|  |  |
| --- | --- |
| **Name of Facility** | ***{facility\_name}*** |
| e-LORA ID | ***{elora\_id}*** |
| Additional Facilities | Medical Cyclotron ***{med\_cyclotron}***  Radiotherapy ***{radiotherapy}***  Diagnostic Radiology ***{diag\_radiology}***  Gamma Chamber (Blood Irradiator) ***{gamma\_chamber}***  Any other ***{anyother}*** |
| Facility Status | ***{facility\_status}***  Reasons for Not in Operation: ***{not\_in\_op\_reason}*** |
| Inspection Date | ***{inspection\_dt}*** |
| Type of Inspection | ***{inspection\_type};*** and  ***{inspection\_nature}*** |
| Inspection Team | ***{inspection\_member\_1}***  ***{inspection\_member\_2}***  ***{inspection\_member\_3}*** |

**1.0 Organization & Administration** (to be filled in, in case the details are not matching with e-LORA)

|  |  |
| --- | --- |
| **1.1 Facility** | |
| Address : | ***{facility\_addr}*** |
| Telephone (O) : | ***{telephone}*** |
| e-mail : | ***{email}*** |
| Type of Facility : (Government / Private / Others) | ***{facility\_type}***  Others : ***{facility\_type\_anyother}*** |

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| **1.2 Organization** (to be filled in, in case the details are not matching with e-LORA) |
| **Employer**  Name : ***{employer\_name}***  Designation :  ***{designation}***  Mobile Number :  ***{emp\_telephone}***  E-mail : ***{emp\_email}***  **Whether employer is the same as mentioned in e-LORA**?  ***{emp\_is\_same}***  **If No**, whether employer change has been initiated in e-LORA? ***{emp\_initiated\_flag}***  **Whether Licensee is same as Employer? *{licence\_same\_as\_emp}***  **If No, Licensee**  Name : ***{licence\_name}***  Designation : ***{licence\_designation}***  Mobile Number :  ***{licence\_telephone}***  E-mail :  ***{licence\_email}***  **Whether Licensee is the same as mentioned in e-LORA? *{licence\_same\_as\_elora}***  **If No**, whether licensee change has been initiated in e-LORA? ***{licence\_changed\_in\_elora}***  **RSO**  Name : ***{rso\_name}***  Designation : ***{rso\_designation}***  Mobile Number :  ***{rso\_telephone}***  E-mail : ***{rso\_email}***  **Whether RSO approval is/are valid? *{rso\_appr\_valid}***  **Operation Staff**  Number of Nuclear Medicine Physician (s) : ***{N\_NMPhy}***  Number of Nuclear Medicine Technologist(s) : ***{N\_NMTech}***  Whether the operation staff are qualified as per AERB requirements? ***{OpStaffQual}***  Whether the operation staff is adequate? ***{OpStaffAdeq}***  *(Consider no. of equipment & workload – Refer RSD Guidelines / consult RSD)*  Whether employee related details are up-to-date in e-LORA? ***{Emp\_uptodate}*** |
| **Observations:**  ***{OStf\_Observations}*** |

**2.0 Consents/Approvals**

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| --- |
| **2.1 Site & Layout Approval** |
| Whether Site and Layout approvals are obtained for all NM installations? ***{SiteLayout}***  Whether NM facility is in a residential building? ***{NM\_resi}***  Whether the facility has been constructed as per AERB approved Plan? ***{Facility\_app}***  **If No,** details of Non-compliances (Safety):  ***{Fac\_det}*** |

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| **2.2 Operation** |
| Whether Authorization for operation is valid? ***{Auth\_valid}***  Whether Authorization for source procurement is valid? ***{Auth\_SrcProc}***  Whether valid license for operation is available? (In case of SPECTCT/PETCT units only) ***{Lic\_Spect}***  **If No,** details of Non-compliances:  ***{Lic\_det}*** |
| **Observations:**  ***{Con\_Observation1}*** |

**3.0 Compliance to Previous Inspection Findings**

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| a) Whether any Inspection was carried out in the past? ***{Past\_Insp}***  Date of inspection: ***{insp\_dt}***  b) Whether NCs, if any are already complied? ***{NC\_complied}***  **If No,** Particulars of pending recommendations:  ***{Pend\_reco}*** |

