Manual-4

Norms set for the discharge of functions
[Section 4(1)(b)(IV)]

Copy of Standard Operating System (SOPs) in r/o Medical Record Department, DSCI is attached herewith.

DELHI STATE CANCER INSTITUTES

- centres par excellence in the service of humanity
(A group of autonomous institutions under the Govt. of NCT of Delhi)
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SOP FOR MEDICAL RECORDS DEPARTMENT

INTRODUCTION

Delhi State Cancer Institute (DSCI) is a Premier Oncology Institute under the Govt of NCT of Delhi, which has branches in East Delhi (Dilshad Garden) and West Delhi (Janakapuri). DSCI(East) has facility of General Ward and Private Ward including Semi-private and Private Wards, DSCI. DSCI caters to cancer patients from not only from Delhi, but also its neighbouring states of Uttar Pradesh, Haryana, Punjab. DSCI has even treated international patients from Neighbouring countries like Nepal, Pakistan and Afghanistan etc in the past

OBJECTIVES OF MEDICAL RECORD DEPARTMENT (MRD)

Medical Record Department plays very important role in Delhi State Cancer Institute and involves in activities like efficient Medical Records Management i.e. collection, compilation, analysis, maintaining and upkeep of the cancer patient's record from Indoor and Outdoor patients.

The department provides multiple benefits not only to the patients but also to running hospital efficiently. Being a super specialty hospital under GNCT of Delhi, OPD / IPD Files of cancer patients are being preserved in the mobile compactors / Steel Racks for safety purpose and for easy storage as well as easy retrieval. The files are arranged sequentially by Medical Record Number / UHID Number, starting with the lowest and going to the highest

Coding and indexing of patient's data is also done according to ICD-10 standard and internationally accepted practices. Following which it will make easier for comparisons, future planning and research work for medical professionals.

2494/RA/DSCI/DSCI
2/6/23

MRO

02/06/23

FUNCTIONS OF MEDICAL RECORD DEPARTMENT

The functions of the Medical Record Department at this Institute are as under:-

- Collection, compilation, indexing/coding of patient's data, analysis of data, preparation of various reports/returns.
- Preserving of Indoor & Outdoor Patients Files in Modern Mobile Compactors for safety reasons
- Preparation of Monthly Morbidity Report in ICD-10 Format according to the guidelines of W.H.O.
- Entry of Death cases through Online Institutional Death Registration with East Delhi Municipal Corporation (EDMC)
- Forwarding of Monthly Report for Communicable and Non-Communicable Diseases to the Directorate of Health Services, GNCTD
- Disposal of Insurance Claim Cases on the life of patient
- Correction/Rectification in record of cancer patients being treated at this Institute.
- Providing of Treatment / Case Summary in r/o patients at this Institute
- Dealing with patients related grievances
- Attending of Court Cases in r/o patient in the Court of Law

TIME LIMIT FOR DISPOSAL OF REQUESTS RECEIVED IN MRD

- For Life Insurance Claim Cases on the life of patient – **10-15 Days**
- Correction / Rectification in record of patient – **2 Days**
- Correction / Rectification in record of expired patients – 7 Days
- Providing of treatment / case summary – **3-7 Days**

CONFIDENTIALITY OF MEDICAL RECORDS

The Medical documents / records / details of treatment of patient cannot be disclosed / shared, which are confidential and should be protected from disclosure. However, this information can be divulged only under following conditions:-

- If the patient / legal heir authorizes disclosure.
- Court orders its revelation.
- In the public interest, to avoid harm/injury.

RETENTION OF MEDICAL RECORDS

Medical Records (OPD / IPD / Death Files) of cancer patients at this Institute may be stored in digitized form before weeding out of old records for at least past ten years or as per availability which may be required in future for research and policy planning purposes. We have also adopted the retention period of AIIMS, New Delhi in following manner:-

(i) OPD records for 10 years (last attendance in the hospital)

(ii) IPD records for 10 years (as per date of discharge)

(iii) Death files for 10 years

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AMENDMENTSHEET

Sl. No.	Page no	Date of amendment	Details of the amendment	Reasons	Signature of the reviewing authority	Signature of the approval authority

CONTROL OF THE DOCUMENT

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in ideally identifiable and retrievable form.

The holder of the copy of this manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

The Manual is reviewed at least once a year (or in between SOS if so required) and is updated as relevant to the Hospital policies and procedures.

The Authority over control of this manual is as follow:

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The Original Procedure Manual with Signatures on the Title page is considered as **"Master Copy"**, and the photocopies of the master copy for the distribution are considered as **"Controlled Copy"**.

Distribution List of the Manual

Sr.No.	Officials	Signature of Officials receiving copy

CLINICAL RADIATION ONCOLOGY WORKFLOW

Step 1: Patient comes and moves towards OPD counter on Ground floor

Step 2: New patients are issued a UHID number and patients registered under radiation oncology are directed to come to the Radiation Oncology Section in the ground floor.

Step 3: Patients then meet the Senior Resident / Assistant/ Associate Professor/Professor and their history is recorded on the OPD book/tumor board Performa. They are examined and investigations (lab/ biopsy/ slider view/ imaging) are advised as required. They may also require cross consultation or advice by other specialty, so they may be sent for expert opinion or diagnostic procedure as required.

Step 4: After complete evaluation the case file is presented in tumor board for multi-disciplinary opinion and a treatment plan is outlined based on international guidelines based on evidence, based medicine

Step 5: Patients may require surgery, radiotherapy and chemotherapy or all of these. The treatment plan is explained to the patients and the attendants in their language and also they are explained about the options available.

Step 6: Patient requiring Radiation therapy meets the Radiation Oncologist and they are explained about the course side effect, outcome prognosis and precautions required and also financial counseling is done.

Step 7: According to the suggested disease or treatment mode of radiotherapy is decided.
There are two modes:

- External radiation therapy (See Annexure-A)
- Brachytherapy (See Annexure-B)

Step 8: Mould room/CT request form is filled according to the type of the treatment, instructions for immobilization and imaging. Patients are sent to Radiation reception for further assistance and then sent to mould room (See Annexure –C)

Step 9: A mould room procedure viz immobilization with thermoplastic casts / vacloc is done by Technologist and a CT scan is acquired in treatment position with fiducially markers by Technologist (See Annexure –D).

Step 10: Treatment planning is done by the Medical Physicist as prescribed by the Radiation Oncologist and the plan is approved by Radiation Oncologist. (See Annexure-E)

Step 11: Before the implementation of treatment RapidArc/IGRT/IMRT patient specific QA is done by the Medical Physicist (See Annexure –G)

Step 12: Patient is taken for the treatment and first day treatment and set up is seen by the Radiation Oncologist along with Medical Physicist and Technologist. (See Annexure-F). All patients are monitored by CCTV during the treatment as nobody can accompany the patient while radiation is on. Technologist can also verbally communicate with them from console for any specific instruction or even for their reassurance.

Some patients may require radiation sensitizers or protectors. They are administer as per protocol by sister in charge under supervision of doctor.

Step 13: Patient is provided with an appointment card and daily he/she is supposed to come for the treatment on scheduled time as indicated on radiation appointment card and report at the radiation reception, who co-ordinates with the Technologist and sends the patient for daily treatment.

Step 14: Patients receive treatment in fractions and when planned treatment is completed, they are given a treatment summary indicating the dose, technique and intent of treatment and follow up advice.

CARE AND PRECAUTION DURING RADIATION THERAPY

All patients are counseled about the diet required during radiation therapy .They are subjected to complete clinical examinations and required Laboratory investigations .The findings of examination and investigations, determine the nutritional requirements of patients and the same are reassessed.

Patients are counseled by their treating doctor about the expected side effects, precautions and care during radiation therapy. They are periodically re-stressed upon by other radiation staff for better patient understanding care during radiation therapy. Care during treatment is noted down on patient's daily appointment card and also on OPD book provided to patients.

DAYS AND HOURS OF OPERATION OF RADIATION THERAPY

Radiation therapy is delivered from Monday to Friday 9 am – 6:00 pm (till the last patient, whichever is later) onwards where radiation therapy is delivered to the patients after initial warm up & daily QA of the machine. Sundays and public holidays are non-working. However emergency services are provided in Emergency department and emergency radiation therapy may be given if required in the department .On Saturdays Dosimetry and machine calibration is done (See Annexure-I).

SOP for Radiotherapy

Objective:

To ensure consistently safe, effective, efficient, appropriate, & timely therapeutic services to each patient referred to the radiotherapy department of the hospital.

Purpose: Smooth running of radiotherapy department to ensure uninterrupted patient services.

Scope: Entire Radiotherapy Department

Sl. No.	Activity/Description	Responsibility
1.	**Statutory compliance**	
	1.1 HOD & RSO shall be responsible for compliance to AERB registration pertaining to equipment using in the department **a)** eLORA registration/licensing of the institution/department, RSO & all equipment shall be done & maintained **b)** Periodic QA of equipment's & premises (as per AERB guidelines) will be done through the AMC/CMC provider and submitted to AERB. **c)** Radiation workers will be identified & TLD badge monitoring shall be done for them as per AERB guidelines. **d)** Periodic health check including blood cell count & general physical examination shall be conducted & recorded for all radiation workers as per AERB guidelines. **e)** Availability, maintenance, QA of all radiation barriers(lead aprons, goggles, gonadal shields, lead curtains) **f)** Education, training & monitoring regarding radiation safety practices shall be done by RSO. **g)** These activities will extend to pretreatment planning areas involving low voltage radiations and both Tele-therapy and Brachytherapy units involving high voltage radiation and use of radiation sources accordingly. **1.2** HOD & RSO shall be responsible for compliance to **Atomic Energy Regulatory Board** (**AERB)** regulations pertaining to all the therapeutic equipment's well as planning CT equipment used in pretreatment planning procedure in the department. **a) AERB** registration of the Institute/department/equipment & personnel handling these equipment shall be done & maintained. **b) AERB** registration of the institute/department/equipment & personnel handling these equipment shall be done & maintained. **c)** Daily & monthly reporting on relevant formats to competent authority shall be done.	HOD Radiotherapy /Hospital RSO

	d) All mandated relevant displays and signage shall be maintained as per **AERB** guidelines.	
2.	**Signage's**	HOD Radiotherapy
	2.1 Statutory Signage's: All safety & statutory signing's & displays as per **AERB** guidelines shall be placed inside/outside all equipment rooms (as per guidelines). The displays shall be in languages & formats as per guidelines. **2.2 Informative signage**–At the minimum following Information signage's shall be displayed (using appropriate languages, font sizes & format) at eyelevel. The signage shall be static & permanent (i.e., no standees, posters, running scripts): **a)** Services provided with room numbers **b)** Timings **c)** Directions **d)** Safety related education signage's Simulator **e)** CT simulator & Mould Room procedure **f)** Treatment Units (Linear Accelerator and Brachytherapy unit) **2.3 Radiations safety signage's:** Safety signage should be as recommended by AERB including restrictions of patient/attendant entry, hazard lights and pictorial signage's appropriate for the services involving usage of Radiations. **2.4 Radiation Emergency Contact:** Display of telephone numbers to be contacted for radiation emergency. (Annexure - H)	HOD Radiotherapy
3	**Equipment**	HOD/Senior Technologist
	3.1 Procurement & installation of equipment's shall be as per government rules. **3.2** Operation of equipment shall be by appropriate personnel qualified & trained for the specific jobs **3.3** Daily calibration, morning check out procedure or **Daily QA** shall be performed by the operator Technologist and on duty **Medical Physicist** at the time of switching on in the morning. **3.4** Daily cleaning of cleanable parts of the equipment shall be ensured by the operator at the time of switching off. **3.5** Periodic maintenance (preventive) & periodic calibration & QA shall be done by the service engineers from the AMC/CMC provider. There records shall be maintained by the Technical In charge. **3.6** Department shall maintain an equipment log book with information regarding all equipment under the following categories: **a)** Main Therapeutic Equipment-e.g. Linear accelerators, Brachytherapy units	

	b) Pretreatment planning equipment's… e.g. CT Simulators etc. **c)** Each unit shall be identifiable with a traceability number as reflected on the unit & in the log book. **3.7** All equipment shall have dedicated history sheet where details regarding purchase, operation, functionality, maintenance & breakdown shall be maintained. **3.8** Inventory of all accessory and ancillary equipment.	
4	**Staff/Personnel**	HOD Radiotherapy
	4.1 Availability of appropriately qualified and trained staff as per the scope of services. **4.2** Availability, job descriptions, rosters, leave records etc. shall be ensured as per government guidelines/rules. **4.3** Appropriate numbers and mix of the following staffs shall be available to provide patients services for routine & emergency treatments. **a)** Radiation Oncologists—Consultants & Resident doctors **b)** Technical Staff **c)** Nursing staff **d)** Nursing orderly staff **e)** Lower Division Clerk **4.4** Nursing staff may be required in the department, where contrast injections /sedation procedures are being carried out. **4.5** All Staff shall be trained on respective core activity & work under supervision during induction period (1week). **4.6** Training of all staff shall also be periodically done for the following at the minimum: **i.** Radiation Protection Rules **ii.** BMW waste rules **iii.** Radiation safety and Infection control practices	
5	**Materials**	HOD Radiotherapy /Senior Technical
	5.1 Consumables and non-consumable materials required in the department shall be listed in a log book e.g., -Consumables – thermoplastic cast, contrast media, syringes, saline, injectors etc. Non Consumables - Protective devices (lead aprons). **5.2** The procurement shall be as per government rules. **5.3** Storage shall be in safe place with appropriate environment control. **5.4** Appropriate stock & inventory shall be maintained to prevent stock outs, over stocking of slow moving items & expiry of items without utilization. Good inventory practices like Vital, Essential, Desirable (VED), First Expiry First out (FEFO), ABC* etc. shall be used. **5.5** Record of issuing & consumption shall be maintained & periodically sent to appropriate authority. **5.6** All instances of stock outs/non-moving stocks/expired stock shall be logged	

	& analyzed. It shall be reported to appropriate authority & Corrective and Preventive Action (CAPA) shall be suggested.	
6	**Drugs & Medication**	
	6.1 Medication shall include the following: **a)** Contrast media –I/V–nonionic/ionic **b)** Contrast media –oral **c)** Medication for resuscitation in crash cart/Emergency Tray **d)** Medicines for sedation/anesthesia **e)** Gases – piped gases, oxygen cylinders/nitrous oxide cylinder **6.2** Procurement shall be as per government rules **6.3** Storage shall be in safe place with appropriate environment control. **6.4** Appropriate stock & inventory shall be maintained to prevent, stock outs, overstocking of slow moving items & expiry of items without utilization. Good inventory practices like Vital, Essential, Desirable (VED), First Expiry First Out (FEFO), ABC* etc. shall be used. **6.5** Record of issuing & consumption shall be maintained & periodically sent to appropriate authority. **6.6** All in stances of stock outs/non-moving stocks/expired stock shall be logged & analyzed. It shall be reported to appropriate authority & CAPA shall be suggested.	Nursing Officer /Technologist
7	**Patient work flow protocol**	
	Arrival of patient in radiotherapy department: **7.1** A central reception /help desk will register /schedule the patient for radiotherapy as per the instructions in the patient file seen by Resident doctors in Main OPD. **7.2** Transport of patient from OPD/ IPD shall be the responsibility of the sender department. **7.3** One trolley & wheel chair shall be available in the department to shift a critical patient to ICU/ ward, in case of an adverse event. **7.4** Central reception /help desk shall be responsible for providing the following information the to the patients– **a)** Date & time of simulation planning procedure **b)** Necessary Preparation like full bladder/ empty bladder etc. **c)** List of previous reports with scanning images to be brought. **d)** Any patient coming for planning procedure requiring contrast injection/ sedation/ intervention shall be instructed to be accompanied by a responsible adult/next of skin mark. **e)** Case of queries regarding routine medication shall be addressed by /referred to available Radiation Oncologist/doctor in the department.	Nursing orderly /Technologist
8	**Appropriateness/justification**:	Radiation

		Oncologist
	8.1 All therapeutic requisition forms will be duly filled by their referring **Radiation Oncologist** with appropriate indication & clinical details, appropriate diagnosis, proper TNM staging (if relevant) **8.2** The details shall be verified by a Radiation Oncologist before starting the radiotherapy treatment. **8.3** Current best practices, availability of equipment and patient safety shall be kept in mind while choosing the appropriate treatment for a particular clinical situation. **8.4** In case the therapy request is found unjustified/unsafe/unavailable, further clarification shall be sought from their referring Radiation Oncologist before accepting it. **8.5** The above shall be re-verified on the day of treatment by the **Radiation Oncologist**, **Medical Physicist** and **Technologist** on duty at Respective treatment units.	
9	**Scheduling**	
	9.1 Scheduling shall be done on first come first scheduled basis taking into account the staging and prognosis of the disease. **9.2** Priority slots shall be kept for Emergent and Urgent palliative and hemostatic treatment, Indoor patients, and Intensive care patients. **9.3** Pediatric patients, senior citizens, other vulnerable patients, and patients on certain medication (e.g., Diabetics) shall be prioritized. On the day of study by the operator in-charge.	
10	**Patient Information**	Nursing Officer /Technologist
	10.1 Instructions regarding full Bladder/Empty Bladder, Skin Mark etc. Accompanying person shall be given in writing, at the time of scheduling **10.2** All the details of the procedure will be explained to the patient by the Nursing Officer or technician. **10.3** Prior to starting the treatment Radiation Oncologist shall confirm that informed consent has been taken. **10.4** Information about use of ionizing radiation their adverse effects, shall be given at the time of planning and before starting the treatment. Help desk reception also shall be empowered to provide the information. Follow up advice during and post treatment shall be provided by the Radiation Oncologist verbally/ documented in the patients File and OPD Card.	
11	**Informed Consent**	Nursing Officer /Technologist
	11.1 Where there is use of ionizing radiation, contrast Injection / sedation /invasive procedure, involved a formal **Informed consent** will be documented. **11.2** The Consent will document the indications, benefits, risks and possible alternatives to the proposed treatment.	

	11.3 It will be signed and dated by the Radiation Oncologist, Patient/ guardian and an impartial witness. Pretreatment risk assessment check list can be included in the consent format.	
12	**Pre- treatment safety check/risk assessment**:	
	12.1 For planning simulation procedure last menstrual period (LMP) shall be ascertained, and documented, wherever appropriate to ensure that unnecessary radiation exposure is not given to pregnant women. **12.2** For contrast injection, a check list containing history of allergy, HT, DM, renal disease, cardiac disease, asthma, must be checked & documented; preferably as a part of consent. Recent Serum creatinine levels shall be documented to screen for renal dysfunction. **12.3** In addition to risk of contrast, as part of consent. The adverse effects of Ioninising radiations should be informed and documented in the consent form. **12.4** Separate consent shall be taken for sedation.	
13	**Patient Identification**	
	13.1 A three level patient identification check should be performed before taking up the patient for planning procedure or for daily treatment .one of which shall be UHID number., By asking the name of the patient and not by calling them, and if available matching the face of patients with the digital picture available in the system **13.2** At the time of simulation and treatment, correct patient for correct treatment of correct side/site shall be ensured by the Technologist/Radiation Oncologist performing the procedure. All images will be appropriately labeled for patient ID, side marker & date of examination and date of treatment. **13.4** At the time of planning and before starting the treatment, patient ID shall be verified on requisition form , imaging films, planning Dicom images , pretreatment portal images, at every step by Radiation Oncologist, Medical Physicist and Technologist involved. **13.5** At the time of completion of treatment the Radiation Oncologist shall ensure to provide correct treatment summary for correct patient, containing all the vital information of the dose delivered mentioning about CTV, GTV and PTV for future references.	Radiation Oncologist /Technologist/ Medical Physicist /Nursing Officer Radiation Oncologists /Technologist
14	**Patient preparation**:	
	14.1 Removal of metallic artifacts, change of clothing, where ever required. **14.2** For planning CT simulation, change of clothing, removal of metallic articles where ever required. **14.3** Oral contrast water/air, rectal contrast/water/air, IV line wherever appropriate	Nursing officer /Technologist
15	**Performance of the procedure:**	

	15.1 Procedure for planning simulation **a)** For a Non contrast CT simulation, no special preparation is required. But patient may be asked to follow the full bladder protocol during planning and treatment depending upon the site involved **b)** As with most other planning and treatment procedures, jewelry and other metallic articles should be removed and handed over to the accompanying person. **c)** Patient is appropriately positioned and may asked to hold breath/ be still while planning image is taken **15.2** For contrast enhanced CT simulation procedure **a)** Informed consent should be taken before taking up the patient for study **b)** Preparation as advised at the time of booking depending on area to be planned for treatment.	Technologist /Radiation Oncologist /Nursing officer
	c) Change of clothes and removal of metallic articles/jewelry. **d)** IV line cannulation for injection of appropriate amount of contrast to be placed. **e)** Administration of barium suspension as appropriate to examination. (or oral contrast specially in case of carcinoma of Esophagus) **f)** Patient appropriately positioned & image taken, keeping ALARA principle in mind. **15.3** At the time of starting of treatment **a)** Patient arrives at scheduled time for treatment at the radiotherapy reception. **b)** Patient's identification is checked and confirmed by the receptionist and the concerned Doctor is informed about patient's arrival. **c)** The Radiation Oncologist will verify and approve the treatment plan prepared by Medical Physicist the approved plan is accordingly sent to the Linear Accelerator (treatment unit) for starting up the treatment. **d)** Patient is then taken on the treatment couch after necessary preparations like changing of clothes, full bladder protocol if required, after going through the three level identification check **e)** Patient is properly positioned as was done during planning, keeping all the details in record e.g. Head rest, immobilization cast, arms and legs position during planning. **f)** After setup , Medical Physicist is asked to provide the treatment shift details and patient is shifted in reference to planning isocentre to treatment isocentre **g)** Pretreatment portal image or CT is taken on treatment unit with the help of EPID to verify the accuracy of the treatment to be delivered. **h)** The portal images are matched with the planning images as	Nursing officer / Technologist/ Medical Physicist / Radiation Oncologist

	imported through DICOM and verified by the Radiation Oncologist. **i)** Any shift if required Is applied in table position as approved by Radiation Oncologist to accurately deliver the prescribed dose to the target volume. **j)** After performing all the necessary checks and shifts as approved the treatment is delivered in fractions prescribed. Not exceeding the permissible dose levels. **k)** Patient is relived after treatment and will be scheduled for certain number of days as prescribed for treatment.	
	15.4 Performing Brachytherapy **a)** Patient arrives as scheduled with requisition form & pre advised preparation.(NPO as anesthesia required) **b)** Procedure of Application (insertion of applicator for brachy therapy) is performed by a team of Doctors Radiation Oncologist, including anesthesia team, Nurses etc in the adjacent Minor OT. **c)** After successful application the patient is shifted to the brachy therapy unit and portal images are taken in AP and LAT views by Technologist for planning purpose **d)** The rectal marker is placed and bladder is also marked with contrast injection for accurate planning before taking up the portal images **e)** Then the planning section is performed by the Medical Physicist as per the prescription requisite form duly signed by Radiation Oncologist. **f)** Planning is done considering maximum coverage to the target volume and minimum dose to the bladder and rectum , by physicist **g)** The verified and approved plan by Radiation Oncologist is then transferred to the brachy unit **h)** Treatment is delivered according to the approved plan by the Technologist on duty conspiring safety in all the aspects, as it involves direct source of radiation to be inserted inside the patient. **i)** After completion of treatment, the source is drawn back in the safe position automatically, but it's the duty of the Technologist to ensure the proper parking of the source at safe place before releasing the patient from the unit. **j)** After all the safety measuring steps and after completion of treatment the patient is shifted to post-operative care for observation under resident doctor and nursing staff. **k)** After few hours of observation the patient is shifted to general ward after removal of applicator, rectal markers etc. **l)** From ward patient can be discharged if stable.	Technologist /Radiation Oncologist/ Anesthesiologist /Nursing Officer
16	**Radiation protection**:	

	16.1 AERB guidelines and ALARA principle will be followed for all radiation exposures **16.2** Patient Protection: Appropriate imaging, ascertaining pregnancy status of female patients, use of gonadal covers/ lead shields wherever appropriate, use of low dose exposures, especially for children. **16.3** Staff protection: Appropriate rosters /rotation of technical staff from radiation to non-radiation areas. Provision of radiation protection barriers/lead apron /thyroid shield, lead goggles/gonadal shields wherever appropriate. Provision of TLD badges for monitoring of radiation exposures. Radiation workers shall mandatorily be wearing the TLD badges during working hours. **16.4** Leakage surveys of installation sites of all radiation equipment to ensure that staff, patient & visitors to the department are protected. Entry to radiation rooms shall be restricted by suitable signage's and red light. Attendants assisting the patient shall be preferably males. Female attendant shall be Screened for pregnancy status	Technician/ Radiologist Technologist & RSO
17	**After completion of treatment**	Nursing Officer /Technologist
	17.1 The department will ensure separate treatment summary for emergency, OPD and IPD patients. **17.2** A complete schedule of follow-up visits along with the required tests list should be handed over the patient or attendant before leaving. **17.3** A diet chart by the dietician will be handed over to the patients for better and fast recovery. **17.4** For IPD patients, the departmental orderly will personally collect /the treatment summary. For OPD patient, the dispatch of treatment summary will be done from a common dispatch center in the department. **17.5** At the time of hand over of the treatment summary, it shall be ensured by checking patient identifiers that correct report is handed over to the correct patient.	
18	**Maintenance of records** **18.1** All the departmental records shall be classified as under: **a)** Office Files **b)** Leave records **c)** Equipment records **d)** Monitoring records **e)** Material & consumable records **f)** Patient work load related data **g)** Records pertaining to patients (e.g., request forms, consent forms, reports and images(hard/softcopies)	Technologist

	h) Others/miscellaneous **18.2** Records pertaining to patients shall be stored in retrievable conditions for at least 3 years. **18.3** All other office / maintenance records shall be retained as per GNCTD rules. **18.4** Department will ensure that blank forms & format for consent and treatment prescription or diagnostic request are available in the department.	
19	**Inventory Control**	Senior Technologist
	19.1 Departmental inventory of material shall be maintained by the store In-charge or technical in charge. The following shall be defined for each items **a)** Buffer stock **b)** Reorder level **19.2** Issue register shall be maintained & kept up to date All instance of stock outs/ nonmoving stock/expired unused stock shall be logged & analyzed in departmental committee for appropriate Corrective and Preventive Action (CAPA).	
20	**Equipment maintenance–repair & Down time management**	Technologist/ Medical Physicist
	a) Downtime of equipment clause shall be incorporated in every equipment maintenance contract **b)** Contingency plan for downtime of each equipment shall be documented. It will ensure uninterrupted patient service. **c)** Periodic preventive maintenance calendar for all equipment shall be available along with contact details of each vendor. **d)** Response time for complaints shall be monitored for each equipment. Timely renewal of maintenance contract & statuary compliance shall be ensured.	
21	**Day to day working of the department**	HOD Radiotherapy
	HOD shall ensure the following (at minimum)for Smooth day to day functioning of the department **a)** Rosters **b)** Leave Records **c)** Grievance handling **d)** Disciplinary procedure **e)** Facility Management **f)** Housekeeping **g)** The HOD will take daily/weekly, scheduled and unscheduled rounds to ensure good Facility management & housekeeping	

ANNEXURE-A

External beam Radiotherapy

External beam Radiotherapy (EBRT) is a method for delivering a beam of high-energy x- rays. The beam is generated outside the patient (we use linear accelerator) and is targeted at the tumour site. This high energy x-rays can deposit their dose to the area of the tumour to destroy the cancer cells and with careful treatment planning, spare the surrounding normal tissues. No radioactive sources are placed inside the patient's body. We are using **Varian Linear Accelerator** with Dynamic Arc machine with which we can use Photons for treating cancer patients.

