Yes	No
Document any significant differences and any agreed upon plan to resolve the discrepancies: ----------		

VI – VERIFICATION OF PUBLIC PROTECTION:

VI.I – CONTROL OF VISITORS:

a). Are visitors accompanied in controlled areas?	Yes	No
b). Is adequate information provided to visitors entering controlled areas?	Yes	No
c). Are there adequate controls over entries into supervised areas & appropriate postings?	Yes	No

VI.II – SOURCES OF EXPOSURE:

a). Are the shielding & other protective measures optimized for restricting public exposure to external sources of radiation?	Yes	No
b). Are the floor plans & arrangement of equipment as described in the application appropriate considering any public areas adjacent to the installation?	Yes	No

VI.III – RADIOACTIVE WASTE AND DISCHARGES:

a). Have provisions been made to transfer waste to an authorized waste disposal facility at the end of use?	Yes	No
b). If any sealed sources are no longer in use and being stored, does the authorized organization have a plan for timely transfer or disposal of the sources?	Yes	No
c). Are there provisions for control of discharges to the environment in the event of contamination?	Yes	No

VI.IV – MONITORING OF PUBLIC EXPOSURE:

a). Are routine periodic measurements of exposure rates in public areas adjacent to areas used for diagnostic & therapeutic purposes or radioactive materials made by staff or qualified experts?	Yes	No
b). Do surveys show that the room shielding is adequate and the dose rates outside the areas meet authorized radiation levels?	Yes	No
c). Record independent measurements made during the inspection: ----------		
Type/model no. of survey meter:		
Date last calibrated:		
Are the inspector's independent measurements in agreement with the organization's routine measurements?	Yes	No
Document any significant differences and any agreed upon plan to resolve the different results: ----------		

VII – EMERGENCY PREPAREDNESS:

VII.I – EMERGENCY PLAN:

a). Is there a written plan?	Yes	No
b). Is the plan periodically reviewed and updated?	Yes	No
c). Does the plan take into account lessons learned from operating experience and accidents at similar facilities?	Yes	No

VII.II – TRAINING AND EXERCISE:

a). Have workers involved in implementing the plan received training?	Yes	No
b). Have provisions been made for the plan to be rehearsed at suitable intervals in conjunction with any designated emergency response authorities?	Yes	No
c). Date of the last rehearsal?	Yes	No

VIII – VERIFICATION OF MEDICAL EXPOSURE:

VIII.I – RESPONSIBILITIES:

a). Is no patient treated unless the exposure is prescribed by a medical professional?	Procedures? Followed?	Yes Yes	No No
b). Are there an adequate number of trained medical and paramedical personnel to discharge assigned tasks?		Yes	No
c). Are diagnostic imaging & QA requirements fulfilled with the advice of a qualified expert in nuclear medicine physics?		Yes	No

VIII.II – JUSTIFICATION:

a). Are diagnostic medical exposures justified by taking into account the benefits and risks of alternative techniques that do not involve medical exposure?	Yes	No
b). Are standards available and followed for radiological examinations for screening of large populations or for occupational, legal or health insurance purposes?	Yes	No

VIII.III – OPTIMIZATION:

a). Do medical practitioners ensure that appropriate equipment is used, that the exposure of patients is the minimum necessary to achieve the diagnostic objective, and that relevant information from previous examinations is taken into account to avoid unnecessary additional examinations?	Yes	No
b). Do the medical practitioners, the technologists or other imaging staff endeavour to achieve the minimum patient exposure consistent with acceptable image quality by: i). Appropriate selection of the radiopharmaceutical & its activity, noting special requirements for children and for patients with impaired organ functions? ii). Use of methods for blocking the uptake in organs not under study and for accelerated excretion when applicable? iii). Appropriate image acquisition and processing?	Yes Yes Yes Yes	No No No No
c). Are radiological examinations causing exposure of women who are pregnant or likely to be pregnant avoided unless there are strong clinical reasons for such examinations?	Yes	No
d). For lactating mothers, is discontinuation of nursing recommended until the radiopharmaceutical is no longer secreted in an amount estimated to give an unacceptable dose to the nursing child?	Yes	No
e). Is the administration of radionuclides to children for diagnostic procedures carried out only if there are strong clinical indications, and the amount of radioactivity is reduced according to body weight, body surface area or other appropriate criteria?	Yes	No

VIII.IV – CALIBRATION:

a). Is the calibration of sources used for medical exposure traceable to a standard dosimetry laboratory?	Yes	No
b). Are unsealed sources calibrated in terms of activity of the radiopharmaceuticals to be administered, with the activity being determined and recorded at the time of administration?	Yes	No

VIII.V – CLINICAL DOSIMETRY:

Are representative absorbed doses determined and documented?	Yes	No

VIII.VI – QUALITY ASSURANCE:

Does the medical QA programme include:

a). measurements and verification of physical parameters at the time of commissioning and periodically thereafter?	Procedures? Followed?	Yes Yes	No No
b). written records of relevant procedures and results?	Procedures? Followed?	Yes Yes	No No
c). verification of the appropriate calibration and conditions of operation of dosimetry and monitoring equipment?	Procedures? Followed?	Yes Yes	No No
d). verification of patient identity?	Procedures? Followed?	Yes Yes	No No
e). regular and independent quality audit reviews?	Procedures? Followed?	Yes Yes	No No

VIII.VII – DOSE CONSTRAINTS:

a). Does the dose constraints to be applied on case to case basis in the optimization of protection for persons exposed for medical research purposes specified, if such medical exposure does not produce direct benefit to the exposed individual?	Yes	No
b). Have dose constraints been established for individuals knowingly exposed while voluntarily helping in the care or comfort of patients undergoing medical diagnosis?	Yes	No

VIII.VIII – INVESTIGATION OF ACCIDENTAL MEDICAL EXPOSURE:

a). Did the registrant or licensee promptly investigate any or all instances where:	Yes	No
i). a diagnostic dose was substantially greater than intended or resulting in doses repeatedly and substantially exceeding guidance levels?	Yes	No
ii). there was an equipment failure, accident, error, mishap or other unusual occurrence with the potential for causing a patient exposure significantly different from that intended?	Yes	No
b). With respect to any incidents investigated, did the registrant or licensee:	Yes	No
i). calculate or estimate the doses received and their distribution within the patient?	Yes	No
ii). indicate the corrective measures required to prevent recurrence of such an incident?	Yes	No
iii). implement all corrective measures that were under their control?	Yes	No
iv). submit a written report to PNRA as soon as possible, stating the cause of the accident, the dose received and the corrective measures taken to avoid a recurrence?	Yes	No
v). inform the patient and his attending physician about the incident?	Yes	No

REFERENCES

1. International Atomic Energy Agency, "Nuclear Medicine Resource Manual", IAEA, Vienna (2006).
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3. Pakistan Nuclear Regulatory Authority, "Regulations on Radiation Protection", PAK/904, PNRA, Islamabad (2004).
4. Pakistan Nuclear Regulatory Authority, "Regulations for the licensing of Radiation Facility (ies) other than Nuclear Installation (s)", PAK/908, PNRA, Islamabad (2004).
5. Institute for Nuclear Information, "Recommendation on Radiation Protection- Quality Assurance Systems at Workplaces Using Nuclear Medicine, Equipment Technology", Zbraslav, Co.

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