#### MANUAL 4

### Norms set for the discharge of fuctions

## |Section 4(1)(b)(IV)|

Store follows the guidelines recorded in manual of procurement of goods and services and General financial rules 2023.

Various duties performed by Store Keeper posted in DSCI under the supervision of MOIC. Store are as under:-

- a. Preparation of Annual Demands
- b. Inventory management
- c. Look after the expiry and slow moving items
- d. Issuing of indents
- Coordination with other departments for timely disposal of items available in store within their respective shelf life
- Maintenance of records like indents voucher, Challan, bills, stock issue registers, demands, etc.
- g. Looking after NIRANTAR portal for CPA items
- h. Looking after GeM portal for CRAC and verification of bills
- i. Maintenance of closing stock
- j. Other miscellaneous works related to stock entries.
- k. Maintenance of inventory in E-Hospital
- Follow up with other Delhi Government Hospitals regarding exchange of slow moving items.
- m. Verification of bills (NON CPA)
- n. Look after the RTI and grievance related to Store
- o. Attend the meetings of Purchase committees
- p. Maintain physical stock verification within the store
- q. Coordinate with inspection committees for the inspection of goods received in store
- Participation in various committees constituted for floating of tenders and bids on GeM and E-Procurement

# 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.



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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.

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# **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.

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# 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

	Mr Rajat Kumar Hospital Executive-III Delhi State Cancer Institutes	Johnson
Prepared By	Mr Mukul Kumar Hospital Executive-III Delhi State Cancer Institutes	waterof
Checked by	Sh Hemant Kumar Sharma Medical Record Officer Delhi State Cancer Institutes	W
Approved By	Dr Kishore Singh Director & CEO Delhi State Cancer Institutes	Like

# Manual-4

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

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HEMANT SHARMA
Medical Record Officer
Delhi State Cancer Institute
Dilshad Garden, Delhi-110095



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Checked by	Sh Hemant Kumar Sharma Medical Record Officer Delhi State Cancer Institutes	W
Approved By	Dr Kishore Singh Director & CEO Delhi State Cancer Institutes	Histe



#### 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.



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#### 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.



# 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 use the 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





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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:

# Ms PALLAVI SHARMA Technologist.

Nuclear Medicine Department Delhi State Cancer Institute

Signature:

## Checked By

Dr PANKAJ TYAGI

Assoc. Prof. Gastro. In-charge Nuclear Medicine Department, Delhi State Cancer Institute

Dr Pankaj Tyagi In-charge Nuclear Medicine Delhi State Cancer Institute Signature: In-charge Nucles Cancer Institute

Delhi State Cancer Institute

Delhi-110095

Delhi-110095

The Original Procedure Manual war Signatures on the Title page is considered as

Prepared By

#### Mr SASINDRAN M

Medical Physicist & Radiological Safety Officer Nuclear Medicine Department

Delhi State Cancer Institute

LHI STATE CANCER INSTITUTE

Signature:

## Approved By

Dr VATSALA AGGARWAL

Director

Delhi State Cancer Institute

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# STANDARD OPERATING PROCEDURE (SOP) NUCLEAR MEDICINE DEPARTMENT

#### 1. INTRODUCTION

- 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

- 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

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- 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.

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- 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

 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

- Check the referring physician's request for radionuclide study.
- ii. Check medications and advice preparation accordingly.
- 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

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

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### 4.4 Receipt of Radioactivity

### 4.4.1. Purpose

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

## 4.4.2 Instruments/Materials Required.

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

# 4.4.3 Protocol for Opening Radioactive Parcels.

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

- 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.

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- 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

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

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- 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



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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:

- 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 (99mTc / 68Ga).

#### 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:

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



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- 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:

- Waste produced from short half-lives radionuclides like <sup>99m</sup>Tc and <sup>18</sup>F should be separated from those of longer half-lives and placed in the separate lead lined waste containers.
- Waste produced from medium half-life radionuclides like <sup>131</sup>I and 99mTc can be stored in the waste room for decay up to 10 half-lives.
- 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

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disposal process.

v. All radioactive waste disposals shall be recorded.

#### c. Return and Disposal of Unused Sealed Source:

- Sealed sources such as <sup>56</sup>Ge and <sup>137</sup>Cs etc. are used for calibration and quality control of Nuclear Medicine instrument.
- Unused sealed source must be kept in the designated area/ waste room for decay or until return back to manufacturer.
- 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 And Decontamination At Workplace

#### 4.7.1 Procedure for monitoring contamination

- 4.7.1.1 Survey method using Calibrated Radiation Meter for fixed and removable contamination.
  - 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.
  - Calculate the indicated total surface contamination bysubtract the background from the surface reading

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v. Record the result.