Electron therapy

Electron beams are useful for treating superficial lesions because the maximum of dose deposition occurs near the surface. The dose then decreases rapidly with depth, sparing underlying tissue. The energies we have are 5,7,8,10,12, and 14. Depending on the energy this translates to a treatment range of approximately 1–5 cm (in water-equivalent tissue). Energies above 18 MeV are very rarely used. Electrons have the advantage over X rays in certain circumstances because of their property of delivering maximum energy at a particular depth, below that depth radiation is practically non-existent. In situations where we have to give radiation to superficial areas and save the underlying normal tissue from getting radiation we use electrons. e.g. neck node over spinal cord, chest wall, scalp over brain etc.

B) Photon therapy:

Treatment using high energy photons of energy 6MV is called photon therapy. These methods include:

- **3D Conformal therapy**

Three dimensional (3-D) conformal radiation therapy is a technique where the radiation beams used in treatment are shaped to match the tumour with the help of multi leaf collimator.

- **Intensity Modulated Radiation Therapy (IMRT)**

Intensity Modulated Radiation Therapy (IMRT) is the very advanced technique which allows radiation to be more exactly shaped to fit each tumour. With IMRT, the radiation beam can be

broken up into many "beam lets," and the intensity of each beam let scan be adjusted individually. Using IMRT, it is possible to deliver higher dose of radiation to the tumour, thereby increasing the effectiveness at killing cancer cells with less damage to nearby healthy tissues. It reduces side effects or accompaniments of radiation.

Various indications are Brain tumours, head and neck carcinoma, thoracic malignancies, carcinoma prostate, etc.

- **Image guided radiotherapy(IGRT)**

In Image guided radiotherapy (IGRT), repeated imaging scans are performed during the treatment. This imaging scan is processed by computers and allows positioning the patient to exact location as planned before radiation strikes the target. Repeated imaging increase the precision for higher doses of radiation to the tumour and thereby decreasing the total radiation dose to normal tissue.

- **4D Respiratory Gating**

4D gating is a mechanism where moving tumours can be treated like lung cancers, breast tumours or abdominal malignancies .Where tumour changes its position between (interaction) and during (interaction) the treatment .4 D gating adjust for target motion and positional uncertainty and localize the target with greater accuracy.

- **Rapid arc**

Rapid arc is a latest advancement in radiotherapy in which the entire treatment duration can be reduced to few minutes especially useful for patients who cannot lie down in isolation for long duration. Apart from duration the treatment technique renders better dose distribution and a better tumour control.

ANNEXURE-B

Brachytherapy

Brachytherapy is a procedure of radiation therapy where radiation source is placed in close proximity to tumour or inside tumour bed. It is means of irradiating the desired area to high dose of radiation for better local control. It may be done alone or in combination of external beam radiation therapy.

There are many methods of brachytherapy viz. Intracavitary, Interstitial, Intra luminal, Surface mould etc.

- **Intracavitary** brachytherapy is done in carcinoma cervix. In such cases initially treatment is done with External beam radiation therapy and then boost dose is given with brachytherapy. **I**ntravaginal or Sorbo is done to boost the local area in post-op cases of Cancer endometrium and carcinoma cervix.

- **Intraluminal** may be done for carcinoma Esophagus, or intrabronchial irradiation.

- **Interstitial** brachytherapy is done in cases of Carcinoma breast, Soft tissue sarcoma, head and neck cancers (tongue, buccal mucosa etc.)

- **Surface mould** is done for superficial lesions eg: skin malignancies etc.

Here we have a dedicated brachytherapy procedure room and treatment room. Procedure room has facility for Gynae application under aseptic care. Treatment room has 24 channel brachytherapy system (Varisource 1X) which can treat a very large tumour in single time.

Varisource iX) is an advanced high dose rate brachytherapy system which uses Iridium 192 for the treatment of tumours.

1) Patient due for brachytherapy first comes to front office reception in the Basement and is assessed by Consultant in charge. Doctor explains about the Procedure and advises necessary investigations as required.

2) If found to be fit meets the brachytherapy sister in charge and she gives the appointment to the patient along with necessary instructions for the procedure

blood investigation (as advised by consultant required prior to procedure, NBM for 5-6 hrs ,shaving and cleaning the desired area as required for the procedure).

3) Nurse in-charge reminds the doctor about the procedure one day prior and also the Medical Physicist so that Quality assurance of the machine and necessary checks may be done.(See Annexure-G)

4) She also ensures that the instruments and applicators are received from CSSD. On the day of application patient meets the doctor and if found to be fit for application is sent to sister for the preparation and front office in charge prepares the bill for the procedure which is deposited on ground floor billing office.

5) Patient is shifted to procedure room/OT (as required for the procedure) along with sister and GDA. All procedures requiring anesthesia are done in main OT (Interstitial brachytherapy).Intraluminal brachytherapy is done along with Gastroenterologist or respiratory physician in Endoscopy room.

6) Patient is admitted in the ward and then shifted to OT/procedure room as required.

7) Doctors performs the procedure under complete aseptic care and applicator is placed.

8) Patient is then shifted to the CT scan room, and imaging is done for planning purpose.

9) Medical Physicist plans and it is evaluated by the consultant. After the plan is approved, it is exported to the machine console and patient is treated.

10) After treatment applications are removed and assessed by doctors for any bleed and sent to ward if admitted with necessary post procedure evacuations.

ANNEXURE-C

MOULD ROOM PROCEDURE

1. Mould Room/C.T Patient nominal register/ Radiotherapy chart & data sheet /RT planning register
2. Verify Patient again, thoroughly instruct the patient about the procedure and make him/her comfortable for the procedure.
3. Take Consent (in the presence of consultant) on the consent form after explaining the procedure to the patient in his own language. Take consent for contrast whenever needed.
4. Take patient's old records, ask patient to remove valuable objects and change to hospital gown.
5. Monitor patient for vitals , events e tc update details in patient file (perform Secure IV access if necessary)
6. Enter patients Name, Age, Sex ,Site of Disease, Consultant's name Setup notes on CT request form
7. Instruction to the patient regarding the procedure is given and with their permission, Patient is positioned based on the parameters for the procedure and protocol,
8. Make immobilization (Orfit cast or Vacloc) according to the prescription and site with the help of accessories provided & label the individual patient's details in each. For Electron beam, radiation shielding cutouts can be made and records are maintained in the registers.
9. **In case of any adverse event, abort procedure, manage the incidence & report it to the authorities concerned.**
10. Patients are made comfortable and relax in waiting area till CT simulation.

ANNEXURE-D

CT SIMULATION (PLANNING CT PROCEDURE)

The goal of simulation is to determine the treatment position that will be used daily, to make devices that will help the patient maintain that position, and to obtain the necessary images for treatment planning.

1. Schedule/Register the patient details in the new study data section of CT Scanner control Console Desktop, select appropriate Orientation of the Patient, Slice thickness protocol, &make all system ready for the Scan

2. Align the Mould Room Accessories to the Flat Carbon Couch Dedicated for Radiotherapy planning with the help of orthogonal lasers before positioning the patient.

3. Inform& Instruct the patient about the CT Scan procedure, if the patient is a known Claustrophobic allow him to settle down for a while, by giving proper awareness make him/her ready for the procedure a, Then align the patient on the setup accessory made for the patient,

4. Immobilize the patient with the help of accessories previously made, mark all the points where the sagittal, Axial & Coronal External laser intersects on the body of the patient or Casts or any other accessories which will be accurate & easy for the execution of EBRT and Further Shift(X, Y, Z) to be done.

5. CT compatible lead fiducial markers are placed at the intersected points and the patient is aligned with respect to the scan limit. Give proper Shielding to the parts other than scan area.

6. Administer contrast if required as per requisition, perform the test & update details in Mould Room/Planning CT requisition form. Document volume of contrast usage in consumable item register

7. Take the 2D Scanogram for the Scan limit planning purpose, plan the limits of the same, Select the desired Slice thickness and scanning parameters like kVp, mAs as low as reasonably achievable, Instruct the patient for the final time regarding breath control, Administration of contrast media if any, Beam ON for the final Scan

8. After the proper acquisition of image data, Release the patient with proper care, send the patient back to the Radiation Oncologist concerned and appointment is given for first day of treatment.

ANNEXURE-E

TREATMENT PLANNING

1. CT scan images are imported on the treatment planning system and patient data is stored with a unique ID.

2. If MRI is also done or data available for the planning purpose the data is imported and image fusion is done by the Radiation Oncologist.

3. Contouring of critical structures and target volume delineation is done by the consultant in charge or his team members like residents.

4. Contour is verified by the Doctors/SR and dose prescription and dose constraint is given on the prescribed format. He/ she must mention the intent of the treatment, Type of radiation technique, energy and any specifications related to patient must be mentioned on the radiation card. The radiation card should be signed by the consultant.

5. Planning is done by the Medical Physicist which may take 1-2 days or more according to the type of plan. One or more plan may be done for comparison.

6. Treatment plan is evaluated by the Doctors/SR along with the Medical Physicist and the best plan is chosen and approved by the Radiation Oncologist otherwise plan is modified if desired by consultant for the specific needs of patient.
7. After the plan is approved the treatment approval is done by the Medical Physicist and print outs of the approved plans are filed in the treatment file.
8. Prior to the scheduling patient specific QA is done by the Medical Physicist.(see Annexure-I)
9. Treatment plan is scheduled for the implementation of the treatment.

ANNEXURE-F

IMPLEMENTATION OF APPROVED TREATMENT

1. Patient comes to the department on scheduled time and meets the front office staff on radiation reception who directs him to the waiting area.

2. Patient changes into hospital gown in the changing area and is directed towards treatment room by GDA.

3. Scheduled treatment plan is mode up to the treatment console.

4. Patient is taken to the treatment room and lies down on treatment couch. Immobilization devices are fixed and laser beam is matched with the marks on the mould.

5. Implementation of plan is done by Technologist in presence of Medical Physicist and Radiation Oncologist.

6. KV/MV imaging or CBCT is taken by the Technologist and matched for shift and with Digitally Reconstructed Radiograph (DRR).

7. After that the shift is recorded on RT chart and applied before the treatment is started.

8. During treatment patient is monitored through CCTV for any discomfort or movement and can also interact with microphonel for reassuring if patient is nervous or apprehensive.

9. Patient is given appointment for next day on the appointment card.

ANNEXURE-G

QUALITY ASSURANCE

Quality assurance (QA) is essential for the safe and effective treatment of the patient.QA is done to ensure accurate and reproducible dose delivery on a day - to- day basis. It is essential that the radiation therapy equipment satisfies the physical requirement expected of it and meet the internationally accepted performance standard.QA is necessary for both external beam therapy and brachytherapy.

- **External beam Therapy**

The aim of these tests are to ensure that the mechanical and radiation parameters are within the specified tolerance limits and the mechanical functions are satisfactory from operational and radiation safety point of view. QA procedure depends on test and test criteria which primarily depend on stability of parameters tested (daily, weekly, monthly and annually).

A) Daily QA: Following are the daily QA which are done before treating the first patients of the day.

S.No	Activity	Control	Output	CTQ	Resp
A.1	X ray output constancy	<3%	pass	Compliance 100%	Medical physicist
A.2	Electron output constancy	<3%	pass		
A.3	Lasers	<2mm	pass		
A.4	Distance indicator	<2mm	pass		
A.5	Door interlocks	Functional	pass		
A.6	Intercom(CCTV)	Functional	pass		

Monthly QA:

S. No	Activity	Control	Output	CTQ	Resp
C.1	X ray output constancy	<2%	pass	Compliance 100%	Medical physicist
C.2	Electron output constancy	<2%	pass		
C.3	Backpointor constancy	<2mm	pass		
C.4	X ray central axis dosimetry parameter constancy (PDD, TAR, TPR)	<2%	pass		
C.5	Electron central axis dosimetry parameter constancy (PDD)	<2% at therapeutic depth	pass		
C.6	X ray beam flatness constancy	<2%	pass		
C.7	Electron beam flatness constancy	<3%	pass		
C.8	X ray and electron beam symmetry	<3%	pass		
C.9	Emergency off switches	Functional	pass		
C.10	Wedge and electron cone interlocks	Functional	pass		
C.11	Light/radiation field coincidence	2mm or 1 % on a side	pass		
C.12	Gantry/collimator angle indicators	1º	pass		
C.13	Tray position and applicator position	Functional	pass		

C.14	Field size indicators	<2mm	pass		
C.15	Cross-hair centering	<2mm Diameter	pass		

B) Annual QA:

S. No	Activity	Control	Output	CTQ	Resp
D.1	X ray/electron output calibration constancy	<2%	pass	Compliance 100%	Medical physicist
D.2	Field size dependence of X ray output constancy	<2%	pass		
D.3	Output factor constancy for electron applicators	<2%	pass		
D.4	Central axis parameter constancy (PDD, TAR, TPR)	<2%	pass		
D.5	Off-axis factor constancy	<2%	pass		
D.6	Transmission factor constancy for all treatment Accessories	<2%	Pass		
D.7	Wedge transmission factor constancy	<2%	pass		
D.8	Monitor chamber linearity	<2%	pass		
D.9	X ray output constancy with the gantry angle	<2%	pass		
D.10	Electron output constancy with the gantry angle	<2%	pass		
D.11	Off-axis factor constancy with the gantry angle	<2%	pass		
D.12	Arc mode Safety interlocks	Functional	pass		

D.13	Collimator rotation isocentre	<2mm Diameter	pass	Compliance 100%	Medical physicist
D.14	Gantry rotation isocentre	<2mm Diameter	pass		
D.15	Table rotation isocentre	<2mm Diameter	pass		
D.16	Coincidence of collimator, gantry and table axes with the isocentre	<2mm Diameter	pass		
D.17	Coincidence of the radiation and mechanical isocentre	<2mm Diameter	Pass	Compliance 100%	Medical physicist
D.18	Table top sag	<2mm	pass		
D.19	Radiation protection Survey	<2mR/hr	pass		
D.20	Treatment table position Indicators	<2mm /1º	pass		
D.21	Latching of wedges and locking tray	Functional	pass		
D.22	Jaw symmetry	<2mm	pass		
D.23	Field light intensity	Functional	pass		

F) Patient Specific QA

IGRT and IMRT and techniques make use highly complex machines to deliver the radiation to the Target (Planned Target Volume).These systems are controlled by highly sophisticated computers and delivery mechanism. The Quality Assurance of these systems helps to deliver a Quality therapy to the patients.

QA test is carried before the treatment. Each IMRT/IGRT plan is analyzed by following methods

1) **Gamma Analysis**

1.1 I- Matrixx

TPS generated Dose fluence map and irradiated plans fluence map are compared using Omni Pro IMRT Software. Pass criteria are as follows Dose fluence maps - 3%

- Distance to Agreement (DTA) - 3mm

DTA

The DTA is the distance between a dose point in the calculated distribution and the nearest point in the measured distribution containing the same dose value. The user can define pass/fail criteria for the dose difference distance.

Dose Fluence map

Comparing two dose distributions by simplest methods, e.g. comparing iso-doses or difference may not be appropriate in case of dose fluence map. Misjudgement when checking the agreement of two dose distributions may occur in the following cases:

- The difference between two dose-distributions can be large in high-gradient regions, even if the iso-doses are relatively close to each other.
- The iso-dose distance between two dose distributions can be large in regions with a flat dose distribution, although the difference in dose may be quite small.

If both parameters (dose and iso-dose distance) are outside their pass/fail

Criteria, the agreement "fails “according to the gamma method.

If only one parameter is outside the defined pass/fail criteria but the other well

Inside, the result of the comparison can still pass the calculation.

1.2 Portal Dosimetry

TPS Generated Dose fluence map and EPID acquired Dose fluence map are compared, using the gamma evaluation criteria (3% and 3mm of DTA), Gamma Avg. Gamma Max, and Gamma >1% of all the fields are evaluated.

2. Correlation Coefficient

The correlation coefficient **r** describes how well two data-distributions are correlated to each other.

- *r*=1 means that they are highly correlated,
- *r*=0 means that there is no statistical correlation between the two distributions.

Correlation coefficient is determined using OmniPro I`MRT software

3. Histogram Analysis of Gamma

Histogram displays the data value (e.g. the dose) on the x-axis, and the number of pixels in this range is displayed on the y-axis (I Matrixx)

4. MLC Movement analysis

During every IMRT plan execution, MLC movement is recorded and analysed using Argus Software.

• Brachytherapy

The Quality Assurance of these systems helps to deliver a Quality therapy to the patient.

Daily QA: Daily QA is executed before treating the first patients of the day.

S. No	Activity	Test Methodology	Control	CTQ	Resp
1.	Door interlock test	Verify that source automatically retracts when door opens	Pass	Compliance 100%	Medical Physicist
2.	Console keytest	Stops the source motion unless the console key is released	Pass		
3.	After loader key test	Stops the source motion unless the after loader key is released	Pass		
4.	Emergency button test	Verify that source automatically retracts when the emergency button is activated	Pass		
5.	Console interrupt test	Verify that source automatically retracts when the console interrupt button is activated	Pass		
6.	Intercom/Audiovisual	To check whether it is functional	Pass		
7.	Catheter misconnect test	Verify source motion is stopped when the catheter is misconnected	Pass		
8.	Probe connect test	Verify source motion is stopped when the probe is not connected	Pass		
9.	Dose Delivery accuracy	Verify date ,time and source strength in treatment unit planning computer	Pass		

Quarterly/Source exchange QA: After every source exchange the following QA must be performed.

S. No	Activity	Test Methodology	Control	CTQ	Resp
1.	Source calibration test	Intercompare secondary standard used for quarterly calibration against departmental substandard.	Pass	Compliance 100%	Medical Physicist
2.	Positional Accuracy test	Verify that radioactive source position agrees with dummy marker against dwell position markers used in simulation	Pass		
3.	Temporal accuracy test	Verify timer linearity and absolute accuracy.	Pass		
4.	Treatment room radiation test	Safety integrity of radiation installation	Pass		
5.	Position verification test	Verify position of simulation markers agrees with radioactive source.	Pass		
6.	Obstruction detection test	Verify that source automatically retracts when there is any obstruction in its path.	Pass		
7.	Wipe test	To check whether there is any contamination inside the catheter where the source movement has occurred	Pass		
8.	Door interlock test	Verify that source automatically retracts when door opens.	Pass	Compliance 100%	
9.	Console key test	Stops the source motion unless the console key is released	Pass		

10.	After loader key test	Stops the source motion unless the after loader key is released	Pass		Medical Physicist
11.	Console interrupt test	Verify that source automatically retracts when the console interrupt button is activated.	Pass		
12.	Emergency button test	Verify that source automatically retracts when the emergency button is activated.	Pass		
13.	Intercom/Audiovisual	To check whether it is functional	Pass		
14.	Catheter misconnect test	Verify source motion is stopped when the catheter is misconnected	Pass		
15.	Probe connect test	Verify source motion is stopped when the probe is not connected	Pass		
16.	Dwell timer test	Check that treatment unit correctly decays source Strengths and corrects dwell times for decay.	Pass		
17.	Dose Delivery accuracy	Verify date ,time and source strength in treatment unit planning computer	Pass		

Annual QA: Besides the quarterly QA, below QA needs to be done

S. No	Activity	Test Methodology	Control	CTQ	Resp
1.	Radiation protection QA	Exposure rates outside the radiation facility should meet the regulations and the leakage radiation rates around the unit should be acceptable.	Pass	Compliance 100%	Medical Physicist

ANNEXURE-H

IN CASE OF RADIATION EMERGENCY CONTACT FOLLOWING:

S. No.	Name of the officer	Designation	Contact Number
1	**Dr Vatsala Aggarwal**	**DIRECTOR**	9718990112
2	**Dr Pragya Shukla**	Asstt. Prof Radiation Clinical Oncologist, Chairman, RS Committee	9560390107
3	**Mr M Sasindran**	Medical Physicist & RSO, Member Secretary, RS Committee	9971491227
4	**Ms Mamta Mahur**	Medical Physicist, Member, RS Committee	9560390150
5	**Dr Surendra Kumar**	Asstt. Prof Anaesthesia , Member, RS Committee	8800190660
6	**Mr Deepanshu Goel**	Asstt. Engineer (Civil), Member, RS Committee	9811190710
7	**Mr Parveen**	Security In-Charge	8287523900
8	**Police (GTB Complex)**	SHO (PS. GTB Complex)	011 2213 1069

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AMENDMENTSHEET

Sl. No.	Page no	Date of amendment	Details of the amendment	Reasonns	Signature of the reviewing authority	Signature of the approval authority

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The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in a readily identifiable and retrievable form.

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The Manual is reviewed atleast once a year (or in between SOS if so required) and is updated as relevant to the Hospital policies and procedures.

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Name: Designation : HOD /Dept. In charge Signature:	Medical Superintendent Name: Signature:	Quality – Nodal Officer Name: Signature:

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SOP for Radiology

Objective:

To ensure consistently safe, effective, efficient, appropriate, & timely imaging diagnostic servicesto each patient visiting the hospital.