**4.0 Procedures Performed**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  | | --- | --- | | In-vivo non-imaging | ***{IV\_NImg}*** | | In-vivo imaging | ***{IV\_Img}*** | | Low Dose Therapy  (with I-131) | ***{LD\_TI131}*** | | High Dose Therapy  (with I-131) | ***{HD\_TI131}*** | | Beta therapy  (other than I-131) | ***{Beta\_T}*** | | Alpha therapy | ***{Alpha\_T}*** | | Any other | ***{Anyother\_Proc}*** |   Whether the above procedures are as per the authorization issued to the facility? ***{Proc\_Auth}*** |
| **Observations:**  ***{Con\_Observation2}*** |

**5.0 Equipment / Source Inventory / Handling Tools**

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Radioisotopes:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **S.No.** | **Description** | **Isotope** | **Activity / Date** | **Remarks** | | 1 | Sealed Sources (calibration & Check sources) | ***{Src\_1}*** | ***{S1\_Act}***  ***{Act\_Ason1}*** | ***{S1\_desc}*** | | ***{Src\_2}*** | ***{S2\_Act}***  ***{Act\_Ason2}*** | ***{S2\_desc}*** | | 2 | Disused Sources (calibration & Check sources) | ***{DU\_Src\_1}*** | ***{DU\_S1\_Act}***  ***{DU\_Act\_Ason1}*** | ***{DU\_S1\_desc}*** | | 3 | **Others** | ***{DU\_Src\_2}*** | ***{DU\_S2\_Act}***  ***{DU\_Act\_Ason2}*** | ***{DU\_S2\_desc}*** |   Whether the above information is as maintained in e-LORA?  ***{DU\_info\_elora}*** |

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| **Imaging Equipment:**   |  |  |  |  | | --- | --- | --- | --- | | **S.No.** | **Description** | **No. of Units** | **Remarks** | | 1 | Gamma Camera | ***{Gam\_Cam}*** | ***{Img\_Remarks}*** | | 2 | SPECT | ***{Spect\_eqp}*** | | 3 | SPECT-CT | ***{SpectCT\_eqp}*** | | 4 | PET | ***{Pet\_eqp}*** | | 5 | PET-CT | ***{PetCT\_eqp}*** | | 6 | PET-MRI | ***{PetMRI\_eqp}*** |   **Non-Imaging Equipment:**   |  |  |  |  | | --- | --- | --- | --- | | **S.No.** | **Description** | **No. of Units** | **Remarks** | | 1 | Thyroid Uptake Probe | {Thy\_Up\_Prb} | ***{Nimg\_Remarks}*** | | 2 | Gamma probe (used in case of sentinel node detection) | {Gamma\_Prb} | | 3 |  |  |   **High Dose Therapeutic Facilities:**   1. No. of Isolation Rooms : ***{N\_IsoRoom}*** 2. Capacity of each delay tank (in litres) : ***{DT\_cap}***   **Low Dose Therapeutic Facilities:**  Whether separate area is earmarked for low dose therapy administered patients? ***{LDT\_place}***  Whether the above information is as per the Authorization issued by AERB? ***{NIMG\_comply}***  **Handling Tools:**  Whether the following Safety features / handling tools (as applicable) are available & functional?   |  |  |  |  | | --- | --- | --- | --- | | **S.No.** | **Facilities** | **Available** | **Functional** | | 1 | Fume hoods | ***{Fumehood}*** | ***{Fumehood\_func}*** | | 2 | L-Bench | ***{LBench\_Avlbl}*** | NA | | 3 | Lead bricks | ***{LeadBricks\_Avlbl}*** | NA | | 4 | Sink | ***{Sink\_Avlbl}*** | ***{Sink\_func}*** | | 5 | Remote handling tools | ***{RemHandTools\_Avlbl}*** | ***{RemHandTools\_func}*** | | 6 | Lead apron | ***{LeadApron\_Avlbl}*** | NA | | 7 | Decontamination kit | ***{DecontKit\_Avlbl}*** | NA | | 8 | Hand gloves | ***{HandGloves\_Avlbl}*** | NA | | 9 | Syringe shield | ***{SyringeShld\_Avlbl}*** | NA | | 10 | Syringe carrier | ***{SyringeCarrier\_Avlbl}*** | NA | | 11 | Patient viewing system  (eg. CCTV / Window) | ***{PtntView\_Avlbl}*** | ***{PtntView\_func}*** | |
| **Observations:**  ***{HT\_Observation}*** |