#### 4.7.1.2 Wipe test method for removable contamination.

- Use cotton swab or wipe test smears to take severals amples from different areas.
- ii. An area of 100cm2 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

0.37Ba/cm<sup>2</sup>

For Beta

3.7Bq/cm<sup>2</sup>

#### 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 <sup>2</sup>
2	Laboratory areas (surveyed)	3.7 Bq/cm <sup>2</sup>
3	Other non-active areas	0.37Bq/cm <sup>2</sup>

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

- i. Caution line tape mark off perimeters and areas of operation.
- 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:

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### (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:
    - 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 decontamination procedures.
  - 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.
- 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

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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.
- 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

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

#### RECORD

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

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#### 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 contaminated body area.
      - Contaminated personnel should shower using liquid soapor equivalent. Begin with the head and proceed to the feet.

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- 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.

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

#### b. Indirect methods.

- Indirect measurement of contaminant includes nasal swipes to determine respiratory intake of radioactive aerosols, and also urine and faeces sampling to establish internal contamination.
- Alpha and beta emitter, the most hazardous internal contaminants, 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).
- Nuclear Medicine Physicist shall record all readings in Contamination Survey Report Form.

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#### RECORD

No.	Record Name			Record Keeping Period
	Contamination Form	Survey	Report	3 years

## 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:

#### 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.

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#### 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.



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# 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.

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 Period	Keeping
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.

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#### 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 decontamination and the types of protective devices and survey equipment that will be 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:

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- 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 Period
	Standard Operating Procedure inthe Events of Emergencies	3 years

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## 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 be recorded.
  - b) Need for urgent patient attention.

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.

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- 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.

# Death of the patient following a nuclear medicine scanning.

- If a patient dies during the scanning, the Nuclear MedicineSpecialist 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

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#### 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

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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. It is 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
	Radiation Exposure ReceivedBy 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 <u>Purpose</u>

- To maintain the equipment in proper working condition.
- ii. To protect the equipment from mechanical, physical environmental damage.

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#### 4.12.2 Dos and Don'ts

- 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,

 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

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

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- 7. Return to patient and help into the wheelchair.
- 8. Return wheelchair to a central point.
- 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.
- Make sure all the sonograms are uniform and variance values and colour code are within manufacturer prescribed limits.
- 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

- In women of childbearing age, pregnancy and lactation status should be determined.
- 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.
- 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)

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### 4.14.1 18 F- FDG PET CT Study (Oncology Imaging)

### a) Indications

 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. Turnour 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

- 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

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- 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:

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

4.14.2 C-11 CHOLINE PET SCAN: 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.
- 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.

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- 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.

#### 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 11C- 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



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#### 4.15.1 Purpose

- To assure that structural barrier for radioactive source is adequate.
- To ensure that the premises of radiation exposure levels in public, supervised and controlled areas are within prescribed limits.
- 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

- 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.
- 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.

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- 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.
- 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

- 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

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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.
  - 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

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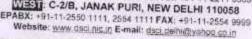
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Begin imaging 2–4 hr after tracer administration

### 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.

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- 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 Key.
- Use dual-headed SPECT camera: 360-degree contoured acquisition arc,3-degree angular Sampling increment,15–30 sec per view,128 x 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
  - Patient Preparation
    - Hydration
    - · Adults: drink 300-500 ml of water

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- 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

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#### 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

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- 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

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### MEDICAL CYCLOTRON SOP

### Standard Operating Procedure (SOP) of Cyclotron

- Step1: Check all the preliminary parameters before starting Cyclotron and maintain all the record of checklists.
- Step2: CHECK the cyclotron control cabinets room AC is Switched ON or not, and set the temperature to 19°C
- 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.
- Step6: Fill the Target with O18 Water and check the Target Pressure.
- 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
- Step9: Click the irradiation, start Irradiation when it is highlighted.
- 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

Foil Current and number running foil

i. Probe Current

j. He Cooling Pressure

k. Irradiation Time

I. Estimated Activity

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- 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.
- Step15: Set the Cyclotron control cabinated room AC to 24°C.
- 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°C and Helium (valve 20) and Vacuum pump should be ON for 4 minutes.

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

Step2: ADDITION OF MANNOSE TRIFLATE FOR LABELLING

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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°C. it will take 1 minute.

## Standardoperating 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°C 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

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- 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°C
- 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.

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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.

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.
- 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.

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- 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** 

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- 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:



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#### 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 Dee panshu 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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