Purpose: Smooth running of radiology department to ensure uninterrupted patient service

Scope : Entire **Radiology Department**

Sl. No.	Activity/Description	Responsibility	Ref Doc/ Record
1.	**Statutory compliance**		
1.1	HOD & RSO shall be responsible for compliance to AERB registration pertaining to equipment using X rays in the department a) eLORA registration/licensing of the institution/department, RSO & all equipment shall be done & maintained b) Periodic QA of equipments& premises (as per AERB guidelines) will be done through the AMC/CMC provider and submitted to AERB. c) Radiation workers will be identified & TLD badge monitoring shall be done for them as perAERB guidelines. d) Periodic health check including blood cell count & general physical examination shall be conducted & recorded for all radiation workers as per AERB guidelines. e) Availability, maintenance, QA of all radiation barriers (lead aprons, goggles, gonadal shields, lead curtains) f) Education, training & monitoring regarding radiation safety practices shall be done by RSO. g) These activities will extend to Cath Labs, DSA labs, C arms in OT etc.	HOD Radiology Deptt. Head/Hospital RSO	

1.2	HOD & P NDT Nodal Officers shall be responsible for compliance to PCPNDT regulations pertaining to US/ECHO/Doppler as well as CT & MRI equipment in the in the department. a) PCPNDT registration of the institute/department/ equipment & personnel handling these equipment shall be done & maintained. b) Daily & monthly reporting on relevant formats to competent authority shall be done. c) All mandated relevant displays and signage shall be maintained as per PCPNDT guidelines.	HOD & PNDT Nodal Officer	
2.	**Signages**	HOD Radiology	
2.1	Statutory Signages: All safety & statutory signangs & displays as per AERB & PCPNDT guidelines shall be placed inside/outside all equipment rooms (as per guidelines). The displays shall be in languages & formats as per guidelines. For PCPNDT, copy of registration certificates & display regarding non declaration of sex of fetus in prescribed format, shall be done in every room where USG/ ECHO equipment is installed. 	HOD Radiology	

2.2	Informative signage – At the minimum following information signages shall be displayed(using appropriate languages, font sizes & format) at eye level. The signage shall be static & permanent (i.e., no standees, posters, running scripts): a) Services provided with room numbers. b) Timings c) Directions d) Safety related education signages X Ray rooms – as (2.1)& (2.3) US/Echo – as above (2.1)		
2.3	Safety signage – Radiation safety Radiations safety signages: Safety signage should be as recommended by AERB including restrictions of patient/attendant entry, hazard lights and pictorial signages appropriate for radiology services (Example picture given) outside of the radiation		
2.4	Display of telephone numbers to be contacted for respective safety codes e.g., code blue/code red/code violet in all rooms where I/V contrast is given.		
3	**Equipment**	HOD/Senior Technician In charge	
	3.1 Procurement & installation of equipments shall be as per government rules. 3.2 Operation of equipment shall be by appropriate personnel qualified & trained for the specific jobs 3.3 Daily calibration shall be performed by the operator technician at the time of switching on in the morning. 3.4 Daily cleaning of cleanable parts of the equipment shall be ensured by the operator at the time of switching off. 3.5 Periodic maintenance (preventive) & periodic calibration & QA shall be done by the service engineers from the AMC/CMC provider. The records shall be maintained by the TechnicalIn charge.		

	3.6 Department shall maintain an equipment log book with information regarding all equipment under the following categories: a) Main Imaging Equipment - e.g., X ray, US, CT, machines, injectors, Boyles apparatus b) Each unit shall be identifiable with a traceability number as reflected on the unit & in the log book. 3.7 All equipment shall have dedicated history sheet where details regarding purchase, operation, functionality, maintenance & breakdown shall be maintained. 3.8 Inventory of all accessory and ancillary equipment.		
4	**Staff/Personnel**	HOD	
	4.1 Availability of appropriately qualified and trained staffs as per the scope of services. 4.2 Availability, job descriptions, rosters, leave records etc shall be ensured as per government guidelines/rules. 4.3 Appropriate numbers and mix of the following staffs shall be available to provide patients services for routine & emergency imaging. a) Radiologists – Consultants & Resident doctors b) Technical Staff c) Nursing staff d) Ancillary staff e) Data Entry Operator 4.4 Nursing staff may be required in the department, where contrast injections/sedation/invasive procedures are being carried out. 4.5 All Staff shall be trained on respective core activity & work under supervision during induction period (1 week). 4.6 Training of all staff shall also be periodically done for the following at the minimum: i. BLS ii. BMW waste rules		

	iii. Radiation safety Infection control practices		
5	Materials	HOD/Technician I/C of store	
	5.1 Consumables and non consumable materials required in the department shall be listed in alog book e.g., - Consumables – Films, contrast media, signages, saline, injectors etc. Non Consumables – Protective devices (lead aprons), cassettes, screens, grids etc 5.2 The procurement shall be as per government rules. 5.3 Storage shall be in safe place with appropriate environment control. 5.4 Appropriate stock & inventory shall be maintained to prevent stock outs, overstocking of slow moving items & expiry of items without utilization. Good inventory practices like Vital, Essential, Desirable (VED), First Expiry First Out (FEFO), ABC* etc shall be used. 5.5 Record of issuing & consumption shall be maintained & periodically sent to appropriate authority. 5.6 All instances of stock outs/non-moving stocks/expired stock shall be logged & analysed. It shall be reported to appropriate authority &Corrective and Preventive Action (CAPA) shall be suggested.		
6	**Drugs & Medication**		
	6.1 Medication shall include the following: a) Contrast media – I/V – nonionic/ionic b) Contrast media – oral c) MR contrast media – I/V d) Medicines for patients preparation e.g., buscopan, Lasix, betablockers, GTN etc e) Medication for resuscitation in crash cart/ Emergency Tray f) Medicines for sedation/anesthesia	Staff nurse/Technician	

	g) Gases – piped gases, oxygen cylinders/nitrous oxide cylinder 6.2 Procurement shall be as per government rules 6.3 Storage shall be in safe place with appropriate environment control. Appropriate stock & inventory shall be maintained to prevent, stock outs, overstocking of slow moving items & expiry of items without utilization. Good inventory practices like Vital, Essential, Desirable (VED), First Expiry First Out (FEFO), ABC* etc shall be used. 6.4 Record of issuing & consumption shall be maintained & periodically sent to appropriate authority. 6.5 All instances of stock outs/non-moving stocks/expired stock shall be logged & analysed. It shall be reported to appropriate authority & CAPA shall be suggested.		
7	**Patient workflow protocol**		
	Arrival of patient in radiology department: 7.1 A central reception/help desk will register/schedule the patient for imaging asper the request form. 7.2 Transport of patient from OPD/ IPD shall be the responsibility of the sender department. 7.3 One trolley & wheel chair shall be available in the department to shift a critical patient to ICU/ward, in case of an adverse event. 7.4 Central reception/help desk shall be responsible for providing the following information the to the patients – a) Date & time of imaging b) Preparation like NPO, full bladder etc. c) List of items like towel/water bottle etc to be brought. d) Any patient coming for imaging requiring contrast injection/sedation/intervention shall be instructed to be accompanied by a responsible adult/next of kin. e) Case of queries regarding routine	Deptt. Staff/ Technician	

	medication shall be addressedby/referred to available radiologist/doctor in the department. f) Method and time for collection of report		
8	**Appropriateness/justification**:	Radiologist	
	8.1 All imaging request forms will be duly filled by the referring clinician, with appropriate indication & clinical details, details of previous imaging, provisional diagnosis, current clinical questions (if relevant) 8.2 These details shall be verified by a radiologists before scheduling the study. 8.3 Current best practices, availability of equipment and patient safety shall be kept in mind while choosing the appropriate imaging for a particular clinical situation. 8.4 In case the imaging request is found unjustified/unsafe/unavailable, further clarification shall be sought from the referring doctor before accepting it. 8.5The above shall be re-verified on the day of imaging by the radiologist on duty at respective imaging stations.		
9	**Scheduling**		
	9.1 Scheduling shall be done on first come first scheduled basis taking into account the capability of the imaging services. 9.2 Priority slots shall be kept for Emergent and Urgent studies,Indoor patients, Intensive care patients. 9.3 Pediatric patients, senior citizens, other vulnerable patients, and patients on certain medication (e.g., Diabetics) shall be prioritized on the day of study by the operator in-charge.		
10	**Patient Information**	Staff nurse/technician	
	10.1 Instructions regarding NPO/ Full Bladder etc. Accompanying person shall be given in writing, at the time of scheduling 10.2 All the details of the procedure will be		

	explained to the patient by the staff nurse or technician. 10.3 Prior to imaging radiologist shall confirm that informed consent has been taken. 10.4 Information about report collection shall be given at the time of imaging. Help desk reception also shall be empowered to provide the information. Follow up imaging advice shall be provided by the radiologist verbally/documented in the report.		
11	**Informed Consent**	Sister/Technician	
	11.1 Where there is contrast injection/sedation/invasive procedure, a formal **Informed consent** will be documented. 11.2 The Consent will document the indications, benefits, risks and possible alternatives to the proposed procedure. 11.3 It will be signed and dated by the Radiologist, Patient/guardian and an impartial witness. Pre entry risk assessment checklist can be included in the consent format.		
12	**Pre-entry safety check/risk assessment**:		
	12.1 For X-ray/plain CT , last menstrual period (LMP) shall be ascertained, and documented, wherever appropriate to ensure that unnecessary radiation exposure is not given to pregnant women. 12.2 For contrast injection, a check list containing history of allergy, HT, DM, renal disease, cardiac disease, asthma, must be checked & documented; preferably as a part of consent. Recent Serum creatinine levels shall be documented to screen for renal dysfunction. 12.3 For invasive/intervention procedures INR must be checked & documented in addition to risk of contrast, as part of consent. 12.4 Separate consent shall be taken for sedation.		
13	**Patient Identification**		
	13.1 Correct patient must be identified for correct procedure at the time of performing the procedure, compiling the report and during	Technician/Radiologist/ Nurse	

	dispatch of report. At least two identifiers shall be used to identify correct patient, one of which shall be UHID number. 13.2 At the time of imaging , correct patient for correct imaging of correct side/site shall be ensured by the technician/radiologist performing the imaging. All images will be appropriately labeled for patient ID, side marker & date of examination. 13.4 At the time of compiling the report, patient ID shall be verified by the radiologist on the envelope, request form, imaging films & reports. 13.5 At the time of report dispatch, the technician/dispatch desk person shall ensure correct report for correct patient by using at	Radiologist/technician	
14	**Patient preparation**:		
	14.1 Removal of metallic artifacts, change of clothing, wherever required. 14.2For ultrasound, change of clothing, filling or emptying of bladder wherever required. 14.3 For CT, change of clothing, removal of metallic articles wherever required. 14.4 Oral contrast water/air, rectal contrast/water/air, IV line wherever appropriate	Nurse/technician	
15	**Performance of the procedure:**		
	15.1 Procedure for taking plain X ray a) For most x-ray examinations(except x-ray of abdomen& spine) no special preparation is required. b) As with most other imaging procedures, jewelry and other metallic articles should be removed and handed over to the accompanying person. c) Patient is appropriately positioned and asked to hold breath/ be still while film isexposed.		
	15.2 Performing Barium studies	Technician/Radiologist/	

	a) NPO b)Preparation as advised at the time of booking depending on area to be examined. c) Change of clothes and removal of metallic articles/jewelry. d) Administration of barium suspension as appropriate to examination. e) Patient appropriately positioned & images taken, keeping ALARA principle in mind.	Reporting Nurse	
	15.3 Performing Urographic examinations a), b) & c) as above. d) informed consent as above of no.11 e) IV line cannulation for injection of appropriate amount of contrast. f) Patient appropriately positioned & images taken, keeping ALARA principle in mind.	Technician/Radiologist/ Reporting Nurse	
	15.4 Performing USG/Doppler a) Patient arrives as scheduled with full bladder for pelvic area and NPO for abdominal examination. b) Radiologist performs the scan using appropriate transducer with assistance of staff nurse. c) Observations recorded and report generated by Radiologist.	Radiologist/Nurse	
	15.5 Performing CT Scan a) Patient arrives as scheduled with requisition form & preadvised preparation. b) Can be contrast or non contrast examination c) For contrast examination-informed consent as above d) All metallic objects removed from area of interest. e) Patient positioned for area to be examined f) IV contrast is injected in appropriate quantity. g) Scanning is to be done choosing	Technician/Radiologist/ Reporting Nurse	

	appropriate protocol as per indication h) Post processing of acquired images. i) Filming in soft tissue, lung, bone window as appropriate in minimum of films in all requisite information. j) Reporting by Radiologist.		
	15.6 Performing interventions a) Ensure availability of attendant /referring doctor b) Proper procedure risk assessment & investigation as appropriate (BT/CT/INR etc) c) All aseptic precautions to be taken d) Universal precaution to be followed all the time e) Done under USG/Fluoro/CT guidance f) Proper labeling and identification of sample g) Appropriate dispatch of collected samples to be ensured by sister/radiologist to referring department/concerned lab. h) Patient to be monitored post procedure as required. i) Inform patient regarding report collection		
16	**Radiation protection**:		
	16.1 AERB guidelines and ALARA principle will be followed for all radiation exposures 16.2 Patient Protection: Appropriate imaging, ascertaining pregnancy status of female patients, use of gonadal covers/lead shields wherever appropriate, use of low dose exposures, especially for children. 16.3 Staff protection: Appropriate rosters/rotation of technical staff from radiation to non-radiation areas. Provision of radiation protection barriers/ lead apron/ thyroid shield, lead goggles/ gonadal shields wherever appropriate. Provision of TLD badges for monitoring of radiationexposures. Radiation workers shall mandatorily be wearing the	Technician/Radiologist Technician & RSO	

	TLD badges during working hours. 16.4Leakage surveys of installation sites of all radiation equipment to ensure that staff, patient &visitors to the department are protected. Entry to radiation rooms shall be restricted by suitable signages and red light. Attendants assisting the patient shall be preferably males. Female attendants shall be screened for pregnancy status		
17	**Processing films/ images**		
	17.1 After exposure and completion of procedure, films will be processed by the available methods. Wet processing is discouraged. If still in use, the technician/ dark room assistant will ensure availability of required solutions at appropriate concentration & temperature, every day. Maintenance of automaticprocessor. 17.2 Dry view /laser/computer methods of image processing are preferred. The choice will depend on the daily throughputs. 17.3 The images will be checked for quality, patient identity, and urgency of reporting, at the time of compiling them for reporting in respective envelopes. 17.4 The technician in charge shall ensure that these envelopes shall reach the reporting station in separate piles for 'urgent' & 'routine'. 17.5 Processing of CT images shall be done by the radiologist to ensure that all findings and regions are represented on the films with appropriate annotations wherever necessary.		
18	**Report compilation**:	Radiologist	
	18.1 Radiologist will ensure compilation of an 'in context' report taking into consideration the clinical details provided by the referring		

	clinicians. 18.2 Patient identity will be checked by the radiologist while compiling the report. 18.3 Quality of X ray/ other images will be ensured to be of diagnostic value. Repeat scans will be ordered if deemed necessary. 18.4 The timeline of reporting will be adhered to, as per the defined turn around time by the department. 18.5 Turn around time for the report: The department/hospitals shall be required to define the turn around time of the radiology reports in two categories for each modalities – a) Routine report (not more than 48 hours) b) Urgent (not more than 6 hours) Emergency report will also be intimated to the treating physician verbally/telephonically. 18.6 The contents of the report shall include the following, at the minimum-- a) Patient identification b) Type of study, region, projection c) Whether any I/V contrast/oral contrast given. Please indicate the name, dose, rate of contrast & whether any adverse events (AE) occurred. d) Details of any medical preparation/sedation, if given. e) Salient findings (positive & negative) f) Provisional diagnosis g) Differential diagnosis Follow up advice, if any.		
19	**Dispatch of report/ Handover**	Staff/Technician	
	19.1 The department will ensure separate dispatch of report for emergency, OPD and IPD patients. 19.2 The patient/accompanying person shall be informed at the time of imaging, how, when & from where the dispatch of report will be done		

	19.3 For IPD patients, the departmental orderly will personally collect/dispatch the report For OPD patient, the dispatch will be done from a common dispatch center in the department. 19.4 For ER patients the orderly from Radiology department shall personally deliver/collectthe report. 19.5 At the time of dispatch, it shall be ensured by checking patient identifiers that correct reportis handed over to the correct patient.		
20	**Maintenance of records** 20.1 All the departmental records shall be classified as under: a) Office Files b) Leave records c) Equipment records d) Monitoring records e) Material & consumable records f) patient workload related data g) Records pertaining to patients (e.g., request forms, consent forms, reports and images (hard/soft copies) h) Others/miscellaneous 20.2 Records pertaining to patients shall be stored in retrievable conditions for at least 3 years. 20.3 MLC records shall be in a separate cupboard under lock & key as per rules (in department/MRD section). 20.4 All other office / maintenance records shall be retained as per GNCTD rules. 20.5 Department will ensure that blank forms & format for reporting are available in the department.	Technician / office staff	
21	**Codes**	HOD	
	Display of contact number (rescue number) for all relevant codes. **Code Blue:** All staff in Radiology department		

	shall be trained on CPR at least 6 monthly. Doctors (radiologists shall be BLS/ACLS trained). Liaison with the hospitals code blue team shall be done for smooth rescue. Code blue teams shall be made. Mock drills shall be carried out at least 6 monthly to ensure compliance. **Code Red & code violet: Desirable**		
22	**Inventory Control**	Technician/Store keeper	
	22.1 Departmental inventory of material shall be maintained by the store In charge ortechnician incharge. The following shall be defined for each items a) Buffer stock b) Reorder level 22.2 Issue register shall be maintained & kept up to date All instance of stock outs/ non moving stock/expired unused stock shall be logged & analysed in departmental committee for appropriate CAPA.		
23	**Equipment maintenance– repair & downtime management**	PMS/Technician/Radiologist	
	23.1 Downtime of equipment clause shall be incorporated in every equipment maintenance contract 23.2 Contingency plan for downtime of each equipment shall be documented. It will ensure uninterrupted patient service. 23.3 Periodic preventive maintenance calendar for all equipment shall be available along with contact details of each vendor. 23.4 Response time for complaints shall be monitored for each equipment. Timely renewal of maintenance contract &statuary compliance shall be ensured.		
24	Day to day working of the department	HOD Radiology	
	HOD shall ensure the following (at minimum) for smooth day to day functioning of the department		

	a) Rosters b) Leave Records c) Grievance handling d) Disciplinary procedure e) Facility Management f) Housekeeping g) The HOD will take daily/weekly, scheduledand unscheduled rounds to ensure good facility management & housekeeping		

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AMENDMENTSHEET

Sl. No.	Page no	Date of amendment	Details of the amendment	Reasons	Signature of the reviewing authority	Signature of the approval authority

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STANDARD OPERATING PROCEDURE (SOP) NUCLEAR MEDICINE DEPARTMENT

1. INTRODUCTION

i. Nuclear medicine is a broad speciality on its own. It comprises diagnostic examinations that result in images of body anatomy and function.

ii. The images are developed based on the detection of energy emitted from a radioactive substance given to the patient, either intravenously.

iii. Generally, radiation to the patient is similar to that resulting from standard X-ray examinations

iv. The functional information provided by nuclear medicine examinations is unique and currently unattainable by using other imaging procedures. For many diseases, nuclear medicine studies yield the most useful information needed to make a diagnosis and to determine appropriate treatment, if any. Nuclear medicine is much less traumatic than exploratory surgery, and allergic reaction to the radiopharmaceutical material is extremely rare.

2. LIST OF SERVICES

i. ONCOLOGY IMAGING
ii. BONE SCAN
iii. THYROID SCAN
iv. PARATHYROID SCAN
v. RENAL SCAN

3. JOB RESPONSIBILITES

3.1. Head of The Department (HOD)/ Professor

- Planning, proposing, processing the proposals, procuring & maintaining of machinery, equipment's & instruments.
- Duties related to Medical Education & Research
- Supervise duties
- Staff Training
- Supervise the medical, paramedical and technical staff
- Administrative functions.
- To exhibit keen interest, initiative & drive in the overall development of the Department.

3.2. SENIOR RESIDENT

- Staff training
- Supervise the medical, paramedical and technical staff
- Take patient histories.
- Interaction with various other clinical colleagues & departments

- Plan and coordinate studies for patients.
- Processing & reporting of diagnostic studies
- Coordinate & conduct Research activities
- Play an active role in the clinical, research and administrative activities of the institute
- Plan and execute new projects
- Image data processing.
- Assist HOD in reporting studies.

3.3. Nuclear Medicine Physicist & RSO

- Supervise the work of the technical staff.
- Prepare Annual Status Reports according to AERB / BARC regulation.
- Dealing with AERB/BARC as per the requirement
- Regular check e-LORA
- Obtain NOC for isotopes.
- QC of all the equipment
- Radiation monitoring.
- Personnel monitoring and records maintenance.
- Ensure Radiation Safety.
- Display of Radiation Symbols
- Periodic training/classes of Radiation safety
- Ensuring the periodic Radiation Safety meeting

3.4. Nuclear Medicine Technologist

- Maintain department records –
  - Patient records
  - Inventory of consumables
  - Inventory of isotopes
  - Equipment log book
- QC of all the equipment.
- Patient preparation.
- Acquisition of studies.
- Elution of isotopes.
- Radiopharmaceutical preparation.
- Basic data processing and film exposure.

3.5. Nursing Staff

- To ensure delivery of patient care through implementation of prescribed medication and monitoring effects.
- To provide nursing care to patients based on established clinical practice standards.
- To collaborate with other disciplines to ensure effective and efficient patient care delivery.

- To promote a safe environment for patients, visitors and co-workers including the implementation of infection control policies of the hospital.
- Maintain the Inventory of medical consumables
- Check that the central oxygen, suction apparatus, BP apparatus, stethoscope etc. are in working condition.
- To supervise the policy of waste segregation
- To see the every procedure tray must be clean
- Other miscellaneous work assigned by the supervisor

4. STANDARD OPERATING PROCEDURE

4.1 INSTRUMENTS/MATERIALS REQUIRED

i. PET-CT, SPECT CT, Medical Cyclotron, Isotope Calibrator, Contamination Monitor, Survey meter, Pocket Dosimeter, Thermoluminiscent Device (TLD) Badges, Lead Shields, required amount of radioactivity.

4.2 Patient Scheduling

i. Check the referring physician's request for radionuclide study.
ii. Check medications and advice preparation accordingly.
iii. Explain the procedure briefly – time duration, cost of the investigation, things to be brought by the patient for the test.
iv. Give appropriate time, considering the available resources (Radioactivity/radio pharmaceutical, available camera time etc). Enter the appointment details in **Appointment Register.**

4.3 Patient Scheduling

i. Explain the procedure to the patient (Check for test specific contraindications, please refer Precautions). Get the informed written consent form signed by the patient.
ii. Evaluate the ability of the patient to tolerate the procedure by recording the relevant history of the patient in **Patient History Form.**
iii. Ensure that an access for administration of radioactivity is available (IV line, Urinary catheter, feeding tube. etc).
iv. Check the need for sedation or pre medication.
v. Check for any specific contraindications for the study requested.
vi. Make sure that the informed consent is obtained whenever and wherever necessary.

4.4 Receipt of Radioactivity

4.4.1. Purpose

i. To ensure safe handling of radioactivity.
ii. To check the external contamination, exposure rates conforms the stipulated values.

4.4.2 Instruments/Materials Required.

i. Survey meter cum contamination monitor, absorbent paper, gloves, isotope calibrator.

4.4.3 Protocol for Opening Radioactive Parcels.

i. The Radioactive consignment is transported and delivered directly to the nuclear medicine department by the vendor in a NON passenger vehicle.

ii. Upon receipt of the consignment. Put on disposable gloves, identify the package for accuracy (Type, Category, Consigner, Consignee and Transport index). A radiopharmaceutical consignment received in nuclear medicine departments are of **TYPE – A.**

Categories of packages

Category	**Limit on maximum radiation level at The external surface of the package (mrem/hr)**	**Limit on the Transport index**
I - WHITE	0.5	0.0
II – YELLOW	50	1.0
III – YELLOW	200	10.0

iii. Visually inspect the package for damage, if damage is apparent, notify and seek help from the Radiological Safety Officer (RSO).
iv. Measure the exposure at 1-meter distance, ensure the value does not exceed transport index indicated on the package.

v. Open the package and verify that the contents agree with the packing slip.

vi. Check the integrity of the generator and look for evidence of breakage.

vii. Wipe the surface of the final source container, especially if there is any reason to suspect contamination. Assay and decontaminate the surface.

viii. Monitor the empty package and packing material with survey meter instrument and discard contaminated objects as radioactive waste, if not contaminated remove the radiation labels and discard them as regular waste.

ix. Complete the details and document the receipt of the package, subsequent inspection and tests. Enter the details in Isotope Receipt Record.

x. Any off-normal situations such as:

Damage to the package.

Package engulfed in fire.

Misplacement and theft of the package.

Loss of identity of the package.

Shall be intimated for assistance and advice in the matter to the competent authority at:

Chairman, Crisis management group, Department of atomic energy, Mumbai 400001

Telephone: 022-2023978, 2830441 FAX – 022-2830441

And

Head, Radiological Physics and advisory division, BARC, CT & CRS,

Anushakthi Nagar, Mumbai 400094, Telephone: 022-5519209, FAX – 5519209.