**6.0 Operational Safety**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| |  |  |  | | --- | --- | --- | | **S.No.** | **Description** | **Status** | | 1 | Whether the flooring in laboratory satisfactory? | ***{LabFloor}*** | | 2 | Whether work surface is smooth & covered with adsorbent sheet? | ***{WorkSurfCov}*** | | 3 | Whether doors & walls painted with smooth and washable paints? | ***{DoorWallsPaint}*** | | 4 | Whether separate rooms are provided for each of the radioactive operations as per guidelines? | ***{SepRoom\_RA}*** | | 5 | Whether sinks are provided in each of the rooms where radioactive material is handled? | ***{SinkRooms}*** | | 6 | Whether sinks are made of non-porous material like SS or Glazed Ceramic? | ***{SinksNonPoros}*** | | 7 | Whether type of taps fitted at the sinks are elbow-operated? | ***{TapsElbow}*** | | 8 | Whether radiation warning symbols are displayed where required? | ***{RadWarnSym}*** | | 9 | Whether emergency procedures for radioactive spillage/mis-administration are pasted at appropriate place in the facility? | ***{EmergencyProc}*** | | 10 | Whether ventilation of the radioactive handling rooms is satisfactory? | ***{Vent\_RA}*** | | 11 | Whether illumination inside the radioisotope laboratory is satisfactory? | ***{Illuminate}*** | | 12 | Whether separate drainage system provided for Nuclear Medicine facility? | ***{Drain\_NM}*** | | 13 | Whether the delay tank (in case of HDTF) is properly cordoned off? | ***{DelayTank\_HDTF}*** | | 14 | Whether the delay tank is maintained properly? | ***{DelayTank\_Maint}*** | | 15 | Whether any provision is made for indication of radioactive effluent levels in the delay tank? | ***{DTEffl\_lvl}*** | | 16 | Any modifications done to the existing approved radiation installation? | ***{Modi\_inst}*** | |
| **Observations:**  ***{OS\_Observations}*** |

**7.0 Radiation Protection**

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| **7.1 Personnel Monitoring** |
| a) Whether the facility has registered with a personnel  monitoring service (PMS) provider? ***{PMS\_regd}***  b) Whether PMD is provided to all radiation workers? ***{PMDtoall}***  c) Whether PMD is provided to the trainees (if any)? ***{PMDtoTrainee}***  d) Whether PMDs are being worn by workers appropriately? ***{PMDWorker}***  e) Whether proper storage of PMDs is available? ***{PMD\_stored}***  f) Whether a control TLD is available and kept at a radiation free Area? ***{CtlTLD\_Avlbl}***  g) Whether radiation workers have access to their personnel monitoring records? ***{PMRec\_Axs}***  h) Whether PMS was suspended any time during last three years? ***{PMS\_Susp}***  If yes, reasons thereof? ***{PMS\_Susp\_reasons}***  i) Whether any excessive exposure was reported during last three years? ***{EE\_Cases}***  If Yes, whether dose recorded was found to be genuine? ***{EE\_DoseRec\_OK}***  Whether adequate measures taken to avoid recurrence of such  excessive exposure? ***{EE\_msrs\_adeq}***  What are the measures taken? ***{EE\_recur\_meas}***  j) Whether pocket dosimeters are available? ***{PockDosi\_Avlbl}***  If Yes, whether the dosimeters are used while working? ***{PockDosi\_used}***  If Yes, whether dose records are maintained? ***{PockDosi\_records}*** |
| **7.2 Radiation Surveillance** |
| a) Whether the following radiation monitoring / measuring instruments are available?   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **S.No.** | **Instrument** | **Available** | **Functional** | **Calibration**  **Valid** | | 1 | RSM | ***{RSM\_avlbl}*** | ***{RSM\_func}*** | ***{RSMCalib\_vld}*** | | 2 | Contamination Monitor | ***{ContMon\_Avlbl}*** | ***{ContMon\_func}*** | ***{ContMon\_Valid}*** | | 3 | Dose Calibrator | ***{DoseCalib\_Avlbl}*** | ***{DoseCalib\_func}*** | ***{DoseCalib\_Valid}*** | | 4 | Gamma Zone Monitor (in case HDTF) | ***{GammaZoneMon\_Avlbl}*** | ***{GammaZoneMon\_func}*** | ***{GammaZoneMon\_Valid}*** | | 5 | Direct Reading dosimeters  (not mandatory) | ***{DRD\_Avlbl}*** | ***{DRD\_func}*** | ***{DRD\_Valid}*** |   b) Whether the measuring / monitoring equipment are appropriate for radiation type and energy? ***{MonEquip\_apt}***  c) Whether periodic radiation protection survey performed? ***{RPS\_Periodic}*** |
| **Observations:**  ***{RadSurv\_Observations}*** |