4.5 STORAGE OF RADIOACTIVEMATERIAL

i) Radioactive materials should be stored in storage area or designated area or specific area.

ii) Stored radioactive materials must be adequately shielded.

iii) Nuclear Medical physicist must ensure the storage area must be locked at all time and can only be accessed by appointed personnel.

iv) Radiation warning sign must be displayed on the storage area door.

v) Only appointed personnel are allowed to mobilise the radioactive material from the storage area

vi) Radioactive materials that have been removed from the storage area have to be checked and ensure in a good condition.

vii) The details of the radioactive materials including type of sources, activity, relocation and the

name of person responsible must be recorded whenever the radioactive material is taken in/out from the storage area.

viii) Storage area must be checked & monitored regularly to detect presence.

ix) In the event of fire breakout, Nuclear Medicine Physicist / RSO has to inform fire fighter thelocation of stored radioactive materials.

x) Record of all finding and investigation must be kept for future reference.

4.6 Radioactive Waste Management

Radioactive waste generated from sealed or unsealed sources in NuclearMedicine is generally in a form of a solid or liquid. These include:

A. Liquid wastes:

i. Unused radiopharmaceuticals and remains of labelled compoundsfrom radioassay kits.
ii. Excreta from patients who have received radiopharmaceuticals inthe course of diagnostic or therapeutic studies.
iii. Supernatant solution from radioassay kits.
iv. Water used to rinse or wash contaminated apparatus
v. Remains of radioactive stock and standard solution.

B. Solid wastes:

i. Contaminated syringes, swabs, needles, drip set, preparation vials, bottles and drinking straws used in nuclear medicine.
ii. Contaminated absorbent papers, towels, bed linens, patient's gowns or hospital's clothing, bed, syringe shields and disposable gloves.
iii. Used radionuclide generator (^{99m}Tc / ^{68}Ga).

4.6.1 Work Instruction

A. Responsibilities: The Nuclear Medicine Physicist/RSO or appointed personnel is responsible for ensuring that these procedures are carried out and all trained staff must follow these procedures. Any problems relating to the storage and disposal ofradioactive waste must be referred to the Nuclear Medicine Physicist/RSO or appointed personnel.

B. Disposal of Radioactive Wastes:

a. Solid Radioactive Waste:

i. Each radioactive waste should be separated according tohalf-lives of radionuclides.

ii. All sharp items generated from radioactive waste (syringe, needle, vial, etc.) shall be deposited into lead lined sharp bins with radioactivity hazard symbol outside the shielded bin at designated area.

iii. All non-sharp items generated from radioactive waste (gloves, absorbent paper and etc.) shall be deposited into lead lined radioactive waste bin with radioactivity hazard symbol outside the shielded bin at designated area.

iv. After the waste bin is maximum two-third full, the bin shall be closed with lid and securely sealed and labelled properly.

v. The appointed personnel shall collect these radioactive waste and transfer into the designated radioactive waste room for decay process.

vi. The radioactive waste shall be stored for decaying up to 10half-lives. After 10 half-lives the dose rate shall be measured before send to third party for disposal process.

vii. There are two options for radionuclide generators:

- Returning to the supplier after use or
- Waiting for decay and dismounting of the elution column afterwards. After a waiting time of 1.5 — 2 months, when the activity and the dose rate are so low that the elution column can be removed, the generator can be dismantled and the material be considered as non-radioactive. Labels should then be removed. Approval from appropriate authority must be obtained prior to dismantling.

viii. All radioactive waste disposals shall be recorded.

b. Disposal of Liquid Radioactive Waste:

i. Waste produced from short half-lives radionuclides like ^{99m}Tc and ^{18}F should be separated from those of longer half-lives and placed in the separate lead lined waste containers.

ii. Waste produced from medium half-life radionuclides like ^{131}I and 99mTc can be stored in the waste room for decay up to 10 half-lives.

iii. Excreta from patients receiving radiopharmaceuticals for diagnostic scan can be discharged directly into the hospital sewerage system.

iv. The radioactive waste shall be stored for decaying up to 10half-lives. After 10 half-lives the dose rate shall be measured before send to third party for

disposal process.

v. All radioactive waste disposals shall be recorded.

c. Return and Disposal of Unused Sealed Source:

i. Sealed sources such as ^{68}Ge and ^{137}Cs etc. are used for calibration and quality control of Nuclear Medicine instrument.
ii. Unused sealed source must be kept in the designated area/ waste room for decay or until return back to manufacturer.
iii. The user must write and get an approval from appropriate authority for disposal purpose.
iv. By practical approach the unused sealed source must be returned to the manufacturer. If a user is unable to return the used sealed source to its manufacturer, the user shall obtain a written approval from appropriate authority prior to sending the used sealed source to the radioactive waste management facility. The radioactive waste management facility shall be approved by the appropriate authority.
v. The dose rate shall be measured and recorded before send to manufacturer.

RECORD

No.	Record Name	Record Keeping Period
	Radioactive Waste Disposal Form	3 years after disposal

4.7 Procedure For Contamination AndDecontamination At Workplace

4.7.1 Procedure for monitoring contamination

4.7.1.1 Survey method using Calibrated Radiation Meter for fixed and removable contamination.

i. Set the instruments parameters. Cover the probe/radiation meter with plastic to avoid contact. Test the battery, reset the reading and measure background reading at about 3-5 m from the contaminated surface.
ii. Assess the potential contaminant area.
iii. Obtain a reading by hold the detector at a distance about 1cm from the contamination surface.
iv. Calculate the indicated total surface contamination bysubtract the background from the surface reading

v. Record the result.

4.7.1.2 Wipe test method for removable contamination.

i. Use cotton swab or wipe test smears to take severals amples from different areas.

ii. An area of 100cm^2 is simply wiped.

iii. Place sample in separate small vial, plastic or envelope.

iv. Label each vial or envelope noting the location of thesamples.

v. Samples are place in a liquid scintillation counter or well-counter.

Recommended limits for contamination on work surfaces.

For alpha : 0.37Bq/cm^2

For Beta : 3.7Bq/cm^2

Surface contamination limits:

S.No	Category of areas	Limit of Surface Contamination
1	Monitored area (e.g.: Inside fume hood, L Bench)	37 Bq/cm^2
2	Laboratory areas (surveyed)	3.7 Bq/cm^2
3	Other non-active areas	0.37Bq/cm^2

4.7.2 Procedure for Decontamination of Radioactive Spill. Prepare decontamination supplies list as below:

i. Caution line tape mark off perimeters and areas ofoperation.

ii. Radiation Contamination Meters.

iii. Decontamination solution (Radiacwash / Soap / Detergent).

iv. Disposable absorbent towels / paper towel / absorbentmaterial.

v. Hazardous waste containers / plastic bags.

vi. Tong or forceps.

There are two category of radioactive spill:

(i) Minor spill, (ii) Major spill

i. **Minor spill happen if:** Those where small drops or easily cleaned spills are contained on absorbent pads and pose no major hazards to workers. All spills of radioactive material are classified as a minor spill unless any of the following conditions are met; in which case it would be defined as a major spill.

a. Minor spills procedure such as:

i. Notify all other persons in the room at once.
ii. Keep the number of persons necessary to deal with the spillto a minimum.
iii. Confine the spill immediately.
iv. Decontaminate the area.
v. Monitor for residual loose contamination.
vi. If unable to decontaminate to acceptable levels, notify the Nuclear Medicine Physicist/RSO.
vii. No person can resume work until decontamination iscomplete.
viii. Consult Nuclear Medicine Physicist/RSO to determine if a bioassay is required.

ii. **Major spill happen if:** When a spill involves breakage of storage vial or contentsspilled from vial or syringe.

- When a spill involves any radioisotope of very highradio toxicity.
- When a spill involves release of volatile material.
- When it is suspected that inaccessible areas are contaminated.
- When reasonable efforts to decontaminate are notsuccessful.
- When there is any doubt about appropriate decontaminationprocedures.
- Any rupture or suspected rupture of a sealed source.

a. **Major Spill procedure such as:**

i. Notify all persons not involved in the spill to vacate the labat once.
ii. If the spill is liquid take measures to contain the spill.Delineate outer margin of spill with tape.
iii. Switch off all air circulating devices.
iv. Vacate the room and immediately notify Nuclear Medicine Physicist/RSO.
v. Ensure persons vacating the lab remain in the immediatearea to be monitor

for personal contamination.

vi. Take immediate steps to decontaminate personnel involvedas necessary.

vii. Post warning signs to prevent entry into contaminated area.

viii. Proceed to decontaminate area, wipe test for loosecontamination and survey for fixed contamination.

ix. Prohibit any work in the area until survey results are knownand approval is given by Nuclear Medicine Physicist/RSO.

x. Ensure the complete history of the incident is documented.

xi. Surface contamination derived limit in Table 1.

xii. Care must be taken not to permit the detector probe totouch any potentially contaminated surfaces.

4.7.2.1 Decontamination procedure

i. The contaminated area should be decontaminated by using decontamination solution and disposable absorbent towels/paper towel or any absorbent material.

ii. Allow the decontamination solution to settle on the contaminated area for several minutes before proceed with decontamination process.

iii. If the contamination occurred on top of an absorbent material, remove the contaminated material, put it into plastic bag and dispose it as radioactive waste. Small objects such as tongs and glassware can be cleaned by agitated submersion in a hot water.

iv. The Nuclear Medicine Physicist/RSO should be informed of the contamination incident as soon as possible.

v. Contamination and Decontamination Survey Report.

vi. Nuclear Medicine Physicist shall record all readings on Contamination andDecontamination Form.

RECORD

No.	Record Names	Record Keeping Period
	Contamination and Decontamination Form	3 Years

Major and minor spill criteria:

S NO	Isotope	Major spill	Minor spill
1	99mTc	>100 mCi	<100 mCi
2	131 iodine	>1 mCi	<1 mCi
3	153 Samarium	> 1 mCi	<1 mCi
4	18 Fluorine	>10 mCi	<10 mCi

4.8 Procedure for Personnel Contamination

Objective: To ensure all internal and external decontamination procedures on personnel arecarried out effectively.

4.8.1 External Contamination: Proper monitoring of personnel can detect and measure alpha, beta or gamma emitters: radiation type depends on isotope in contaminant.

a. Localized Contamination:

i. Decontamination Procedures:

- Remove contaminated clothing. Bag, label and store inradioactive waste room for decay.
- Survey for any residual contamination on the body.
- Cover uncontaminated body area with plastic sheet if necessary to avoid spread of contamination.
- Wash affected area with running tap water and detergent.
- Use mechanical action of flushing and/or friction of clothes,sponge or soft brush.
- Rinse area with running tap water and gentle dry.
- After drying, survey the contaminated body area to determine effectiveness of decontamination and record all readings.

b. Specific Contaminated Body Part:

i. Decontamination Procedure – General Body

- Survey entire body and record all readings.
- Visibly mark (e.g. with marker pen) the highly contaminatedbody area.
- Contaminated personnel should shower using liquid soapor equivalent. Begin with the head and proceed to the feet.

- Make an effort not to contaminate hairy areas if they arefree of radioactivity initially.
- Survey entire body again marking highest levels found.
- Record all readings.

ii. Decontamination Procedure - Eyes

- Irrigate with copious amounts of water.
- Survey the affected eye and record all readings.
- After decontamination, treat irrigation induced conjunctivitisas usual.

iii. Decontamination Procedure - Hair Areas

- Survey and record all readings.
- Wrap or position personnel to avoid spread of contamination.
- Wash with plenty of water or equivalent.
- Dry with clean uncontaminated towel. Do not shave hair — ifnecessary, hair may be cut, but do not injure skin.
- Survey and record all readings.

4.8.2 Internal Contamination

4.8.2.1 Internal Contamination Measurement.

a. Direct methods.

i. Whole body counters.
ii. Thyroid uptake system.

b. Indirect methods.

i. Indirect measurement of contaminant includes nasal swipes to determine respiratory intake of radioactive aerosols, and also urine and faeces sampling to establish internal contamination.
ii. Alpha and beta emitter, the most hazardous internalcontaminants, detected through bioassay sampling.
iii. Accurate bioassays require carefully executed sampling overtime and knowledge of type and time of contamination. (For more details please refer Guidelines for Bioassay sampling, IAEA).
iv. Nuclear Medicine Physicist shall record all readings in Contamination Survey Report Form.

RECORD

No.	Record Name	Record Keeping Period
	Contamination Survey Report Form	

4.9 PROCEDURE FOR RADIATION INCIDENT AND ACCIDENT:

OBJECTIVE: This procedure serves as a guide to individuals and nuclear medicine centers when handling radiation incident and accident. It is recommended that good radiation practice should be implemented in the interests of reducing radiation exposure and risks.

4.9.1 Types of radiation incidents and accidents.

A variety of incidents and accident may occur in nuclear medicine practice which can result in the inadvertent radiation exposure of a patient, a member of the public or a staff member. All incidents should be investigated, including 'near misses', to minimize the likelihood of such incidents occurring again. These include:

A) Operating errors.

Operating errors are due to:

i. Human Factors.

a. Staff.

- Administration problems (e.g. failed administration, incorrect labelling of pharmaceutical, incorrect dosage of radiopharmaceutical or extravasation etc.).
- Acquisition problems (e.g. incorrect field, inadequate counts obtained, inadequate views obtained, artefacts etc.)
- Computer problems (e.g. accidental deletion of patient studies).

b. Patient.

- Mainly movement due to (e.g. inadequate instructions to patient, inadequate sedation especially in children or unable to image child).

ii. Machine factors

- Power interruption.
- Computer problems (e.g. component damage).
- Mechanical problem.

Procedure:

- If operating error is detected by any staff, he or she should inform Nuclear Medicine Physicist/RSO.
- Nuclear Medicine Physicist/RSO will investigate and confirm the error.
- If problem persists, inform HOD and all the staffs involved and stop all related procedures immediately.
- Nuclear Medicine Physicist/RSO should contact the related equipment engineer to investigate and rectify the fault, if necessary.
- Record the event by filling up the repeat study form.

B) Loss, Theft or Sabotage of Radioactive Source.

It is critical to have an up-to-date inventory so that it can be determined immediately which source(s) is (are) missing, what its type and activity are, when and where it was last known to be, and who last took possession of it.

- Inform directly to Nuclear Medicine Physicist/RSO, and record the incident.
- HOD, with the help of Nuclear Medicine Physicist/RSO will conduct a local search.
- Check all possibilities in the hospital.
- If still not found, notify the appropriate authority (AERB) of such theft, loss or sabotage within 24 hours after discovering the theft, loss or sabotage.
- Submit a complete report of the theft, loss or sabotage in writing to (AERB) within 30 days after the notification to (AERB)

The report shall contain:

- A description of the radiation source, including its quantityand its chemical and physical forms.
- A description of the circumstances under which the theft/loss/ sabotage occurred. Location or probable location of the radiation source.
- The possible radiation exposure to individuals, circumstances under which the exposure may occur and the extent of potential hazard to members of the public.
- The action which has been taken or will be taken to recover the radiation source.
- The procedures or measure have been or will be adopted to prevent a recurrence of the theft, loss or sabotage of the radiation source.
- Any other information as the necessary.

C) Rupture or Damage of Sealed/Unsealed Sources

- Evacuate the area immediately.
- Inform the Nuclear Medicine Physicist/RSO who should confirm the spillage or radiation leakage and supervise the decontamination and monitoring procedures (refer to SOP for Contamination and Decontamination at Workplace).
- Record the event and make a report to appropriate authority.

D) Emergency Transfer of Patient Containing Radionuclide.

- Nuclear Medicine Physicist/RSO will confirm the defect related with the diagnostic equipment.
- With permission from the HOD, carry out the contingency arrangement which is coordinated by Nuclear Medicine Physicist/RSO.
- Arrange appointment at other nuclear medicine centres.
- Follow local procedure of transferring patient to other centre.
- Before transporting the patient, Nuclear Medicine Physicist/RSO should survey the dose rate of the patient or group of patient at 1 meter distance.
- Record the reading of the patient in the Emergency Transfer of Patient form.
- The Nuclear Medicine Physicist/RSO should provide adequate radiation monitoring devicefor staff involved in the transporting of the patients.
- The dose rate of the staff involved to the patient should berecorded.

RECORD

No.	Record Name	Record Keeping Period
1.	Emergency Transferring of Patients Containing Radionuclide Form	3 Years

4.10MANAGEMENT OF RADIATION EMERGENCY

OBJECTIVE: This procedure is a guideline for Nuclear Medicine Physicist/RSO to assist related emergency team / related agencies such as Police and Fire Department with facility specifications and radiation protection in the events of emergency.

4.10.1 Minor Fire.

Procedure: In order to handle a Minor Fire effectively, the following procedure shall be followed:

- The first person who discovered the fire shall immediately attempt toput out the fire by approved methods (e.g. fire extinguisher) if other fire hazards or radiation hazards are not present.
- If the attempt is failed and fire category move from minor to major, follow procedures for Major Fire.
- After the minor fire is put out, notify all persons present to vacate thearea and have one individual immediately call the Nuclear Medicine Physicist/RSO
- Once the fire is put out, isolate the area to prevent the spread of possible contamination.
- Nuclear Medicine Physicist/RSO will survey all persons involved in combating the fire for possible contamination.
- Persons involved, if contaminated, need to remove contaminated clothing and flushing contaminated skin with warm water, then washing with a mild soap (refer to SOP for Personnel Contamination).
- Nuclear Medicine Physicist/RSO and his team will then determine a plan of decontaminationand the types of protective devices and survey equipment that willbe necessary to decontaminate the area.
- Allow no one to return to work in the area unless approved by the Nuclear Medicine Physicist/RSO.
- Nuclear Medicine Physicist/RSO will supervise decontamination activities.
- Nuclear Medicine Physicist/RSO needs to consult with Hospital Emergency Team to ensure thatthere are no other possibilities of another fire starting and to assist inconducting investigation for root cause of fire.
- Nuclear Medicine Physicist/RSO will consider the need for bioassays if radioactive material is suspected to have been ingested, inhaled, or absorbed through the skin.
- Appropriate authority needs to be informed verbally within 24 hours and written report is submitted within 30 days of incident.

4.10.2 Major Fire and Natural Disaster.

Procedure: The following general guideline shall be followed:

- The first person who discovered the event shall notify all persons in the area to stop, secure their work and leave immediately.
- Notify the Police/Fire Department and briefly describe the nature of the situation.
- Notify the Nuclear Medicine Physicist/RSO and Hospital Emergency Team (Refer to hospital emergency action plan).
- Upon arrival of the Police/Fire Department personnel, Nuclear Medicine Physicist/RSO shall inform them where radioactive materials are stored or where radioisotopes were being used, inform them of the best possible entrance route to the radiation area, as well as any precautions tobe taken to avoid exposure or risk of creating further radioactive contamination.
- Police/Fire Department take charge upon arrival and proceed with the assistance of hospital Nuclear Medicine Physicist/RSO.
- Allow no one to return to work in the area unless clearance has been made by the Police/Fire Department.
- All the involved person (medical emergency response team, any victim that contaminated) should follow the instructions of the Nuclear Medicine Physicist/RSO (e.g., survey, decontamination techniques, provision of bioassay samples, requested documentation).
- Nuclear Medicine Physicist/RSO will determine necessary corrective actions, consider need for bioassays if radioactive material is suspected to have been ingested, inhaled, or absorbed through the skin.
- Nuclear Medicine Physicist/RSO will assist Police/Fire Department to investigate the root cause of the incident.
- Nuclear Medicine Physicist/RSO needs to notify appropriate authority verbally within 24 hours and written report is submitted within 30 days of incident.

RECORD

No.	Record Name	Record Keeping Record
1.	Standard Operating Procedure inthe Events of Emergencies	3 years

4.11PROCEDURE FOR SPECIAL PROCEDURES INNUCLEAR MEDICINE

A variety of special procedures may occur in nuclear medicine practice which can result in the inadvertent radiation exposure of a patient, a member of the public or a staff member. These include:

a) Medical emergencies involving radioactive patients
b) Need for urgent patient attention and including surgery
c) Death of the patient
    i. Death of the patient following a nuclear medicine scanning
    ii. Organ donation
    iii. Precautions during autopsy
    iv. Preparation for burial and visitation
    v. Cremation

WORK INSTRUCTION

a) Medical emergencies involving radioactive patients.

For patient who required resuscitation:

- Responsible medical personnel should notify the relevant people (e.g staff involved in resuscitation in the hospital).
- Notify Nuclear Medicine Physicist/RSO and inform the emergency situation.
- Nuclear Medicine Physicist/RSO will provide the disposable gloves, gowns and pocket dosimeters to the staff involved in resuscitation.
- Nuclear Medicine Physicist/RSO should measure the radiation level of the patient and estimate time of exposure allowed to the staff involved in resuscitation. Rotation of staff should be carried out during the resuscitation.
- Do not apply direct mouth-to-mouth resuscitation.
- Materials/equipment that has come into direct contact with the patient should be checked for contamination after the resuscitation and handled accordingly.
- All the detail regarding radiation exposure from patients containing radionuclide and personnel involve must berecorded.

b) Need for urgent patient attention.

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Attention should be paid to the following points:

- The Nuclear Medicine Physicist/RSO shall advise and supervise on radiation safety issues to the relevant staff in the ICU/CCU/operation theatre.
- If a transfer is required, the fact that the patient may still contain radioactive source should not interfere with the clinical management of the case.

- In the case of patient administered with radioactive sourcefor whom intubation, catheterization or use of a nasogastric tube may be necessary, staff should wearprotective gowns and gloves when handling the patient in order to avoid radionuclide contamination.
- Spillage of body fluid should be contained as far as possible by means of absorbent pads, and the pads should be discarded in the waste bag label with radiation signage.
- Any suction bottles or urine bags used must not be discarded until checked for contamination by Nuclear Medicine Physicist/RSO.
- Nuclear Medicine Physicist/RSO shall check all the contaminated items before dispose as normal clinical waste.

c) Death of patient.

i. Death of the patient following a nuclear medicine scanning.

- If a patient dies during the scanning, the Nuclear Medicine Specialist shall consult the Nuclear Medicine Physicist/RSO on how to minimize exposure to the person handling the body. The movement of the body should be minimised, using strict procedures for prevention of contamination from body fluid, until the Nuclear Medicine Physicist/RSO arrive.
- Body fluid may be radioactive and catheterisation of the cadaver should only be performed under the direct supervision of the Nuclear Medicine Physicist/RSO.
- Deceased body released for autopsy, embalming, cremation or burial should have a label identifying theradionuclide and its activity at the time of release, together with a release statement signed by the Nuclear Medicine Physicist/RSO.
- Transportation of a deceased body containing radioactive source shall follow the As Low As Reasonably Achievable (ALARA) concept.
- Other practical measures for dealing with deceased body shall include:

  - Notify the relevant people who will be handling the deceased body.
  - Staff involved in handling a deceased body should wear disposable gloves, gowns and pocket dosimeter.
  - Nuclear Medicine Physicist/RSO shall measure the radiation level from thedeceased body and estimate the time of exposure allowed to the staff.
  - Material/equipment that has come into direct contactwith the dead body shall be checked for contamination at the end of the procedure.
  - Prepare relevant documentations and notify the appropriate authority within 24 hours.
  - All details regarding radiation exposure from the deceased body containing radioactive source and personnel involved shall be

recorded.

ii. Organ donation.

It is not advisable to donate the organs to avoid any unnecessaryradiation exposure to member of public.

iii. Precautions during autopsy.

- Procedures for personal protection normally observed during an autopsy to provide adequate protection against external radiation exposure or contamination withradioactive material.
- The pathologist should be informed of the radiation levels likely to be encountered and of the hazards involved. The methods employed and the precautions adopted should be chosen accordingly in consultation with the Nuclear Medicine Physicist/RSO.
- The fluids from the procedure shall be disposed via the sewerage system.
- The equipment used in autopsy should later be decontaminated by thorough rinsing in a detergent solution followed by washing in running water.

iv. Preparation for burial and visitation.

- The physician involved should identify a radioactivepatient (the date, type of radionuclide, and the amount of administered activity) and attach a label to the body.
- The body should be surveyed by using radiation survey meter and probe sweeping 1 inch away from the body surface.
- If the level of radiation is less than 1 mSv/hr, there is no need for personal dose control of the staff or of the relatives of the deceased. Preparations for burial and any contact between relatives and the body should be controlled by a competent person, who will label the body with the radiation symbol. There is no need to label the coffin. All objects, clothes, documents, etc. that have been in contact with the deceased must be tested for contamination only if it is not sent for burial or cremation.
- If the level of radiation is higher than 1 mSv/hr, relatives must be prevented from coming into contact with the body, and people must not be allowed to linger near the body. The hospital staff, the coroner, the persons washing and

preparing the corpse for burial, the staff of the undertaker, and the transportation and cemetery staff must be instructed by the Nuclear Medicine Physicist/RSO and monitored for their personal dose rate by means of pocket dosimeters. All objects, clothes, documents, etc. must be tested for contamination only if it is not sent for burial or cremation. Itis expedient to wrap the body in plastic foil immediately after death has occurred, and it should never be handled unless with disposable protective gloves.

v. Cremation.

No.	SOP Title	Record Keeping Period
1.	Radiation Exposure Received By Personnel.	3 years

vi. Misadministration of radiopharmaceutical (wrong Dose, Patient, radiopharmaceutical, Route and administration of radioactivity to a pregnant female patient without confirming pregnancy).

vii. Any other event that may lead to situations of radiological consequence.

Detailed follow up report including the following shall be submitted to the competent authority:

(a) Date and time of occurrence:

(b) Radionuclide, its activity and radiopharmaceutical composition:

(c) Brief description of the incident:

(d) Action taken:

(e) Probable causes of the incident:

4.12 Imaging and non-imaging instrument Preventive Maintenance

4.12.1 Purpose

i. To maintain the equipment in proper working condition.

ii. To protect the equipment from mechanical, physical environmental damage.

4.12.2 Dos and Don'ts

i. Do not use detergents or organic solvents to clean the PET - CT imaging systems, isotope calibrators. Survey instruments.
ii. Clean the surface of the system with a cloth moistened with 95% ethyl alcohol.
iii. Check the cables for nicks, cuts and exposed wires.
iv. Never place any items on the collimator or detector.
v. Never place any items on the operator console or electronic cabinet.
vi. Maintain room temperature for the Gamma camera and PET- CT at a constant level.
vii. Failure to do so may result in damage to the crystal.
viii. Check for proper movement during all mechanical operations and for any unusual noises. In case of any break down enter the details in **Call Log Register.**

4.12.3 Policy for cleaning other instruments:

Lead syringe carriers, Syringe shields, Forceps and vial holders, Contrast injector, Defibrillator,

i. Every morning before the commencement of work. Clean the surface with a cloth moistened with 95% ethyl alcohol. Allow to dry completely prior to use.

Wheel chairs and Strechers:

For the safety of the next patient a wheelchair must be rendered free from contaminants. This assists in the prevention of the spread of infection. This procedure also provides reassurance and confidence to patients.

Procedure for Cleaning Wheelchairs between Patients

1. Collect wheelchair.
2. Take wheelchair to patient's bed end.
3. Put on disposable gloves and apron (Personal Protective Equipment – PPE).
4. Wipe over all areas of the chair that had patient contact including arm rests with 1% sodium hypochlorite.
5. Remove PPE carefully wrapping the cloth within the gloves and dispose of into appropriate waste bin.

6. Clean Hands.
7. Return to patient and help into the wheelchair.
8. Return wheelchair to a central point.
9. Process must be repeated for the next patient movement.

4.12.4 PET CT Quality Control

i. Clean mylar window is unobstructed and free of dust/ iv contrast media.
ii. Perform Tube warm up, followed by Fast cal for the CT.
iii. Initiate PET QC by selecting Daily QC. Follow instructions on the Left monitor.
iv. Make sure all the sonograms are uniform and variance values and colour code are within manufacturer prescribed limits.
v. In the event of colour code yellow/red., inform biomedical department/service engineer.
vi. Record the event in equipment breakdown record Call Log Register.

4.13 PRECAUTIONS IF ANY

4.13.1 General Precautions

i. In women of childbearing age, pregnancy and lactation status should be determined.
ii. Previous incidence of allergic reactions for any of the medicines used for the test should be checked.
iii. Use protective clothing, TLD badges, protective shielding etc.
iv. Check and confirm that the QC files of detectors have been updated.
v. Follow the guidelines when handling, transporting and disposing radioactive material (Refer to precautions section).
vi. Ensure that the ALARA (As Low as Reasonably Achievable) principle has been followed as every step, which involves radiation exposure to the general public and staff members.

4.14 LIST OF STUDIES

4.14.1 ^{18}F- FDG PET CT Study (Oncology Imaging)

a) Indications

i) Staging and restaging of malignant disease, differentiating recurrent or residual disease, monitoring the response to therapy, detection of unknown primary malignancy.

b) Patient Preparation

i) Pre-arrival: Patients are advised to fast for at least 4 hrs, to stop all glucose containing infusion for 6 hours.

ii) Pre-injection:

- The blood glucose level (less than 140mg/dL) may be checked prior to the FDG administration. Tumour uptake of FDG is reduced in hyperglycaemic states.
- For brain imaging, for several min before FDG administration and during the uptake phase of FDG, the patient should be inj a quiet and dark / dim lit room.
- Intravenous injection of the radiopharmaceutical at a site contralateral to the site of concern is followed by the acquisition of the transmission (CT) and emission (PET) images beginning about 60 min later.

c) Dose:

Typically, 5-15 mCi is injected in a peripheral vein (see counts requirements below). Injection speed is not critical (i.e., bolus to 2 minutes). To reduce patient dose to the bladder, patients should be encouraged to void frequently for 3-4 hours after the study.

d) Imaging

i) The CT in the framework of a PET/CT examination comprises the tomogram and the helical CT scan.

ii) For a diagnostic contrast-enhanced CT, standard CT mill ampere-seconds settings or those given by the radiological societies/radiologist are used. The modulation of the tube current is used to lower the radiation exposure of the patient. Depending on the clinical question, intravenous and/or oral contrast agents are used.

iii) PET images are acquired in several bed positions at 2min per bed position.

e) Interpretation Criteria

i) Normal physiologic uptake of FDG can be seen in the brain, myocardium (where the uptake appears in some patients despite prolonged fasting), liver, spleen, stomach, intestines, kidneys and urine.

ii) Increased FDG uptake outside the expected physiological sites of FDG distribution is considered as abnormal. The FDG uptake is co-related with the CT images and interpreted.

iii) Standardized uptake values are increasingly used in clinical studies in addition to visual assessments. SUV is a measurement of the uptake in a tumour normalized on the basis of a distribution volume.

iv) It is calculated as follows:

$$\text{SUV} = \frac{\text{Actvoi(kBq/ml)}.\text{Actvoi(kBq/ml)}}{\text{Actadministered (MBq)/BW(kg)}}$$

4.14.2 <u>C-11 CHOLINE PET SCAN</u>: C-11 Choline PET scan is an imaging test used in detecting sites of prostate cancer that has recurred, despite treatment. It may be used when other imaging has failed. This positron emission tomography (PET) scan uses a special chemical tracer called C-11 Choline Injection. This imaging test is done alongside a low-dose computerized tomography (CT) scan to help further show internal anatomy.

1. **USES OF C-11 CHOLINE PET SCAN**

- Detect possible sites of recurrent prostate cancer that ordinary imaging tests cannot identify.
- Detect early location of the recurrent prostate cancer, which enables identification of small, isolated deposits of cancer, within and outside the prostate; for a more effective treatment.

2. **SYMPTOMS OF PROSTATE CANCER:** Some people have no early symptoms until cancer develops over years, while others show early indications. These signs may include:

- Frequent urination.
- Difficulty in starting or stopping urination.
- Blood in urine or semen (which is quite rare).
- Weak, interrupted, and slow urine stream.
- Applying pressure while urinating.

- Urinary stream splits.
- Discomfort, due to pain or burning sensation, with urination or ejaculation.
- Intense pain in the lower back, hips, or thighs.
- Longer time to urinate.
- Inability to empty the prostate.
- Sudden urging and pressing urination.

3. PREPARATION FOR THE C-11 CHOLINE PET SCAN:

- Don't eat or drink anything, except for water, for 6 hours before the scan.
- Your last meal before the test should include high protein foods and plenty of water.
- Avoid carbohydrate foods and foods with sugar.
- Continue with your prescribed medications.

4. PROCEDURE FOR C-11 CHOLINE PET SCAN

- A small amount of the tracer ^{11}C- CHOLINE (5-15MCI) is injected intravenously.
- After injection patient is asked to lie in supine position on a moving table.
- Intravenous injection of the radiopharmaceutical at a site contralateral to the site of concern is followed by the acquisition of the transmission (CT) and emission (PET) images.
- The CT in the framework of a PET/CT examination comprises the tomogram and the helical CT scan.
- PET images are acquired in continuous bed motion with a average speed 1.4 and also by bed positions at 2min per bed position.

4.15Radiological surveillance program

4.15.1 <u>Purpose</u>

i. To assure that structural barrier for radioactive source is adequate.

ii. To ensure that the premises of radiation exposure levels in public, supervised and controlled areas are within prescribed limits.

iii. To ensure safety of radiation workers, general public from exposure to radiation and imaging equipment's from potential contamination.

4.15.2 Instruments/Materials Required

i. Ionization chamber/GM based Survey meter

4.15.3 Method

i. Operational monitoring – daily before commencement of work and whenever there is a potential chance of contamination of radioactivity. Performed by a radiation worker.

ii. Routine monitoring – at frequent intervals at least once a month, not confining to a common date. Performed by the RSO to confirm the designated areas in the work place, to prove the adequacy of measures against external and internal hazards and to reveal any deterioration in the standard of radiation safety. The survey results are documented and filed in the area monitoring record.

4.16Imaging protocols for quantitative SPECT-CT: Nuclear medicine SPECT-CT systems are routinely used for quantitative imaging. From determining relative kidney performance, to binding ratios in the brain, one of the strengths of gamma camera imaging is its ability to quantify in-vivo physiology for a wide range of conditions and applications.

4.16.1 Acquisition: Some steps that should be followed in the acquisition process are:

i. Steps should be taken to limit the possibility of patient motion. It is important that the patient remains in the same position during both the CT and SPECT acquisition to ensure good image registration and accurate CT attenuation correction.

ii. The optimal collimator will depend on the radionuclide being imaged. Relevant imaging guidelines should be followed when choosing an appropriate collimator.

iii. Step and shoot or continuous acquisition mode of acquisition can be used. The latter can offer a 1–2 min saving on scanning time over 60 rotation angles.

iv. Detector auto-contouring is advised to minimize the distance between the detectors and patient to provide optimal spatial resolution. However, for some applications detectors can be kept at a fixed but close distance.

v. Acquisition should typically be performed with opposing detectors at 180° from one another.

vi. A pixel size smaller than half the full width at half maximum (FWHM) spatial resolution of the system for the radionuclide used is recommended to ensure appropriate spatial sampling. Commonly, a matrix size of 128 × 128 is used. It should be noted that decreasing the pixel size results in a noisier image.

vii. The number of projections is recommended to be similar to the matrix size (e.g. 120–128 projections for a 128 × 128 matrix) to ensure appropriate angular sampling.

viii. The time per projection will depend on the amount of radioactivity in the patient. As noise in the projection data follows a Poisson distribution, and in reconstructed data is much worse, imaging time must be high enough to reduce image noise as much as possible. If multiple fields of view (FOVs) are acquired, the time per projection may have to be decreased for patient comfort.

4.16.2 Reconstruction

Iterative methods are recommended to reconstruct the acquired SPECT projections. Normally, the algorithm used will be that included in the software provided by the vendor of the gamma camera; however, third-party algorithms are also available. For quantitative purposes, the number of up

4.16.3 Corrections

i. **Attenuation correction:** Attenuation correction based on CT data should be used for quantitative SPECT-CT.
ii. **Scatter correction:** To correct for scattered gamma-rays present within the photopeak window, multiple energy window scatter correction methods are typically applied, although model-based scatter correction can also be used if available. Smoothing of the scatter window image may also be beneficial to reduce propagation of image noise from the correction to the reconstructed image. It is important to validate scatter

correction techniques using appropriate phantoms containing areas of no activity, surrounded by uniform activity, to demonstrate that the algorithms do not over-correct the final image.

iii. **Decay correction:** Understanding how and when decay correction is applied is important in quantitative SPECT-CT. Given the relatively long physical half-life of most SPECT radionuclides, its application to ensure differences are accounted for in the acquisition of the first and last projection are relatively minor.. In multiple SPECT field of view studies where the study may take up to 1 h, decay correction should also be performed to ensure consistency of relative pixel values across all acquired projections.

Clinical use cases:

4.16.4 Bone imaging: Technetium-99m labelled bisphosphonates accumulate in newly formed bone and enable visualisation of bone turnover. Many conditions are associated with pathological bone turnover, and bone SPECT-CT using these tracers is an established and powerful diagnostic tool in their diagnosis and management.

f) Skeletal Scintigraphy: Protocol Summary for Whole Body Survey and SPECT

i) Patient Preparation And Follow-Up

- Patient should be well hydrated
- Patient should void immediately before study and should void frequently after procedure (reduces radiation dose to bladder wall)
- Patient should remove metal objects (jewellery, coins, keys) before imaging

ii) Dosage And Route Of Administration

- 20 mCi (740 MBq) technetium-99m diphosphonate adult dose (standard)
- Intravenous injection (site selected to avoid known or suspected pathological condition)
- Adjust dosage for paediatric patients (Webster's rule or weight adjusted; Minimum 74 MBq [2 mCi])

iii) Time of Imaging

- Begin imaging 2–4 hr after tracer administration

iv) PROCEDURE

- Anterior and posterior views of the entire skeleton
- Obtain a minimum of 1000k counts per view for "whole body "imaging systems
- Obtain 300k–500k counts per image if multiple spot views are used
- Use the highest resolution collimator that permits imaging in a reasonable length of time
- Obtain high-count (1000k) spot views or SPECT for more detail

v) SPECT

- Acquisition: contoured orbit,128 × 128 matrix,6-degreebintervals,15–30 sec/stop
- Reconstruction: filtered back projection, Butterworth filter; cut-off 0.4,power 7
- Selection of SPECT acquisition and reconstruction parameter

b) Tc-99m Pertechnetate Thyroid Imaging: Protocol Summary

i) PATIENT PREPARATION

- Discontinue any medications that interfere with thyroid uptake of Tc-99m pertechnetate.
- Nothing by mouth for 4 hours prior to study.

ii) RADIOPHARMACEUTICAL

- Tc-99m pertechnetate,3–5 mCi (111–185 MBq) intravenously

iii) TIME OF IMAGING

- 20 min after radiopharmaceutical administration

iv) IMAGING PROCEDURE

- Gamma camera with a 3- to 6-mm aperture pinhole
- Collimator and a 20% energy window centered at 140 Kev.
- Position the patient supine with the chin up and neck extended.
- Position the collimator so that the thyroid fills about two thirds of the diameter of the field of view.
- Obtain anterior, 45-degree LAO and RAO views (move the collimator rather than the patient).
- Obtain 250k counts per view.
- Mark the chin and suprasternal notch.

- Note the position and mark palpable nodules and surgical scars.
- Place marker sources lateral to the thyroid to calibrate scan

c) Tc-99m Sestamibi Parathyroid Imaging: Protocol Summary

i) PATIENT PREPARATION: None

ii) RADIOPHARMACEUTICAL: 20 mCi (740 MBq), intravenously

iii) TIME OF IMAGING

- Early scans at 15 minutes
- Delayed scans at 2 hours

iv) IMAGING PROCEDURE

- Planar
- Use a high-resolution collimator and a 20% window centered at 140 KeV.
- Position the patient supine with the chin up and neck extended.
- Place markers on the chin and sternal notch.
- Obtain anterior and 45-degree left and right anterior oblique views, 300k counts per view.

v) SPECT IMAGING

- Position patient as above.
- Use a high-resolution collimator and a 20% window centered at 140 Kev.
- Use dual-headed SPECT camera: 360-degree contoured acquisition arc,3-degree angular Sampling increment,15–30 sec per view,128 × 128 matrix with 1.5 zoom, Hanning or Butterworth filter.
- Reconstruct trans axial, coronal, and sagittal planes.
- Re-project images at each sampling angle

d) Dynamic Renal Scintigraphy

i) Patient Preparation

- Hydration
- Adults: drink 300–500 ml of water
- Children: Intravenous hydration 10–15 ml/kg over 30 min;<1 year use dextrose 5% in 0.45% normal saline, >1 year of age D5 in 0.45% normal saline

- Patient must void before starting study

ii) RADIOPHARMACEUTICAL: Tc-99m DTPA

- Adults: 3 - 5 mCi (555 MBq)
- Children: 200 µCi/kg (2 mCi minimum,10mCi maximum)

iii) Instrumentation

- Camera: large field of view gamma
- Collimator: low energy, parallel hole
- Photopeak:15–20% window centered over 140 keV

iv) PATIENT POSITION

- Routine renal imaging: supine, posterior
- Renal transplant: patient supine, camera anterior over allograft

v) COMPUTER ACQUISITION

- Blood flow:1- to 2-sec frames for 60 sec
- Dynamic:30-sec frames for 25 min
- Pre-void image 500k count
- Postvoid image

vi) PROCESSING

- Draw computer region of interest around kidneys and for background area
- Generate time–activity curves for 60-sec flow phase and for 25-min dynamic study

4.17 QUALITY CONTROL OF SPECT AND SPECT/CT

1. Uniformity

- Selecting a radionuclide source of appropriate type, size, (if necessary), quantity and energy
- Selecting an appropriate pulse height analyzer (PHA) photopeak and window
- Obtaining uniformity images using standardized imaging parameters
- Evaluating the images qualitatively and/or quantitatively in comparison to the manufacturer's specifications and the performance requirements based on the studies for which unit is used
- Identifying the source of any non-uniformity (i.e. checking collimator, PHA peak setting)
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

2. Linearity

- Selecting a radionuclide, a linearity phantom and obtaining images
- Identifying any nonlinear distortion in the image
- Determining the source of nonlinearity. (i.e., detector-source geometry)
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

3. Spatial resolution

- Selecting an appropriate radionuclide
- Choosing a phantom that is compatible with the specified resolution of the camera
- Analyzing the resulting images for degradation of resolution
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

4. Sensitivity

- Selecting a source with an appropriate level of activity and half-life
- Assuring identical geometry, source placement and measurement parameters for repetitive checks
- Evaluating results
- Initialing corrective action when necessary
- Maintaining required records for the quality control program

5. SPECT quality control procedures

- Obtaining a high count uniformity flood
- Obtaining a center of rotation correction
- Verifying energy correction and spatial coordinates
- Verifying multi-head detector alignment
- Evaluating reconstruction results of phantom acquisition
- Analyzing the results for degradation
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

4.17.1 Dose calibrator, pocket dosimeter, Survey &contamination meters, Area zone monitors:

- By ensuring calibration is completed with an approved
- By performing a reference check-source test and comparing with previous results
- By maintaining required records for quality control program

MEDICAL CYCLOTRON SOP

Standard Operating Procedure (SOP) of Cyclotron

1. **Step1:** Check all the preliminary parameters before starting Cyclotron and maintain all the record of checklists.
2. **Step2:** CHECK the cyclotron control cabinets room AC is Switched **ON** or not, and set the temperature to 19^0C
3. **Step3:** Open the Master System by using User Name and Password
4. **Step4:** Check the below parameters in System Status Window;
   - **a.** Target Minimum Pressure
   - **b.** He Cooling Pressure
5. **Step5:** Dry the Target with Helium Gas at least 15 min.
6. **Step6:** Fill the Target with O18 Water and check the Target Pressure.
7. **Step7:** Switch on the Magnet by clicking the PET Trace and then Start H for Protons and check the magnet PSMC Current.
8. **Step8:** Click the Production and enter the below details;
   - **a)** User Name
   - **b)** Password
   - **c)** Target Current
   - **d)** Irradiation Time
9. **Step9:** Click the irradiation, start Irradiation when it is highlighted.
10. **Step10:** Observe the System Parameters by clicking System Status and observe below parameters;
    - **a.** Dee Voltages
    - **b.** Delta between Dee Voltages
    - **c.** Ion Source Current and voltage
    - **d.** Running Vacuum Pressure
    - **e.** H Gas flow rate
    - **f.** Target Pressure
    - **g.** Collimators Currents
    - **h.** Foil Current and number running foil
    - **i.** Probe Current
    - **j.** He Cooling Pressure
    - **k.** Irradiation Time
    - **l.** Estimated Activity

11. **Step11:**After Irradiation Time is over, click the delivery option and deliver the Irradiated O18 Water to Hot Cell by checking with Radio chemist
12. **Step12:** Check the Transfer Time.
13. **Step13:** After Transfer dry the Target with Helium Gas upto 15 min.
14. **Step14:** Shutdown the Cyclotron.
15. **Step15:** Set the Cyclotron control cabinated room AC to 24^{0}C.
16. **Step16:** Maintain all the records of Cyclotron Production Parameters.

Standard Operating Procedure (SOP) for FDG Synthesis in FX2N Module

Reagents Required for FDG Synthesis:

1) **15mg cryptand + 0.5mL Potassium Carbonate + 0.5mL water for injection in vial no. 1**
2) **1mL of Na OH in vial no. 2**
3) **20mg of Mannose triflate in 1ml of Acetonitrlle in vial no. 3**
4) **2mL of water for injection invial no. 4**
5) **14mL of water for injection in vial no. 5**

NUCLEOPHILLIC SUBITITUTION REACTION

After fluorine -18 coming in V-Vial, it will come to QMA (Quaternary ammonium anion exchange column) and Oxygen-18 water will go to recovery vial.

Step1: ADDITION OF KRYPTOFIX

Eluent (kryptofix, vial 1) will go through QMA and takes F18 into reaction vessel with the help of vacuum pump. It will take 2 and a half minutes.

Eluent evaporation Step: Set point is 65^{0}C and Helium (valve 20) and Vacuum pump should be ON for 4 minutes.

Eluent Drying Step: Set point is 90^{0}C, valve 20 will be closed, only vacuum pump will be ON for around 6 minutes.

Step2: ADDITION OF MANNOSE TRIFLATE FOR LABELLING

Mannose triflate (Vial 3) will add to reaction vessel with the help of Helium.

It will take 5 minutes for mannose Triflate reaction.

Temperature set point 50^0C. it will take 1 minute.

Stander operating procedure for manual cleaning of FX2 N module

- Switch on Helium gas and compressed air form knob of Hot Cell
- Power should be ON
- Step:1
- Add 2mL each water for injection in first vials and 3mL 70% ethanol in final product vial,
- Switch ON the Vacuum pump & V24
- Set temperature 50^0C and reactor needle down & stirrer ON
- Open V1 & V13 for 15 Seconds.
- Close V1 & V13
- Open V2 for 15 Seconds.
- Close V2
- Open V3 for 15 Seconds.
- Close V3
- Switch OFF the Vacuum pump & V24
- Open V16 & V22 (inside) and V20 & V14 for 3 minutes. (check physical whether 6mL water is going in waste bottle or not also check 3mL of 70% ethanol is passing through output tubing into bulk vial or not).
- Close V16 and V22 (outside) and close V20 and V14.
- Switch ON the Vacuum pump & V24
- Close V1 & V13 for 1 minute.
- Close V1 & V13
- Close V2 for 1 minute
- Close V2
- Close V3 for 1 minute
- Close V3
- **Step:2**

- Add 2mL each Acetone in first 3 vials.
- Open V1 & V13 for 15 Seconds.
- Close V1 & V13
- Open V2 for 15 Seconds.
- Close V2
- Open V3 for 15 Seconds.
- Close V3
- Switch OFF the Vacuum pump & V24
- Open V16 & V22 (inside) and V20 & V14 for 4 minutes. (check physical whether 6mL water acetone is going in waste bottle or not.
- Close V16 and V22 (outside) AND CLOSE V20 and V14.
- Switch OFF and reactor needle UP
- Switch ON the Vacuum pump & V24
- Open V1 & V13 for 2 minute.
- Close V1 & V13
- Open V2 for 2 minutes
- Close V2
- Open V3 for 2 minutes
- Close V3
- Open V4 for 1 minute
- Close V4
- Set temperature 40^0C
- Open V5 & V19 for 1 minute
- Close V5 & V19
- STOP & RESET.
- Close knob and switch OFF power.

Special precautions after target foil rupture

If a foil breaks during production foil fragments might be spread throughout the vacuum chamber. All foil fragment need to be cleared out before any service tasks are performed on the cyclotron.

4.17.1.1.1 Measure the radiation levels when entering the vault. Estimate accumulated dose before proceeding.

If the estimated accumulated dose is acceptable proceed with next step.

If the estimated accumulated dose rate is not acceptable, wait until the estimated accumulated dose has decreased to an acceptable level before proceeding.

2) Measure the radiation levels when opening the vacuum chamber door. Estimate accumulated dose before proceeding.

If the estimated accumulated dose is acceptable proceed with next step.