**8.0 Management Systems & Records**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. Whether safe working procedures have been prepared based on OEM instructions? ***{SafeWP}*** 2. Whether Local Safety Committee (LSC) to oversee safety of the facility/QA of the ***{LSC\_func}***   unit is functional & meeting are held quarterly?   1. Whether preventive maintenance schedule has been prepared & implemented based   on OEM Instructions? ***{PrevMS\_Avlbl}***   1. Whether any modification has been done to the Facility which has a bearing on Safety? ***{Modi\_Facility}***   If Yes, whether approval from AERB has been sought before the modification was done?  ***{Modi\_facility\_apprvl}***   1. Whether periodic safety status reports are filed in e-LORA? ***{SafetyStat\_elora}***   If no, reasons thereof? ***{SafetyStat\_NonRpt\_reasons}***   1. Whether emergency working procedures have been prepared for all unusual conditions   and workers are familiar? ***{Emer\_WP}***   1. Whether any unusual occurrence/accidents (e.g. Misadministration,   Excessive Exposure, Lost Source etc.) encountered since last Inspection? ***{UOR}***  If Yes, whether the same was investigated & reported to AERB? ***{UOR\_rprt}***  If no, reasons thereof? ***{UOR\_NonRpt\_reasons}***   1. Whether corrective actions have been taken by the Facility to prevent   such reoccurrences? ***{UOR\_CorrectAct}***   1. Whether periodic QA programme is available and implemented as   required by the AERB Safety Code/ Manufacturer Specified {QA\_Periodic}  Protocols / Institution QA protocols?  If Yes, please specify details   |  |  | | --- | --- | | Daily Checks | ***{Dailychecks}*** | | Weekly Checks | ***{WeeklyChecks}*** | | Monthly Checks | ***{MonthlyChecks}*** | | Annual Checks | ***{AnnualChecks}*** | | QA after repair / replacement | ***{QA\_Repair}*** |   j) Whether the following records are available?   |  |  |  | | --- | --- | --- | | **S.No.** | **Details of Records** | **Status** | | 1. | Radiation Survey | ***{RadSurvey\_rcrd}*** | | 2. | Personnel Dose Records | ***{PersDose\_records}*** | | 3. | Patient Information Records | ***{PatInfo\_records}*** | | 4. | Activity Procurement & Usage | ***{ActProcUsage}*** | | 5. | Disposal of Radioactive Waste | ***{RAWasteDisp}*** | | 6. | Instruments calibration records | ***{InstCali\_records}*** | | 7. | Delay Tank Sample Collection Records | ***{DTSmplColl\_records}*** | | 8. | Servicing / Maintenance Records of the Imaging Equipment | ***{ImgEquip\_ServMain\_records}*** | | 9. | QA Test | ***{QA\_records}*** | |
| **Observations:**  ***{ManRec\_Observations}*** |

**9.0 Feedback**

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| --- |
| ***{Feedback}***  I/we was/were briefed by the inspector(s) about the above observations mentioned in this report.    **{%EmpSign}**  Name: ***{EmpName}*** |
| |  |  | | --- | --- | | **Name of Inspectors** | **Signature with Date** | | ***1. {Insp\_1}*** | **{%InspSign\_1}** | | ***2. {Insp\_2}*** | **{%InspSign\_2}** | | ***3. {Insp\_3}*** | **{%InspSign\_3}** | |  |  | |