If the estimated accumulated dose rate is not acceptable, wait until the estimated accumulated dose has decreased to an acceptable level before proceeding.

3) Carefully check the entire vacuum chamber for target foil fragments.

The foil fragment will be revealed by high radiation levels at certain spots Radiation levels about 1 mSv/h (100 µSv/h) 10cm in front of your electronic dosimeter indicates target foil fragments.

WARNING Radioactivity

The target foil are extremely radioactive. Handle with care.

Never touch the foil. Use a pair of tweezers when handling the foils to increase the distance from the foils.

If the foil broken, check for foil fragments Remainder that fragments also very radioactive.

To minimise exposure remove the foils from the work area as soon as possible.

4) Dispose of the target foil free fragments in the GE supplied target file container.

5) Check the collimators for foil fragment. If there are any indication of foil fragment on a collimator it needs to be replaced.

6) If the target foil particles are too small to pick up with a pair of tweezers, wipe the area clean using isopropanol and lint- free paper.

Warranty radioactivity

Dispose of the linked free paper in the secure way it may be radioactive.

7) Check the vacuum chamber and area surrounding the cyclotron for radiation. Make sure they are clean from all target foil fragments.

8) Check yourself and your equipment for radiation before leaving the controlled area.

Warranty radioactivity

All people and material living a cyclotron site must be checked for radiation using a doors metre and a surface contamination detector.

Not that material can be radioactive either due to exposure during bombardment or contaminated for example with foil particles.

CYCLOTRON EMERGENCY

The emergency procedures outlined below would be applied in the event of a target pressure loss, cyclotron area monitor alarm, any time a radioactive material delivery from the cyclotron target is delayed for more than 10 minutes beyond the expected time and/or in the event of any accidental radioactive material contamination or exposure:

- Shut down the cyclotron immediately
- Determine the extent and severity of the emergency situation. Wear protective clothing and an audible alarm personnel dosimeter and use a calibrated survey meter to identify areas with elevated exposure rates.
- Place visible barriers [tape, rope, signs, etc.] around identified areas to warn personnel against entry.
- Notify facility RSO.
- If activity transfer delay occurs, the problem may be corrected from the control terminal or by adjustment of the vacuum/ pressure system.
- Do not attempt to correct delivery line problem if personnel exposures greater than 1 mSv [100mR] whole body would be expected from the procedure.

  In case of power failure the cyclotron will default to a fail-safe condition until power is restored. Automatic sequencing will provide for un-attended restart of ancillary systems (e.g. water cooling and vacuum]. The cyclotron will require manual intervention by a qualified operator to restart the beam or deliver target material.

Emergency Procedures

- Keeping radiation doses to workers and members of the public ALARA;
- Ensuring the security of licensed material;
- Responding to radiological emergencies per our internal procedures; and
- Making the required notifications of events.

Emergency procedure for failure of ventilation system in cyclotron

The following procedure should be followed

In case of failure of ventilation system in cyclotron, the operator will switch OFF the flow. The ACS system should be working which will lead to containment of air/gases.

If the ACS system also fails, the flow will go through vent provided with charcoal filter.

Emergency Procedure in case of fire breakout:

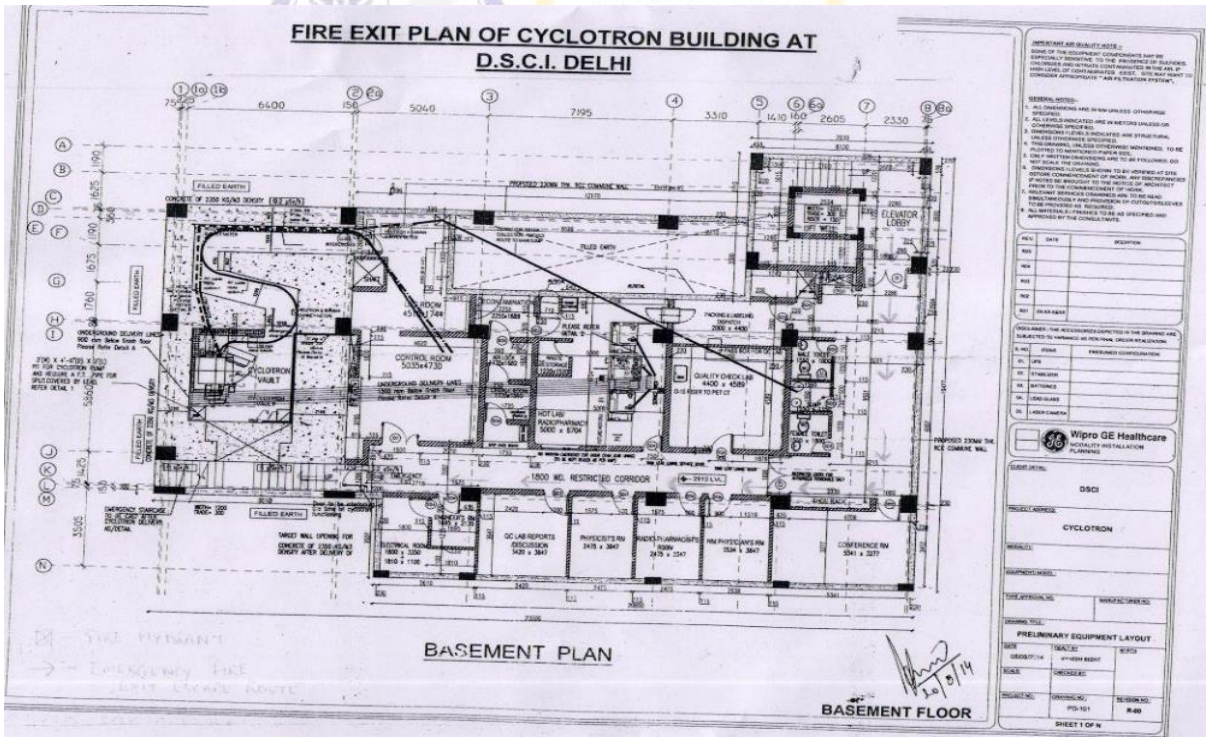
In case of fire breakout, the emergency fire exit plan has to be followed.

All personnel should evacuate the area and proceed towards emergency exit.

The radiation worker is upstairs, will proceed through the corridor towards the emergency exit door.

The workers should proceed through stairs towards outside of the building

The emergency exit plan is attached:



IN CASE OF RADIATION EMERGENCY CONTACT FOLLOWING:

S. No.	Name of the officer	Designation	Contact Number
1	**Dr Vatsala Aggarwal**	Director	9718990112
2	**Dr Pragya Shukla**	Asstt. Prof Radiation Clinical Oncologist, Chairman, RS Committee	9560390107
3	**Mr M Sasindran**	Medical Physicist & RSO, Member Secretary, RS Committee	9971491227
4	**Ms Mamta Mahur**	Medical Physicist, Member, RS Committee	9560390150
5	**Dr Surendra Kumar**	Asstt. Prof Anaesthesia , Member, RS Committee	8800190660
6	**Mr Deeepanshu Goel**	Asstt. Engineer (Civil), Member, RS Committee	9811190710
7	**Mr Parveen**	Security In-Charge	8287523900
8	**Police (GTB Complex)**	SHO (PS. GTB Complex)	011 2213 1069

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Manual-4

Norms set for discharge of functions

[Section 4(1)(b)(IV)]

Library and Information Centre

Library Working Hours:

11: 00 AM to 6:00 PM (Monday to Friday)

11: 00 to 4: 00 PM (Saturday)

Library Membership: All faculty members, doctors, researchers, and staff are eligible for members of library. External users are not permitted in the library. In special case external users can usethe library after permission of competent authorities.

Borrower tickets: Under process

Borrowing facilities: Reference books and current journals are not issued to the users. Books are issued to faculties only. Other members use books and journals in the library.

Services:

1. **Acquisition Services**
2. **Circulation Services**
3. **Reference Services**
4. **Internet/Online Services**
5. **Literature Services**
6. **Photocopying Services**

MANUAL 4

Norms set for the discharge of functions

[Section 4(1)(b)(IV)]

Store observes the SOP's as per GFR 2017 and Manual of Procurement of Goods and Services 2017 and 2023

Store

The following activities are done in the Store.

1. Finalization of Annual Demands

a) Drugs and Surgical Items (Consumable & Non-Consumable):

An Annual Demand of drugs and Surgical Items (Consumable & Non-Consumable) is prepared on the basis of indents received from the HODs/ Incharges of various departments of DSCI as per their annual requirements (devised by calculating the monthly consumption pattern of items).

Availability of Essential drug list is maintained.

Quantification of drugs/consumable surgical items required – quantification of the required item is done on the basis of corrected consumption pattern of the previous year with 10% increase for the next year keeping in view regular increment in the number of patients.

b) Lab Items (Chemical & Reagents, Diagnostic Kits, Glassware items etc.)

Annual Demand of Lab Items (Chemical & Reagents, Diagnostic Kits, Glassware items etc.) is prepared on the basis of indents received from HODs of all the laboratories i.e. Pathology, Microbiology, Lab Medicine (devised by calculating the monthly consumption pattern of items)..

2. Receiving and verification of the Store Items

All the supplies are received in the medical store as per the supply orders. Entries are made in the computer of the every received item and are verified by the concerned Inspection committee in respect of physical appearance, quantity, quality etc. as per the specifications. After that the items are taken in the concerned stock registers.

3. Storage of supplies

Drugs are stored alphabetically and FEFO (first expiry first out) is also followed. Stock is checked physically monthly and a stock status with date of expiry is circulated monthly. Cleaning of shelves and floor is done regularly. The safety stock of every item is maintained to avoid any stock outs. Fire extinguishers are arranged as per requirement of the ware house. Premises are free from rodents, vermin and pests as pests controls are used fortnightly. Refrigerators are available for vaccine and biological drugs with special temperature storage conditions.

4. Record Keeping

The records (stock registers, receiving Vouchers, Issuing Vouchers, various files etc.) of the Store are maintained properly. The Indents are issued on the basis of consumption pattern and justified requirements. Entries of the Indents are made in the Inventory software also for double book keeping.

5. Annual Physical Verification and Audit

Records and stocks of the Store are annually physically verified by the committee which is constituted by the authentic authorities of the hospital. The Annual Audit of the records is done by the Audit party of the State Govt. and Central Govt. every year.

DELHI STATE CANCER INSTITUTES
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AMENDMENTSHEET

Sl. No.	Page no	Date of amendment	Details of the amendment	Reasons	Signature of the reviewing authority	Signature of the approval authority

CONTROL OF THE DOCUMENT

The holder of the copy of this manual is responsible for maintaining it in good and safe condition and in ideally identifiable and retrievable form.

The holder of the copy of this manual shall maintain it in current status by inserting latest amendments as and when the amended versions are received.

The Manual is reviewed at least once a year (or in between SOS if so required) and is updated as relevant to the Hospital policies and procedures.

The Authority over control of this manual is as follow:

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The Original Procedure Manual with Signatures on the Title page is considered as **"Master Copy"**, and the photocopies of the master copy for the distribution are considered as **"Controlled Copy"**.

Distribution List of the Manual

Sr.No.	Officials	Signature of Officials receiving copy

STANDARD OPERATING PROCEDURE (SOP) NUCLEAR MEDICINE DEPARTMENT

1. INTRODUCTION

i. Nuclear medicine is a broad speciality on its own. It comprises diagnostic examinations that result in images of body anatomy and function.

ii. The images are developed based on the detection of energy emitted from a radioactive substance given to the patient, either intravenously.

iii. Generally, radiation to the patient is similar to that resulting from standard X-ray examinations

iv. The functional information provided by nuclear medicine examinations is unique and currently unattainable by using other imaging procedures. For many diseases, nuclear medicine studies yield the most useful information needed to make a diagnosis and to determine appropriate treatment, if any. Nuclear medicine is much less traumatic than exploratory surgery, and allergic reaction to the radiopharmaceutical material is extremely rare.

2. LIST OF SERVICES

i. ONCOLOGY IMAGING
ii. BONE SCAN
iii. THYROID SCAN
iv. PARATHYROID SCAN
v. RENAL SCAN

3. JOB RESPONSIBILITES

3.1. Head of The Department (HOD)/ Professor

- Planning, proposing, processing the proposals, procuring & maintaining of machinery, equipment's & instruments.
- Duties related to Medical Education & Research
- Supervise duties
- Staff Training
- Supervise the medical, paramedical and technical staff
- Administrative functions.
- To exhibit keen interest, initiative & drive in the overall development of the Department.

3.2. SENIOR RESIDENT

- Staff training
- Supervise the medical, paramedical and technical staff
- Take patient histories.
- Interaction with various other clinical colleagues & departments

- Plan and coordinate studies for patients.
- Processing & reporting of diagnostic studies
- Coordinate & conduct Research activities
- Play an active role in the clinical, research and administrative activities of the institute
- Plan and execute new projects
- Image data processing.
- Assist HOD in reporting studies.

3.3. Nuclear Medicine Physicist & RSO

- Supervise the work of the technical staff.
- Prepare Annual Status Reports according to AERB / BARC regulation.
- Dealing with AERB/BARC as per the requirement
- Regular check e-LORA
- Obtain NOC for isotopes.
- QC of all the equipment
- Radiation monitoring.
- Personnel monitoring and records maintenance.
- Ensure Radiation Safety.
- Display of Radiation Symbols
- Periodic training/classes of Radiation safety
- Ensuring the periodic Radiation Safety meeting

3.4. Nuclear Medicine Technologist

- Maintain department records –
  - Patient records
  - Inventory of consumables
  - Inventory of isotopes
  - Equipment log book
- QC of all the equipment.
- Patient preparation.
- Acquisition of studies.
- Elution of isotopes.
- Radiopharmaceutical preparation.
- Basic data processing and film exposure.

3.5. Nursing Staff

- To ensure delivery of patient care through implementation of prescribed medication and monitoring effects.
- To provide nursing care to patients based on established clinical practice standards.
- To collaborate with other disciplines to ensure effective and efficient patient care delivery.

- To promote a safe environment for patients, visitors and co-workers including the implementation of infection control policies of the hospital.
- Maintain the Inventory of medical consumables
- Check that the central oxygen, suction apparatus, BP apparatus, stethoscope etc. are in working condition.
- To supervise the policy of waste segregation
- To see the every procedure tray must be clean
- Other miscellaneous work assigned by the supervisor

4. STANDARD OPERATING PROCEDURE

4.1 INSTRUMENTS/MATERIALS REQUIRED

i. PET-CT, SPECT CT, Medical Cyclotron, Isotope Calibrator, Contamination Monitor, Survey meter, Pocket Dosimeter, Thermoluminiscent Device (TLD) Badges, Lead Shields, required amount of radioactivity.

4.2 Patient Scheduling

i. Check the referring physician's request for radionuclide study.
ii. Check medications and advice preparation accordingly.
iii. Explain the procedure briefly – time duration, cost of the investigation, things to be brought by the patient for the test.
iv. Give appropriate time, considering the available resources (Radioactivity/radio pharmaceutical, available camera time etc). Enter the appointment details in **Appointment Register.**

4.3 Patient Scheduling

i. Explain the procedure to the patient (Check for test specific contraindications, please refer Precautions). Get the informed written consent form signed by the patient.
ii. Evaluate the ability of the patient to tolerate the procedure by recording the relevant history of the patient in **Patient History Form.**
iii. Ensure that an access for administration of radioactivity is available (IV line, Urinary catheter, feeding tube. etc).
iv. Check the need for sedation or pre medication.
v. Check for any specific contraindications for the study requested.
vi. Make sure that the informed consent is obtained whenever and wherever necessary.

4.4 Receipt of Radioactivity

4.4.1. Purpose

i. To ensure safe handling of radioactivity.
ii. To check the external contamination, exposure rates conforms the stipulated values.

4.4.2 Instruments/Materials Required.

i. Survey meter cum contamination monitor, absorbent paper, gloves, isotope calibrator.

4.4.3 Protocol for Opening Radioactive Parcels.

i. The Radioactive consignment is transported and delivered directly to the nuclear medicine department by the vendor in a NON passenger vehicle.

ii. Upon receipt of the consignment. Put on disposable gloves, identify the package for accuracy (Type, Category, Consigner, Consignee and Transport index). A radiopharmaceutical consignment received in nuclear medicine departments are of **TYPE – A.**

Categories of packages

Category	**Limit on maximum radiation level at The external surface of the package (mrem/hr)**	**Limit on the Transport index**
I - WHITE	0.5	0.0
II – YELLOW	50	1.0
III – YELLOW	200	10.0

iii. Visually inspect the package for damage, if damage is apparent, notify and seek help from the Radiological Safety Officer (RSO).
iv. Measure the exposure at 1-meter distance, ensure the value does not exceed transport index indicated on the package.

v. Open the package and verify that the contents agree with the packing slip.

vi. Check the integrity of the generator and look for evidence of breakage.

vii. Wipe the surface of the final source container, especially if there is any reason to suspect contamination. Assay and decontaminate the surface.

viii. Monitor the empty package and packing material with survey meter instrument and discard contaminated objects as radioactive waste, if not contaminated remove the radiation labels and discard them as regular waste.

ix. Complete the details and document the receipt of the package, subsequent inspection and tests. Enter the details in Isotope Receipt Record.

x. Any off-normal situations such as:

Damage to the package.

Package engulfed in fire.

Misplacement and theft of the package.

Loss of identity of the package.

Shall be intimated for assistance and advice in the matter to the competent authority at:

Chairman, Crisis management group, Department of atomic energy, Mumbai 400001

Telephone: 022-2023978, 2830441 FAX – 022-2830441

And

Head, Radiological Physics and advisory division, BARC, CT & CRS,

Anushakthi Nagar, Mumbai 400094, Telephone: 022-5519209, FAX – 5519209.

4.5 STORAGE OF RADIOACTIVEMATERIAL

i) Radioactive materials should be stored in storage area or designated area or specific area.

ii) Stored radioactive materials must be adequately shielded.

iii) Nuclear Medical physicist must ensure the storage area must be locked at all time and can only be accessed by appointed personnel.

iv) Radiation warning sign must be displayed on the storage area door.

v) Only appointed personnel are allowed to mobilise the radioactive material from the storage area

vi) Radioactive materials that have been removed from the storage area have to be checked and ensure in a good condition.

vii) The details of the radioactive materials including type of sources, activity, relocation and the

name of person responsible must be recorded whenever the radioactive material is taken in/out from the storage area.

viii) Storage area must be checked & monitored regularly to detect presence.

ix) In the event of fire breakout, Nuclear Medicine Physicist / RSO has to inform fire fighter thelocation of stored radioactive materials.

x) Record of all finding and investigation must be kept for future reference.

4.6 Radioactive Waste Management

Radioactive waste generated from sealed or unsealed sources in NuclearMedicine is generally in a form of a solid or liquid. These include:

A. Liquid wastes:

i. Unused radiopharmaceuticals and remains of labelled compoundsfrom radioassay kits.
ii. Excreta from patients who have received radiopharmaceuticals inthe course of diagnostic or therapeutic studies.
iii. Supernatant solution from radioassay kits.
iv. Water used to rinse or wash contaminated apparatus
v. Remains of radioactive stock and standard solution.

B. Solid wastes:

i. Contaminated syringes, swabs, needles, drip set, preparation vials, bottles and drinking straws used in nuclear medicine.
ii. Contaminated absorbent papers, towels, bed linens, patient's gowns or hospital's clothing, bed, syringe shields and disposable gloves.
iii. Used radionuclide generator (^{99m}Tc / ^{68}Ga).

4.6.1 Work Instruction

A. Responsibilities: The Nuclear Medicine Physicist/RSO or appointed personnel is responsible for ensuring that these procedures are carried out and all trained staff must follow these procedures. Any problems relating to the storage and disposal ofradioactive waste must be referred to the Nuclear Medicine Physicist/RSO or appointed personnel.

B. Disposal of Radioactive Wastes:

a. Solid Radioactive Waste:

i. Each radioactive waste should be separated according tohalf-lives of radionuclides.

ii. All sharp items generated from radioactive waste (syringe, needle, vial, etc.) shall be deposited into lead lined sharp bins with radioactivity hazard symbol outside the shielded bin at designated area.

iii. All non-sharp items generated from radioactive waste (gloves, absorbent paper and etc.) shall be deposited into lead lined radioactive waste bin with radioactivity hazard symbol outside the shielded bin at designated area.

iv. After the waste bin is maximum two-third full, the bin shall be closed with lid and securely sealed and labelled properly.

v. The appointed personnel shall collect these radioactive waste and transfer into the designated radioactive waste room for decay process.

vi. The radioactive waste shall be stored for decaying up to 10half-lives. After 10 half-lives the dose rate shall be measured before send to third party for disposal process.

vii. There are two options for radionuclide generators:

- Returning to the supplier after use or
- Waiting for decay and dismounting of the elution column afterwards. After a waiting time of 1.5 — 2 months, when the activity and the dose rate are so low that the elution column can be removed, the generator can be dismantled and the material be considered as non-radioactive. Labels should then be removed. Approval from appropriate authority must be obtained prior to dismantling.

viii. All radioactive waste disposals shall be recorded.

b. Disposal of Liquid Radioactive Waste:

i. Waste produced from short half-lives radionuclides like ^{99m}Tc and ^{18}F should be separated from those of longer half-lives and placed in the separate lead lined waste containers.

ii. Waste produced from medium half-life radionuclides like ^{131}I and 99mTc can be stored in the waste room for decay up to 10 half-lives.

iii. Excreta from patients receiving radiopharmaceuticals for diagnostic scan can be discharged directly into the hospital sewerage system.

iv. The radioactive waste shall be stored for decaying up to 10half-lives. After 10 half-lives the dose rate shall be measured before send to third party for

disposal process.

v. All radioactive waste disposals shall be recorded.

c. Return and Disposal of Unused Sealed Source:

i. Sealed sources such as ^{68}Ge and ^{137}Cs etc. are used for calibration and quality control of Nuclear Medicine instrument.
ii. Unused sealed source must be kept in the designated area/ waste room for decay or until return back to manufacturer.
iii. The user must write and get an approval from appropriate authority for disposal purpose.
iv. By practical approach the unused sealed source must be returned to the manufacturer. If a user is unable to return the used sealed source to its manufacturer, the user shall obtain a written approval from appropriate authority prior to sending the used sealed source to the radioactive waste management facility. The radioactive waste management facility shall be approved by the appropriate authority.
v. The dose rate shall be measured and recorded before send to manufacturer.

RECORD

No.	Record Name	Record Keeping Period
	Radioactive Waste Disposal Form	3 years after disposal

4.7 Procedure For Contamination AndDecontamination At Workplace

4.7.1 Procedure for monitoring contamination

4.7.1.1 Survey method using Calibrated Radiation Meter for fixed and removable contamination.

i. Set the instruments parameters. Cover the probe/radiation meter with plastic to avoid contact. Test the battery, reset the reading and measure background reading at about 3-5 m from the contaminated surface.
ii. Assess the potential contaminant area.
iii. Obtain a reading by hold the detector at a distance about 1cm from the contamination surface.
iv. Calculate the indicated total surface contamination bysubtract the background from the surface reading

v. Record the result.

4.7.1.2 Wipe test method for removable contamination.

i. Use cotton swab or wipe test smears to take severals amples from different areas.

ii. An area of 100cm^2 is simply wiped.

iii. Place sample in separate small vial, plastic or envelope.

iv. Label each vial or envelope noting the location of thesamples.

v. Samples are place in a liquid scintillation counter or well-counter.

Recommended limits for contamination on work surfaces.

For alpha : 0.37Bq/cm^2

For Beta : 3.7Bq/cm^2

Surface contamination limits:

S.No	Category of areas	Limit of Surface Contamination
1	Monitored area (e.g.: Inside fume hood, L Bench)	37 Bq/cm^2
2	Laboratory areas (surveyed)	3.7 Bq/cm^2
3	Other non-active areas	0.37Bq/cm^2

4.7.2 Procedure for Decontamination of Radioactive Spill. Prepare decontamination supplies list as below:

i. Caution line tape mark off perimeters and areas ofoperation.

ii. Radiation Contamination Meters.

iii. Decontamination solution (Radiacwash / Soap / Detergent).

iv. Disposable absorbent towels / paper towel / absorbentmaterial.

v. Hazardous waste containers / plastic bags.

vi. Tong or forceps.

There are two category of radioactive spill:

(i) Minor spill, (ii) Major spill

i. **Minor spill happen if:** Those where small drops or easily cleaned spills are contained on absorbent pads and pose no major hazards to workers. All spills of radioactive material are classified as a minor spill unless any of the following conditions are met; in which case it would be defined as a major spill.

a. Minor spills procedure such as:

i. Notify all other persons in the room at once.
ii. Keep the number of persons necessary to deal with the spillto a minimum.
iii. Confine the spill immediately.
iv. Decontaminate the area.
v. Monitor for residual loose contamination.
vi. If unable to decontaminate to acceptable levels, notify the Nuclear Medicine Physicist/RSO.
vii. No person can resume work until decontamination iscomplete.
viii. Consult Nuclear Medicine Physicist/RSO to determine if a bioassay is required.

ii. **Major spill happen if:** When a spill involves breakage of storage vial or contentsspilled from vial or syringe.

- When a spill involves any radioisotope of very highradio toxicity.
- When a spill involves release of volatile material.
- When it is suspected that inaccessible areas are contaminated.
- When reasonable efforts to decontaminate are notsuccessful.
- When there is any doubt about appropriate decontaminationprocedures.
- Any rupture or suspected rupture of a sealed source.

a. **Major Spill procedure such as:**

i. Notify all persons not involved in the spill to vacate the labat once.
ii. If the spill is liquid take measures to contain the spill.Delineate outer margin of spill with tape.
iii. Switch off all air circulating devices.
iv. Vacate the room and immediately notify Nuclear Medicine Physicist/RSO.
v. Ensure persons vacating the lab remain in the immediatearea to be monitor

for personal contamination.

vi. Take immediate steps to decontaminate personnel involvedas necessary.

vii. Post warning signs to prevent entry into contaminated area.

viii. Proceed to decontaminate area, wipe test for loosecontamination and survey for fixed contamination.

ix. Prohibit any work in the area until survey results are knownand approval is given by Nuclear Medicine Physicist/RSO.

x. Ensure the complete history of the incident is documented.

xi. Surface contamination derived limit in Table 1.

xii. Care must be taken not to permit the detector probe totouch any potentially contaminated surfaces.

4.7.2.1 Decontamination procedure

i. The contaminated area should be decontaminated by using decontamination solution and disposable absorbent towels/paper towel or any absorbent material.

ii. Allow the decontamination solution to settle on the contaminated area for several minutes before proceed with decontamination process.

iii. If the contamination occurred on top of an absorbent material, remove the contaminated material, put it into plastic bag and dispose it as radioactive waste. Small objects such as tongs and glassware can be cleaned by agitated submersion in a hot water.

iv. The Nuclear Medicine Physicist/RSO should be informed of the contamination incident as soon as possible.

v. Contamination and Decontamination Survey Report.

vi. Nuclear Medicine Physicist shall record all readings on Contamination andDecontamination Form.

RECORD

No.	Record Names	Record Keeping Period
	Contamination and Decontamination Form	3 Years

Major and minor spill criteria:

S NO	Isotope	Major spill	Minor spill
1	99mTc	>100 mCi	<100 mCi
2	131 iodine	>1 mCi	<1 mCi
3	153 Samarium	> 1 mCi	<1 mCi
4	18 Fluorine	>10 mCi	<10 mCi

4.8 Procedure for Personnel Contamination

Objective: To ensure all internal and external decontamination procedures on personnel arecarried out effectively.

4.8.1 External Contamination: Proper monitoring of personnel can detect and measure alpha, beta or gamma emitters: radiation type depends on isotope in contaminant.

a. Localized Contamination:

i. Decontamination Procedures:

- Remove contaminated clothing. Bag, label and store inradioactive waste room for decay.
- Survey for any residual contamination on the body.
- Cover uncontaminated body area with plastic sheet if necessary to avoid spread of contamination.
- Wash affected area with running tap water and detergent.
- Use mechanical action of flushing and/or friction of clothes,sponge or soft brush.
- Rinse area with running tap water and gentle dry.
- After drying, survey the contaminated body area to determine effectiveness of decontamination and record all readings.

b. Specific Contaminated Body Part:

i. Decontamination Procedure – General Body

- Survey entire body and record all readings.
- Visibly mark (e.g. with marker pen) the highly contaminatedbody area.
- Contaminated personnel should shower using liquid soapor equivalent. Begin with the head and proceed to the feet.

- Make an effort not to contaminate hairy areas if they arefree of radioactivity initially.
- Survey entire body again marking highest levels found.
- Record all readings.

ii. Decontamination Procedure - Eyes

- Irrigate with copious amounts of water.
- Survey the affected eye and record all readings.
- After decontamination, treat irrigation induced conjunctivitisas usual.

iii. Decontamination Procedure - Hair Areas

- Survey and record all readings.
- Wrap or position personnel to avoid spread of contamination.
- Wash with plenty of water or equivalent.
- Dry with clean uncontaminated towel. Do not shave hair — ifnecessary, hair may be cut, but do not injure skin.
- Survey and record all readings.

4.8.2 Internal Contamination

4.8.2.1 Internal Contamination Measurement.

a. Direct methods.

i. Whole body counters.
ii. Thyroid uptake system.

b. Indirect methods.

i. Indirect measurement of contaminant includes nasal swipes to determine respiratory intake of radioactive aerosols, and also urine and faeces sampling to establish internal contamination.
ii. Alpha and beta emitter, the most hazardous internalcontaminants, detected through bioassay sampling.
iii. Accurate bioassays require carefully executed sampling overtime and knowledge of type and time of contamination. (For more details please refer Guidelines for Bioassay sampling, IAEA).
iv. Nuclear Medicine Physicist shall record all readings in Contamination Survey Report Form.

RECORD

No.	Record Name	Record Keeping Period
	Contamination Survey Report Form	

4.9 PROCEDURE FOR RADIATION INCIDENT AND ACCIDENT:

OBJECTIVE: This procedure serves as a guide to individuals and nuclear medicine centers when handling radiation incident and accident. It is recommended that good radiation practice should be implemented in the interests of reducing radiation exposure and risks.

4.9.1 Types of radiation incidents and accidents.

A variety of incidents and accident may occur in nuclear medicine practice which can result in the inadvertent radiation exposure of a patient, a member of the public or a staff member. All incidents should be investigated, including 'near misses', to minimize the likelihood of such incidents occurring again. These include:

A) Operating errors.

Operating errors are due to:

i. Human Factors.

a. Staff.

- Administration problems (e.g. failed administration, incorrect labelling of pharmaceutical, incorrect dosage of radiopharmaceutical or extravasation etc.).
- Acquisition problems (e.g. incorrect field, inadequate counts obtained, inadequate views obtained, artefacts etc.)
- Computer problems (e.g. accidental deletion of patient studies).

b. Patient.

- Mainly movement due to (e.g. inadequate instructions to patient, inadequate sedation especially in children or unable to image child).

ii. Machine factors

- Power interruption.
- Computer problems (e.g. component damage).
- Mechanical problem.

Procedure:

- If operating error is detected by any staff, he or she should inform Nuclear Medicine Physicist/RSO.
- Nuclear Medicine Physicist/RSO will investigate and confirm the error.
- If problem persists, inform HOD and all the staffs involved and stop all related procedures immediately.
- Nuclear Medicine Physicist/RSO should contact the related equipment engineer to investigate and rectify the fault, if necessary.
- Record the event by filling up the repeat study form.

B) Loss, Theft or Sabotage of Radioactive Source.

It is critical to have an up-to-date inventory so that it can be determined immediately which source(s) is (are) missing, what its type and activity are, when and where it was last known to be, and who last took possession of it.

- Inform directly to Nuclear Medicine Physicist/RSO, and record the incident.
- HOD, with the help of Nuclear Medicine Physicist/RSO will conduct a local search.
- Check all possibilities in the hospital.
- If still not found, notify the appropriate authority (AERB) of such theft, loss or sabotage within 24 hours after discovering the theft, loss or sabotage.
- Submit a complete report of the theft, loss or sabotage in writing to (AERB) within 30 days after the notification to (AERB)

The report shall contain:

- A description of the radiation source, including its quantityand its chemical and physical forms.
- A description of the circumstances under which the theft/loss/ sabotage occurred. Location or probable location of the radiation source.
- The possible radiation exposure to individuals, circumstances under which the exposure may occur and the extent of potential hazard to members of the public.
- The action which has been taken or will be taken to recover the radiation source.
- The procedures or measure have been or will be adopted to prevent a recurrence of the theft, loss or sabotage of the radiation source.
- Any other information as the necessary.

C) Rupture or Damage of Sealed/Unsealed Sources

- Evacuate the area immediately.
- Inform the Nuclear Medicine Physicist/RSO who should confirm the spillage or radiation leakage and supervise the decontamination and monitoring procedures (refer to SOP for Contamination and Decontamination at Workplace).
- Record the event and make a report to appropriate authority.

D) Emergency Transfer of Patient Containing Radionuclide.

- Nuclear Medicine Physicist/RSO will confirm the defect related with the diagnostic equipment.
- With permission from the HOD, carry out the contingency arrangement which is coordinated by Nuclear Medicine Physicist/RSO.
- Arrange appointment at other nuclear medicine centres.
- Follow local procedure of transferring patient to other centre.
- Before transporting the patient, Nuclear Medicine Physicist/RSO should survey the dose rate of the patient or group of patient at 1 meter distance.
- Record the reading of the patient in the Emergency Transfer of Patient form.
- The Nuclear Medicine Physicist/RSO should provide adequate radiation monitoring devicefor staff involved in the transporting of the patients.
- The dose rate of the staff involved to the patient should berecorded.

RECORD

No.	Record Name	Record Keeping Period
1.	Emergency Transferring of Patients Containing Radionuclide Form	3 Years

4.10MANAGEMENT OF RADIATION EMERGENCY

OBJECTIVE: This procedure is a guideline for Nuclear Medicine Physicist/RSO to assist related emergency team / related agencies such as Police and Fire Department with facility specifications and radiation protection in the events of emergency.

4.10.1 Minor Fire.

Procedure: In order to handle a Minor Fire effectively, the following procedure shall be followed:

- The first person who discovered the fire shall immediately attempt toput out the fire by approved methods (e.g. fire extinguisher) if other fire hazards or radiation hazards are not present.
- If the attempt is failed and fire category move from minor to major, follow procedures for Major Fire.
- After the minor fire is put out, notify all persons present to vacate thearea and have one individual immediately call the Nuclear Medicine Physicist/RSO
- Once the fire is put out, isolate the area to prevent the spread of possible contamination.
- Nuclear Medicine Physicist/RSO will survey all persons involved in combating the fire for possible contamination.
- Persons involved, if contaminated, need to remove contaminated clothing and flushing contaminated skin with warm water, then washing with a mild soap (refer to SOP for Personnel Contamination).
- Nuclear Medicine Physicist/RSO and his team will then determine a plan of decontaminationand the types of protective devices and survey equipment that willbe necessary to decontaminate the area.
- Allow no one to return to work in the area unless approved by the Nuclear Medicine Physicist/RSO.
- Nuclear Medicine Physicist/RSO will supervise decontamination activities.
- Nuclear Medicine Physicist/RSO needs to consult with Hospital Emergency Team to ensure thatthere are no other possibilities of another fire starting and to assist inconducting investigation for root cause of fire.
- Nuclear Medicine Physicist/RSO will consider the need for bioassays if radioactive material is suspected to have been ingested, inhaled, or absorbed through the skin.
- Appropriate authority needs to be informed verbally within 24 hours and written report is submitted within 30 days of incident.

4.10.2 Major Fire and Natural Disaster.

Procedure: The following general guideline shall be followed:

- The first person who discovered the event shall notify all persons in the area to stop, secure their work and leave immediately.
- Notify the Police/Fire Department and briefly describe the nature of the situation.
- Notify the Nuclear Medicine Physicist/RSO and Hospital Emergency Team (Refer to hospital emergency action plan).
- Upon arrival of the Police/Fire Department personnel, Nuclear Medicine Physicist/RSO shall inform them where radioactive materials are stored or where radioisotopes were being used, inform them of the best possible entrance route to the radiation area, as well as any precautions tobe taken to avoid exposure or risk of creating further radioactive contamination.
- Police/Fire Department take charge upon arrival and proceed with the assistance of hospital Nuclear Medicine Physicist/RSO.
- Allow no one to return to work in the area unless clearance has been made by the Police/Fire Department.
- All the involved person (medical emergency response team, any victim that contaminated) should follow the instructions of the Nuclear Medicine Physicist/RSO (e.g., survey, decontamination techniques, provision of bioassay samples, requested documentation).
- Nuclear Medicine Physicist/RSO will determine necessary corrective actions, consider need for bioassays if radioactive material is suspected to have been ingested, inhaled, or absorbed through the skin.
- Nuclear Medicine Physicist/RSO will assist Police/Fire Department to investigate the root cause of the incident.
- Nuclear Medicine Physicist/RSO needs to notify appropriate authority verbally within 24 hours and written report is submitted within 30 days of incident.

RECORD

No.	Record Name	Record Keeping Record
1.	Standard Operating Procedure inthe Events of Emergencies	3 years

4.11PROCEDURE FOR SPECIAL PROCEDURES INNUCLEAR MEDICINE

A variety of special procedures may occur in nuclear medicine practice which can result in the inadvertent radiation exposure of a patient, a member of the public or a staff member. These include:

a) Medical emergencies involving radioactive patients
b) Need for urgent patient attention and including surgery
c) Death of the patient
    i. Death of the patient following a nuclear medicine scanning
    ii. Organ donation
    iii. Precautions during autopsy
    iv. Preparation for burial and visitation
    v. Cremation

WORK INSTRUCTION

a) Medical emergencies involving radioactive patients.

For patient who required resuscitation:

- Responsible medical personnel should notify the relevant people (e.g staff involved in resuscitation in the hospital).
- Notify Nuclear Medicine Physicist/RSO and inform the emergency situation.
- Nuclear Medicine Physicist/RSO will provide the disposable gloves, gowns and pocket dosimeters to the staff involved in resuscitation.
- Nuclear Medicine Physicist/RSO should measure the radiation level of the patient and estimate time of exposure allowed to the staff involved in resuscitation. Rotation of staff should be carried out during the resuscitation.
- Do not apply direct mouth-to-mouth resuscitation.
- Materials/equipment that has come into direct contact with the patient should be checked for contamination after the resuscitation and handled accordingly.
- All the detail regarding radiation exposure from patients containing radionuclide and personnel involve must berecorded.

b) Need for urgent patient attention.

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Attention should be paid to the following points:

- The Nuclear Medicine Physicist/RSO shall advise and supervise on radiation safety issues to the relevant staff in the ICU/CCU/operation theatre.
- If a transfer is required, the fact that the patient may still contain radioactive source should not interfere with the clinical management of the case.

- In the case of patient administered with radioactive sourcefor whom intubation, catheterization or use of a nasogastric tube may be necessary, staff should wearprotective gowns and gloves when handling the patient in order to avoid radionuclide contamination.
- Spillage of body fluid should be contained as far as possible by means of absorbent pads, and the pads should be discarded in the waste bag label with radiation signage.
- Any suction bottles or urine bags used must not be discarded until checked for contamination by Nuclear Medicine Physicist/RSO.
- Nuclear Medicine Physicist/RSO shall check all the contaminated items before dispose as normal clinical waste.

c) Death of patient.

i. Death of the patient following a nuclear medicine scanning.

- If a patient dies during the scanning, the Nuclear Medicine Specialist shall consult the Nuclear Medicine Physicist/RSO on how to minimize exposure to the person handling the body. The movement of the body should be minimised, using strict procedures for prevention of contamination from body fluid, until the Nuclear Medicine Physicist/RSO arrive.
- Body fluid may be radioactive and catheterisation of the cadaver should only be performed under the direct supervision of the Nuclear Medicine Physicist/RSO.
- Deceased body released for autopsy, embalming, cremation or burial should have a label identifying theradionuclide and its activity at the time of release, together with a release statement signed by the Nuclear Medicine Physicist/RSO.
- Transportation of a deceased body containing radioactive source shall follow the As Low As Reasonably Achievable (ALARA) concept.
- Other practical measures for dealing with deceased body shall include:

  - Notify the relevant people who will be handling the deceased body.
  - Staff involved in handling a deceased body should wear disposable gloves, gowns and pocket dosimeter.
  - Nuclear Medicine Physicist/RSO shall measure the radiation level from thedeceased body and estimate the time of exposure allowed to the staff.
  - Material/equipment that has come into direct contactwith the dead body shall be checked for contamination at the end of the procedure.
  - Prepare relevant documentations and notify the appropriate authority within 24 hours.
  - All details regarding radiation exposure from the deceased body containing radioactive source and personnel involved shall be

recorded.

ii. Organ donation.

It is not advisable to donate the organs to avoid any unnecessaryradiation exposure to member of public.

iii. Precautions during autopsy.

- Procedures for personal protection normally observed during an autopsy to provide adequate protection against external radiation exposure or contamination withradioactive material.
- The pathologist should be informed of the radiation levels likely to be encountered and of the hazards involved. The methods employed and the precautions adopted should be chosen accordingly in consultation with the Nuclear Medicine Physicist/RSO.
- The fluids from the procedure shall be disposed via the sewerage system.
- The equipment used in autopsy should later be decontaminated by thorough rinsing in a detergent solution followed by washing in running water.

iv. Preparation for burial and visitation.

- The physician involved should identify a radioactivepatient (the date, type of radionuclide, and the amount of administered activity) and attach a label to the body.
- The body should be surveyed by using radiation survey meter and probe sweeping 1 inch away from the body surface.
- If the level of radiation is less than 1 mSv/hr, there is no need for personal dose control of the staff or of the relatives of the deceased. Preparations for burial and any contact between relatives and the body should be controlled by a competent person, who will label the body with the radiation symbol. There is no need to label the coffin. All objects, clothes, documents, etc. that have been in contact with the deceased must be tested for contamination only if it is not sent for burial or cremation.
- If the level of radiation is higher than 1 mSv/hr, relatives must be prevented from coming into contact with the body, and people must not be allowed to linger near the body. The hospital staff, the coroner, the persons washing and

preparing the corpse for burial, the staff of the undertaker, and the transportation and cemetery staff must be instructed by the Nuclear Medicine Physicist/RSO and monitored for their personal dose rate by means of pocket dosimeters. All objects, clothes, documents, etc. must be tested for contamination only if it is not sent for burial or cremation. Itis expedient to wrap the body in plastic foil immediately after death has occurred, and it should never be handled unless with disposable protective gloves.

v. Cremation.

No.	SOP Title	Record Keeping Period
1.	Radiation Exposure Received By Personnel.	3 years

vi. Misadministration of radiopharmaceutical (wrong Dose, Patient, radiopharmaceutical, Route and administration of radioactivity to a pregnant female patient without confirming pregnancy).

vii. Any other event that may lead to situations of radiological consequence.

Detailed follow up report including the following shall be submitted to the competent authority:

(a) Date and time of occurrence:

(b) Radionuclide, its activity and radiopharmaceutical composition:

(c) Brief description of the incident:

(d) Action taken:

(e) Probable causes of the incident:

4.12 Imaging and non-imaging instrument Preventive Maintenance

4.12.1 Purpose

i. To maintain the equipment in proper working condition.

ii. To protect the equipment from mechanical, physical environmental damage.

4.12.2 Dos and Don'ts

i. Do not use detergents or organic solvents to clean the PET - CT imaging systems, isotope calibrators. Survey instruments.
ii. Clean the surface of the system with a cloth moistened with 95% ethyl alcohol.
iii. Check the cables for nicks, cuts and exposed wires.
iv. Never place any items on the collimator or detector.
v. Never place any items on the operator console or electronic cabinet.
vi. Maintain room temperature for the Gamma camera and PET- CT at a constant level.
vii. Failure to do so may result in damage to the crystal.
viii. Check for proper movement during all mechanical operations and for any unusual noises. In case of any break down enter the details in **Call Log Register.**

4.12.3 Policy for cleaning other instruments:

Lead syringe carriers, Syringe shields, Forceps and vial holders, Contrast injector, Defibrillator,

i. Every morning before the commencement of work. Clean the surface with a cloth moistened with 95% ethyl alcohol. Allow to dry completely prior to use.

Wheel chairs and Strechers:

For the safety of the next patient a wheelchair must be rendered free from contaminants. This assists in the prevention of the spread of infection. This procedure also provides reassurance and confidence to patients.

Procedure for Cleaning Wheelchairs between Patients

1. Collect wheelchair.
2. Take wheelchair to patient's bed end.
3. Put on disposable gloves and apron (Personal Protective Equipment – PPE).
4. Wipe over all areas of the chair that had patient contact including arm rests with 1% sodium hypochlorite.
5. Remove PPE carefully wrapping the cloth within the gloves and dispose of into appropriate waste bin.

6. Clean Hands.
7. Return to patient and help into the wheelchair.
8. Return wheelchair to a central point.
9. Process must be repeated for the next patient movement.

4.12.4 PET CT Quality Control

i. Clean mylar window is unobstructed and free of dust/ iv contrast media.
ii. Perform Tube warm up, followed by Fast cal for the CT.
iii. Initiate PET QC by selecting Daily QC. Follow instructions on the Left monitor.
iv. Make sure all the sonograms are uniform and variance values and colour code are within manufacturer prescribed limits.
v. In the event of colour code yellow/red., inform biomedical department/service engineer.
vi. Record the event in equipment breakdown record Call Log Register.

4.13 PRECAUTIONS IF ANY

4.13.1 General Precautions

i. In women of childbearing age, pregnancy and lactation status should be determined.
ii. Previous incidence of allergic reactions for any of the medicines used for the test should be checked.
iii. Use protective clothing, TLD badges, protective shielding etc.
iv. Check and confirm that the QC files of detectors have been updated.
v. Follow the guidelines when handling, transporting and disposing radioactive material (Refer to precautions section).
vi. Ensure that the ALARA (As Low as Reasonably Achievable) principle has been followed as every step, which involves radiation exposure to the general public and staff members.

4.14 LIST OF STUDIES

4.14.1 ^{18}F- FDG PET CT Study (Oncology Imaging)

a) Indications

i) Staging and restaging of malignant disease, differentiating recurrent or residual disease, monitoring the response to therapy, detection of unknown primary malignancy.

b) Patient Preparation

i) Pre-arrival: Patients are advised to fast for at least 4 hrs, to stop all glucose containing infusion for 6 hours.

ii) Pre-injection:

- The blood glucose level (less than 140mg/dL) may be checked prior to the FDG administration. Tumour uptake of FDG is reduced in hyperglycaemic states.
- For brain imaging, for several min before FDG administration and during the uptake phase of FDG, the patient should be inj a quiet and dark / dim lit room.
- Intravenous injection of the radiopharmaceutical at a site contralateral to the site of concern is followed by the acquisition of the transmission (CT) and emission (PET) images beginning about 60 min later.

c) Dose:

Typically, 5-15 mCi is injected in a peripheral vein (see counts requirements below). Injection speed is not critical (i.e., bolus to 2 minutes). To reduce patient dose to the bladder, patients should be encouraged to void frequently for 3-4 hours after the study.

d) Imaging

i) The CT in the framework of a PET/CT examination comprises the tomogram and the helical CT scan.

ii) For a diagnostic contrast-enhanced CT, standard CT mill ampere-seconds settings or those given by the radiological societies/radiologist are used. The modulation of the tube current is used to lower the radiation exposure of the patient. Depending on the clinical question, intravenous and/or oral contrast agents are used.

iii) PET images are acquired in several bed positions at 2min per bed position.

e) Interpretation Criteria

i) Normal physiologic uptake of FDG can be seen in the brain, myocardium (where the uptake appears in some patients despite prolonged fasting), liver, spleen, stomach, intestines, kidneys and urine.

ii) Increased FDG uptake outside the expected physiological sites of FDG distribution is considered as abnormal. The FDG uptake is co-related with the CT images and interpreted.

iii) Standardized uptake values are increasingly used in clinical studies in addition to visual assessments. SUV is a measurement of the uptake in a tumour normalized on the basis of a distribution volume.

iv) It is calculated as follows:

$$\text{SUV} = \frac{\text{Actvoi(kBq/ml)}.\text{Actvoi(kBq/ml)}}{\text{Actadministered (MBq)/BW(kg)}}$$

4.14.2 <u>C-11 CHOLINE PET SCAN</u>: C-11 Choline PET scan is an imaging test used in detecting sites of prostate cancer that has recurred, despite treatment. It may be used when other imaging has failed. This positron emission tomography (PET) scan uses a special chemical tracer called C-11 Choline Injection. This imaging test is done alongside a low-dose computerized tomography (CT) scan to help further show internal anatomy.

1. **USES OF C-11 CHOLINE PET SCAN**

- Detect possible sites of recurrent prostate cancer that ordinary imaging tests cannot identify.
- Detect early location of the recurrent prostate cancer, which enables identification of small, isolated deposits of cancer, within and outside the prostate; for a more effective treatment.

2. **SYMPTOMS OF PROSTATE CANCER:** Some people have no early symptoms until cancer develops over years, while others show early indications. These signs may include:

- Frequent urination.
- Difficulty in starting or stopping urination.
- Blood in urine or semen (which is quite rare).
- Weak, interrupted, and slow urine stream.
- Applying pressure while urinating.

- Urinary stream splits.
- Discomfort, due to pain or burning sensation, with urination or ejaculation.
- Intense pain in the lower back, hips, or thighs.
- Longer time to urinate.
- Inability to empty the prostate.
- Sudden urging and pressing urination.

3. PREPARATION FOR THE C-11 CHOLINE PET SCAN:

- Don't eat or drink anything, except for water, for 6 hours before the scan.
- Your last meal before the test should include high protein foods and plenty of water.
- Avoid carbohydrate foods and foods with sugar.
- Continue with your prescribed medications.

4. PROCEDURE FOR C-11 CHOLINE PET SCAN

- A small amount of the tracer ^{11}C- CHOLINE (5-15MCI) is injected intravenously.
- After injection patient is asked to lie in supine position on a moving table.
- Intravenous injection of the radiopharmaceutical at a site contralateral to the site of concern is followed by the acquisition of the transmission (CT) and emission (PET) images.
- The CT in the framework of a PET/CT examination comprises the tomogram and the helical CT scan.
- PET images are acquired in continuous bed motion with a average speed 1.4 and also by bed positions at 2min per bed position.

4.15Radiological surveillance program

4.15.1 <u>Purpose</u>

i. To assure that structural barrier for radioactive source is adequate.

ii. To ensure that the premises of radiation exposure levels in public, supervised and controlled areas are within prescribed limits.

iii. To ensure safety of radiation workers, general public from exposure to radiation and imaging equipment's from potential contamination.

4.15.2 Instruments/Materials Required

i. Ionization chamber/GM based Survey meter

4.15.3 Method

i. Operational monitoring – daily before commencement of work and whenever there is a potential chance of contamination of radioactivity. Performed by a radiation worker.

ii. Routine monitoring – at frequent intervals at least once a month, not confining to a common date. Performed by the RSO to confirm the designated areas in the work place, to prove the adequacy of measures against external and internal hazards and to reveal any deterioration in the standard of radiation safety. The survey results are documented and filed in the area monitoring record.

4.16Imaging protocols for quantitative SPECT-CT: Nuclear medicine SPECT-CT systems are routinely used for quantitative imaging. From determining relative kidney performance, to binding ratios in the brain, one of the strengths of gamma camera imaging is its ability to quantify in-vivo physiology for a wide range of conditions and applications.

4.16.1 Acquisition: Some steps that should be followed in the acquisition process are:

i. Steps should be taken to limit the possibility of patient motion. It is important that the patient remains in the same position during both the CT and SPECT acquisition to ensure good image registration and accurate CT attenuation correction.

ii. The optimal collimator will depend on the radionuclide being imaged. Relevant imaging guidelines should be followed when choosing an appropriate collimator.

iii. Step and shoot or continuous acquisition mode of acquisition can be used. The latter can offer a 1–2 min saving on scanning time over 60 rotation angles.

iv. Detector auto-contouring is advised to minimize the distance between the detectors and patient to provide optimal spatial resolution. However, for some applications detectors can be kept at a fixed but close distance.

v. Acquisition should typically be performed with opposing detectors at 180° from one another.

vi. A pixel size smaller than half the full width at half maximum (FWHM) spatial resolution of the system for the radionuclide used is recommended to ensure appropriate spatial sampling. Commonly, a matrix size of 128 × 128 is used. It should be noted that decreasing the pixel size results in a noisier image.

vii. The number of projections is recommended to be similar to the matrix size (e.g. 120–128 projections for a 128 × 128 matrix) to ensure appropriate angular sampling.

viii. The time per projection will depend on the amount of radioactivity in the patient. As noise in the projection data follows a Poisson distribution, and in reconstructed data is much worse, imaging time must be high enough to reduce image noise as much as possible. If multiple fields of view (FOVs) are acquired, the time per projection may have to be decreased for patient comfort.

4.16.2 Reconstruction

Iterative methods are recommended to reconstruct the acquired SPECT projections. Normally, the algorithm used will be that included in the software provided by the vendor of the gamma camera; however, third-party algorithms are also available. For quantitative purposes, the number of up

4.16.3 Corrections

i. **Attenuation correction:** Attenuation correction based on CT data should be used for quantitative SPECT-CT.
ii. **Scatter correction:** To correct for scattered gamma-rays present within the photopeak window, multiple energy window scatter correction methods are typically applied, although model-based scatter correction can also be used if available. Smoothing of the scatter window image may also be beneficial to reduce propagation of image noise from the correction to the reconstructed image. It is important to validate scatter

correction techniques using appropriate phantoms containing areas of no activity, surrounded by uniform activity, to demonstrate that the algorithms do not over-correct the final image.

iii. **Decay correction:** Understanding how and when decay correction is applied is important in quantitative SPECT-CT. Given the relatively long physical half-life of most SPECT radionuclides, its application to ensure differences are accounted for in the acquisition of the first and last projection are relatively minor.. In multiple SPECT field of view studies where the study may take up to 1 h, decay correction should also be performed to ensure consistency of relative pixel values across all acquired projections.

Clinical use cases:

4.16.4 Bone imaging: Technetium-99m labelled bisphosphonates accumulate in newly formed bone and enable visualisation of bone turnover. Many conditions are associated with pathological bone turnover, and bone SPECT-CT using these tracers is an established and powerful diagnostic tool in their diagnosis and management.

f) Skeletal Scintigraphy: Protocol Summary for Whole Body Survey and SPECT

i) Patient Preparation And Follow-Up

- Patient should be well hydrated
- Patient should void immediately before study and should void frequently after procedure (reduces radiation dose to bladder wall)
- Patient should remove metal objects (jewellery, coins, keys) before imaging

ii) Dosage And Route Of Administration

- 20 mCi (740 MBq) technetium-99m diphosphonate adult dose (standard)
- Intravenous injection (site selected to avoid known or suspected pathological condition)
- Adjust dosage for paediatric patients (Webster's rule or weight adjusted; Minimum 74 MBq [2 mCi])

iii) Time of Imaging

- Begin imaging 2–4 hr after tracer administration

iv) PROCEDURE

- Anterior and posterior views of the entire skeleton
- Obtain a minimum of 1000k counts per view for "whole body "imaging systems
- Obtain 300k–500k counts per image if multiple spot views are used
- Use the highest resolution collimator that permits imaging in a reasonable length of time
- Obtain high-count (1000k) spot views or SPECT for more detail

v) SPECT

- Acquisition: contoured orbit,128 × 128 matrix,6-degreebintervals,15–30 sec/stop
- Reconstruction: filtered back projection, Butterworth filter; cut-off 0.4,power 7
- Selection of SPECT acquisition and reconstruction parameter

b) Tc-99m Pertechnetate Thyroid Imaging: Protocol Summary

i) PATIENT PREPARATION

- Discontinue any medications that interfere with thyroid uptake of Tc-99m pertechnetate.
- Nothing by mouth for 4 hours prior to study.

ii) RADIOPHARMACEUTICAL

- Tc-99m pertechnetate,3–5 mCi (111–185 MBq) intravenously

iii) TIME OF IMAGING

- 20 min after radiopharmaceutical administration

iv) IMAGING PROCEDURE

- Gamma camera with a 3- to 6-mm aperture pinhole
- Collimator and a 20% energy window centered at 140 Kev.
- Position the patient supine with the chin up and neck extended.
- Position the collimator so that the thyroid fills about two thirds of the diameter of the field of view.
- Obtain anterior, 45-degree LAO and RAO views (move the collimator rather than the patient).
- Obtain 250k counts per view.
- Mark the chin and suprasternal notch.

- Note the position and mark palpable nodules and surgical scars.
- Place marker sources lateral to the thyroid to calibrate scan

c) Tc-99m Sestamibi Parathyroid Imaging: Protocol Summary

i) PATIENT PREPARATION: None

ii) RADIOPHARMACEUTICAL: 20 mCi (740 MBq), intravenously

iii) TIME OF IMAGING

- Early scans at 15 minutes
- Delayed scans at 2 hours

iv) IMAGING PROCEDURE

- Planar
- Use a high-resolution collimator and a 20% window centered at 140 KeV.
- Position the patient supine with the chin up and neck extended.
- Place markers on the chin and sternal notch.
- Obtain anterior and 45-degree left and right anterior oblique views, 300k counts per view.

v) SPECT IMAGING

- Position patient as above.
- Use a high-resolution collimator and a 20% window centered at 140 Kev.
- Use dual-headed SPECT camera: 360-degree contoured acquisition arc,3-degree angular Sampling increment,15–30 sec per view,128 × 128 matrix with 1.5 zoom, Hanning or Butterworth filter.
- Reconstruct trans axial, coronal, and sagittal planes.
- Re-project images at each sampling angle

d) Dynamic Renal Scintigraphy

i) Patient Preparation

- Hydration
- Adults: drink 300–500 ml of water
- Children: Intravenous hydration 10–15 ml/kg over 30 min;<1 year use dextrose 5% in 0.45% normal saline, >1 year of age D5 in 0.45% normal saline

- Patient must void before starting study

ii) RADIOPHARMACEUTICAL: Tc-99m DTPA

- Adults: 3 - 5 mCi (555 MBq)
- Children: 200 µCi/kg (2 mCi minimum,10mCi maximum)

iii) Instrumentation

- Camera: large field of view gamma
- Collimator: low energy, parallel hole
- Photopeak:15–20% window centered over 140 keV

iv) PATIENT POSITION

- Routine renal imaging: supine, posterior
- Renal transplant: patient supine, camera anterior over allograft

v) COMPUTER ACQUISITION

- Blood flow:1- to 2-sec frames for 60 sec
- Dynamic:30-sec frames for 25 min
- Pre-void image 500k count
- Postvoid image

vi) PROCESSING

- Draw computer region of interest around kidneys and for background area
- Generate time–activity curves for 60-sec flow phase and for 25-min dynamic study

4.17 QUALITY CONTROL OF SPECT AND SPECT/CT

1. Uniformity

- Selecting a radionuclide source of appropriate type, size, (if necessary), quantity and energy
- Selecting an appropriate pulse height analyzer (PHA) photopeak and window
- Obtaining uniformity images using standardized imaging parameters
- Evaluating the images qualitatively and/or quantitatively in comparison to the manufacturer's specifications and the performance requirements based on the studies for which unit is used
- Identifying the source of any non-uniformity (i.e. checking collimator, PHA peak setting)
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

2. Linearity

- Selecting a radionuclide, a linearity phantom and obtaining images
- Identifying any nonlinear distortion in the image
- Determining the source of nonlinearity. (i.e., detector-source geometry)
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

3. Spatial resolution

- Selecting an appropriate radionuclide
- Choosing a phantom that is compatible with the specified resolution of the camera
- Analyzing the resulting images for degradation of resolution
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

4. Sensitivity

- Selecting a source with an appropriate level of activity and half-life
- Assuring identical geometry, source placement and measurement parameters for repetitive checks
- Evaluating results
- Initialing corrective action when necessary
- Maintaining required records for the quality control program

5. SPECT quality control procedures

- Obtaining a high count uniformity flood
- Obtaining a center of rotation correction
- Verifying energy correction and spatial coordinates
- Verifying multi-head detector alignment
- Evaluating reconstruction results of phantom acquisition
- Analyzing the results for degradation
- Initiating corrective action when necessary
- Maintaining required records for the quality control program

4.17.1 Dose calibrator, pocket dosimeter, Survey &contamination meters, Area zone monitors:

- By ensuring calibration is completed with an approved
- By performing a reference check-source test and comparing with previous results
- By maintaining required records for quality control program

MEDICAL CYCLOTRON SOP

Standard Operating Procedure (SOP) of Cyclotron

1. **Step1:** Check all the preliminary parameters before starting Cyclotron and maintain all the record of checklists.
2. **Step2:** CHECK the cyclotron control cabinets room AC is Switched **ON** or not, and set the temperature to 19^0C
3. **Step3:** Open the Master System by using User Name and Password
4. **Step4:** Check the below parameters in System Status Window;
   - **a.** Target Minimum Pressure
   - **b.** He Cooling Pressure
5. **Step5:** Dry the Target with Helium Gas at least 15 min.
6. **Step6:** Fill the Target with O18 Water and check the Target Pressure.
7. **Step7:** Switch on the Magnet by clicking the PET Trace and then Start H for Protons and check the magnet PSMC Current.
8. **Step8:** Click the Production and enter the below details;
   - **a)** User Name
   - **b)** Password
   - **c)** Target Current
   - **d)** Irradiation Time
9. **Step9:** Click the irradiation, start Irradiation when it is highlighted.
10. **Step10:** Observe the System Parameters by clicking System Status and observe below parameters;
    - **a.** Dee Voltages
    - **b.** Delta between Dee Voltages
    - **c.** Ion Source Current and voltage
    - **d.** Running Vacuum Pressure
    - **e.** H Gas flow rate
    - **f.** Target Pressure
    - **g.** Collimators Currents
    - **h.** Foil Current and number running foil
    - **i.** Probe Current
    - **j.** He Cooling Pressure
    - **k.** Irradiation Time
    - **l.** Estimated Activity

11. **Step11:**After Irradiation Time is over, click the delivery option and deliver the Irradiated O18 Water to Hot Cell by checking with Radio chemist
12. **Step12:** Check the Transfer Time.
13. **Step13:** After Transfer dry the Target with Helium Gas upto 15 min.
14. **Step14:** Shutdown the Cyclotron.
15. **Step15:** Set the Cyclotron control cabinated room AC to 24^{0}C.
16. **Step16:** Maintain all the records of Cyclotron Production Parameters.

Standard Operating Procedure (SOP) for FDG Synthesis in FX2N Module

Reagents Required for FDG Synthesis:

1) **15mg cryptand + 0.5mL Potassium Carbonate + 0.5mL water for injection in vial no. 1**
2) **1mL of Na OH in vial no. 2**
3) **20mg of Mannose triflate in 1ml of Acetonitrlle in vial no. 3**
4) **2mL of water for injection invial no. 4**
5) **14mL of water for injection in vial no. 5**

NUCLEOPHILLIC SUBITITUTION REACTION

After fluorine -18 coming in V-Vial, it will come to QMA (Quaternary ammonium anion exchange column) and Oxygen-18 water will go to recovery vial.

Step1: ADDITION OF KRYPTOFIX

Eluent (kryptofix, vial 1) will go through QMA and takes F18 into reaction vessel with the help of vacuum pump. It will take 2 and a half minutes.

Eluent evaporation Step: Set point is 65^{0}C and Helium (valve 20) and Vacuum pump should be ON for 4 minutes.

Eluent Drying Step: Set point is 90^{0}C, valve 20 will be closed, only vacuum pump will be ON for around 6 minutes.

Step2: ADDITION OF MANNOSE TRIFLATE FOR LABELLING

Mannose triflate (Vial 3) will add to reaction vessel with the help of Helium.

It will take 5 minutes for mannose Triflate reaction.

Temperature set point 50^0C. it will take 1 minute.

Stander operating procedure for manual cleaning of FX2 N module

- Switch on Helium gas and compressed air form knob of Hot Cell
- Power should be ON
- Step:1
- Add 2mL each water for injection in first vials and 3mL 70% ethanol in final product vial,
- Switch ON the Vacuum pump & V24
- Set temperature 50^0C and reactor needle down & stirrer ON
- Open V1 & V13 for 15 Seconds.
- Close V1 & V13
- Open V2 for 15 Seconds.
- Close V2
- Open V3 for 15 Seconds.
- Close V3
- Switch OFF the Vacuum pump & V24
- Open V16 & V22 (inside) and V20 & V14 for 3 minutes. (check physical whether 6mL water is going in waste bottle or not also check 3mL of 70% ethanol is passing through output tubing into bulk vial or not).
- Close V16 and V22 (outside) and close V20 and V14.
- Switch ON the Vacuum pump & V24
- Close V1 & V13 for 1 minute.
- Close V1 & V13
- Close V2 for 1 minute
- Close V2
- Close V3 for 1 minute
- Close V3
- **Step:2**

- Add 2mL each Acetone in first 3 vials.
- Open V1 & V13 for 15 Seconds.
- Close V1 & V13
- Open V2 for 15 Seconds.
- Close V2
- Open V3 for 15 Seconds.
- Close V3
- Switch OFF the Vacuum pump & V24
- Open V16 & V22 (inside) and V20 & V14 for 4 minutes. (check physical whether 6mL water acetone is going in waste bottle or not.
- Close V16 and V22 (outside) AND CLOSE V20 and V14.
- Switch OFF and reactor needle UP
- Switch ON the Vacuum pump & V24
- Open V1 & V13 for 2 minute.
- Close V1 & V13
- Open V2 for 2 minutes
- Close V2
- Open V3 for 2 minutes
- Close V3
- Open V4 for 1 minute
- Close V4
- Set temperature 40^0C
- Open V5 & V19 for 1 minute
- Close V5 & V19
- STOP & RESET.
- Close knob and switch OFF power.

Special precautions after target foil rupture

If a foil breaks during production foil fragments might be spread throughout the vacuum chamber. All foil fragment need to be cleared out before any service tasks are performed on the cyclotron.

4.17.1.1.1 Measure the radiation levels when entering the vault. Estimate accumulated dose before proceeding.

If the estimated accumulated dose is acceptable proceed with next step.

If the estimated accumulated dose rate is not acceptable, wait until the estimated accumulated dose has decreased to an acceptable level before proceeding.

2) Measure the radiation levels when opening the vacuum chamber door. Estimate accumulated dose before proceeding.

If the estimated accumulated dose is acceptable proceed with next step.

If the estimated accumulated dose rate is not acceptable, wait until the estimated accumulated dose has decreased to an acceptable level before proceeding.

3) Carefully check the entire vacuum chamber for target foil fragments.

The foil fragment will be revealed by high radiation levels at certain spots Radiation levels about 1 mSv/h (100 µSv/h) 10cm in front of your electronic dosimeter indicates target foil fragments.

WARNING Radioactivity

The target foil are extremely radioactive. Handle with care.

Never touch the foil. Use a pair of tweezers when handling the foils to increase the distance from the foils.

If the foil broken, check for foil fragments Remainder that fragments also very radioactive.

To minimise exposure remove the foils from the work area as soon as possible.

4) Dispose of the target foil free fragments in the GE supplied target file container.

5) Check the collimators for foil fragment. If there are any indication of foil fragment on a collimator it needs to be replaced.

6) If the target foil particles are too small to pick up with a pair of tweezers, wipe the area clean using isopropanol and lint- free paper.

Warranty radioactivity

Dispose of the linked free paper in the secure way it may be radioactive.

7) Check the vacuum chamber and area surrounding the cyclotron for radiation. Make sure they are clean from all target foil fragments.

8) Check yourself and your equipment for radiation before leaving the controlled area.

Warranty radioactivity

All people and material living a cyclotron site must be checked for radiation using a doors metre and a surface contamination detector.

Not that material can be radioactive either due to exposure during bombardment or contaminated for example with foil particles.

CYCLOTRON EMERGENCY

The emergency procedures outlined below would be applied in the event of a target pressure loss, cyclotron area monitor alarm, any time a radioactive material delivery from the cyclotron target is delayed for more than 10 minutes beyond the expected time and/or in the event of any accidental radioactive material contamination or exposure:

- Shut down the cyclotron immediately
- Determine the extent and severity of the emergency situation. Wear protective clothing and an audible alarm personnel dosimeter and use a calibrated survey meter to identify areas with elevated exposure rates.
- Place visible barriers [tape, rope, signs, etc.] around identified areas to warn personnel against entry.
- Notify facility RSO.
- If activity transfer delay occurs, the problem may be corrected from the control terminal or by adjustment of the vacuum/ pressure system.
- Do not attempt to correct delivery line problem if personnel exposures greater than 1 mSv [100mR] whole body would be expected from the procedure.

  In case of power failure the cyclotron will default to a fail-safe condition until power is restored. Automatic sequencing will provide for un-attended restart of ancillary systems (e.g. water cooling and vacuum]. The cyclotron will require manual intervention by a qualified operator to restart the beam or deliver target material.

Emergency Procedures

- Keeping radiation doses to workers and members of the public ALARA;
- Ensuring the security of licensed material;
- Responding to radiological emergencies per our internal procedures; and
- Making the required notifications of events.

Emergency procedure for failure of ventilation system in cyclotron

The following procedure should be followed

In case of failure of ventilation system in cyclotron, the operator will switch OFF the flow. The ACS system should be working which will lead to containment of air/gases.

If the ACS system also fails, the flow will go through vent provided with charcoal filter.

Emergency Procedure in case of fire breakout:

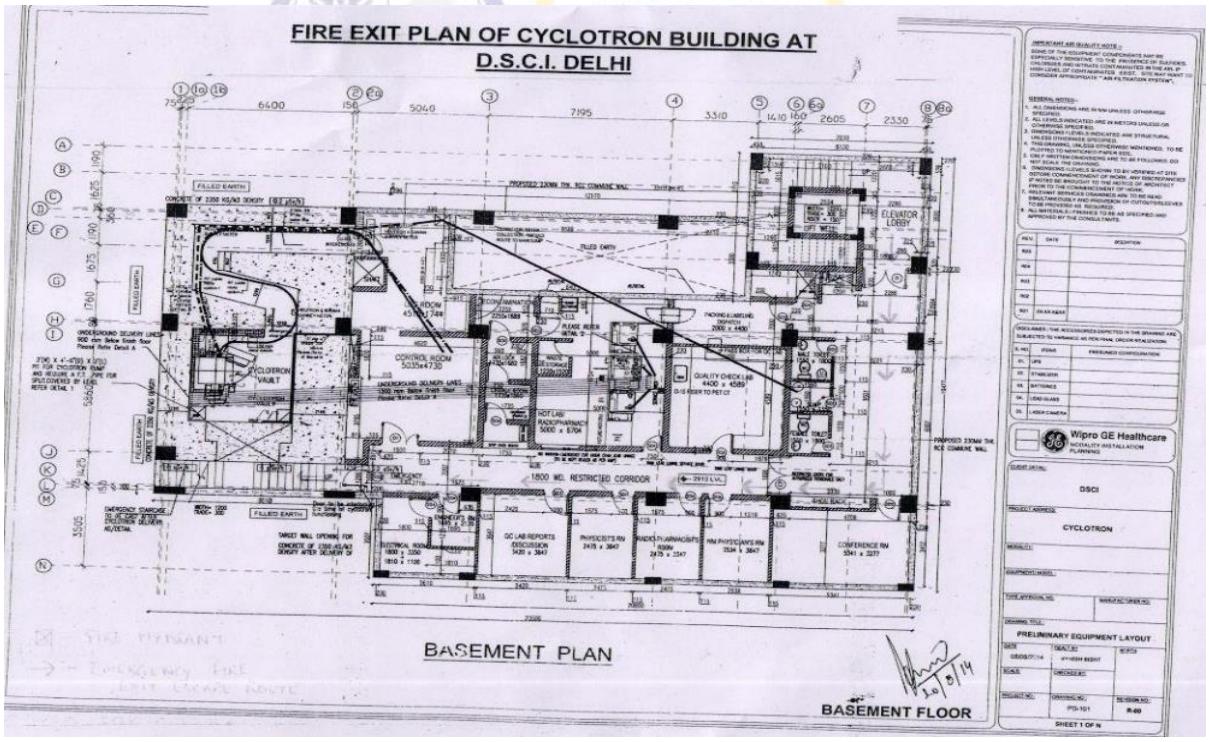
In case of fire breakout, the emergency fire exit plan has to be followed.

All personnel should evacuate the area and proceed towards emergency exit.

The radiation worker is upstairs, will proceed through the corridor towards the emergency exit door.

The workers should proceed through stairs towards outside of the building

The emergency exit plan is attached:



IN CASE OF RADIATION EMERGENCY CONTACT FOLLOWING:

S. No.	Name of the officer	Designation	Contact Number
1	**Dr Vatsala Aggarwal**	Director	9718990112
2	**Dr Pragya Shukla**	Asstt. Prof Radiation Clinical Oncologist, Chairman, RS Committee	9560390107
3	**Mr M Sasindran**	Medical Physicist & RSO, Member Secretary, RS Committee	9971491227
4	**Ms Mamta Mahur**	Medical Physicist, Member, RS Committee	9560390150
5	**Dr Surendra Kumar**	Asstt. Prof Anaesthesia , Member, RS Committee	8800190660
6	**Mr Deeepanshu Goel**	Asstt. Engineer (Civil), Member, RS Committee	9811190710
7	**Mr Parveen**	Security In-Charge	8287523900
8	**Police (GTB Complex)**	SHO (PS. GTB Complex)	011 2213 1069

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