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| **Name of Facility** | ***Apollo Hospitals*** |
| e-LORA ID | ***TN-20381*** |
| Additional Facilities | Medical Cyclotron  ***NA***  Radiotherapy  ***NA***  Diagnostic Radiology  ***YES***  Gamma Chamber (Blood Irradiator)  ***NA***  Any other |
| Facility Status | ***In Operation***  Reasons for Not in Operation: |
| Inspection Date | ***2020-02-18*** |
| Type of Inspection | ***Routine;*** and  ***Unannounced*** |
| Inspection Team | ***M. Senthil Kumar*** |

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

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| **1.1 Facility** | |
| Address : | ***As mentioned in eLORA*** |
| Telephone (O) : | ***4427480030*** |
| e-mail : | ***apollo@gmail.com*** |
| Type of Facility : (Government / Private / Others) | ***Private***  Others : |

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| **1.2 Organization** (to be filled in, in case the details are not matching with e-LORA) |
| **Employer**  Name :  ***As mentioned in eLORA***  Designation :  ***Doctor***  Mobile Number :  ***4427480030***  E-mail :  ***apollo@gmail.com***  **Whether employer is the same as mentioned in e-LORA**?  ***YES***  **If No**, whether employer change has been initiated in e-LORA?  ***NA***  **Whether Licensee is same as Employer?  *YES***  **If No, Licensee**  Name :  Designation :  Mobile Number :  E-mail :  **Whether Licensee is the same as mentioned in e-LORA?  *YES***  **If No**, whether licensee change has been initiated in e-LORA?  ***NA***  **RSO**  Name :  ***As mentioned in eLORA***  Designation :  Mobile Number :  E-mail :  **Whether RSO approval is/are valid?  *YES***  **Operation Staff**  Number of Nuclear Medicine Physician (s) : ***2***  Number of Nuclear Medicine Technologist(s) : ***2***  Whether the operation staff are qualified as per AERB requirements?  ***YES***  Whether the operation staff is adequate?  ***YES***  *(Consider no. of equipment & workload – Refer RSD Guidelines / consult RSD)*  Whether employee related details are up-to-date in e-LORA?  ***NO*** |
| **Observations:**  ***Shri Sarath and Shri Babu Raj. Sarath is qualified from Bharat scan course which is not approved by AERB. Babu raj is ANMPI qualified. All radiation workers involved in NM lab is not updated in eLORA.*** |

**2.0 Consents/Approvals**

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

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| **2.2 Operation** |
| Whether Authorization for operation is valid?  ***YES***  Whether Authorization for source procurement is valid?  ***YES***  Whether valid license for operation is available? (In case of SPECTCT/PETCT units only)  ***YES***  **If No,** details of Non-compliances: |
| **Observations:** |

**3.0 Compliance to Previous Inspection Findings**

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| a) Whether any Inspection was carried out in the past?  ***YES***  Date of inspection:  ***2015-02-18***  b) Whether NCs, if any are already complied?  ***YES***  **If No,** Particulars of pending recommendations: |

**4.0 Procedures Performed**

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| |  |  | | --- | --- | | In-vivo non-imaging | ***YES*** | | In-vivo imaging | ***YES*** | | Low Dose Therapy  (with I-131) | ***YES*** | | High Dose Therapy  (with I-131) | ***YES*** | | Beta therapy  (other than I-131) | ***YES*** | | Alpha therapy | ***YES*** | | Any other |  |   Whether the above procedures are as per the authorization issued to the facility?  ***YES*** |
| **Observations:** |

**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) | ***137Cs*** | ***10.30 mci***  ***1995-09-01*** | ***Purchased from BRIT for dose calibrator calibration*** | |  |  |  | | 2 | Disused Sources (calibration & Check sources) | ***137Cs*** | ***10 micro ci***  ***2017-09-24*** | ***Uptake probe calibration*** | | 3 | **Others** | ***57Co*** | ***Activity not known*** | ***Flood field source*** |   Whether the above information is as maintained in e-LORA?  ***YES*** |

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| **Imaging Equipment:**   |  |  |  |  | | --- | --- | --- | --- | | **S.No.** | **Description** | **No. of Units** | **Remarks** | | 1 | Gamma Camera | ***0*** |  | | 2 | SPECT | ***0*** | | 3 | SPECT-CT | ***1*** | | 4 | PET | ***0*** | | 5 | PET-CT | ***0*** | | 6 | PET-MRI | ***0*** |   **Non-Imaging Equipment:**   |  |  |  |  | | --- | --- | --- | --- | | **S.No.** | **Description** | **No. of Units** | **Remarks** | | 1 | Thyroid Uptake Probe | 1 | ***undefined*** | | 2 | Gamma probe (used in case of sentinel node detection) | 0 | | 3 |  |  |   **High Dose Therapeutic Facilities:**   1. No. of Isolation Rooms : ***1*** 2. Capacity of each delay tank (in litres) :  ***3000 ltrs per tank (Total 2 tanks)***   **Low Dose Therapeutic Facilities:**  Whether separate area is earmarked for low dose therapy administered patients?  ***YES***  Whether the above information is as per the Authorization issued by AERB?  ***YES***  **Handling Tools:**  Whether the following Safety features / handling tools (as applicable) are available & functional?   |  |  |  |  | | --- | --- | --- | --- | | **S.No.** | **Facilities** | **Available** | **Functional** | | 1 | Fume hoods | ***YES*** | ***YES*** | | 2 | L-Bench | ***YES*** | NA | | 3 | Lead bricks | ***YES*** | NA | | 4 | Sink | ***YES*** | ***YES*** | | 5 | Remote handling tools | ***YES*** | ***YES*** | | 6 | Lead apron | ***YES*** | NA | | 7 | Decontamination kit | ***YES*** | NA | | 8 | Hand gloves | ***YES*** | NA | | 9 | Syringe shield | ***YES*** | NA | | 10 | Syringe carrier | ***YES*** | NA | | 11 | Patient viewing system  (eg. CCTV / Window) | ***YES*** | ***NO*** | |
| **Observations:**  ***1)Radiation levels outside waste storage bin inside hot lab was found to be ~20mR/hr. 2) Radioactivity injected patient active toilet is located inside cathlab recovery room (modification from the layout) 3) Decontamination kit list of required items shall be identified and inventory is not maintained.*** |

**6.0 Operational Safety**

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| |  |  |  | | --- | --- | --- | | **S.No.** | **Description** | **Status** | | 1 | Whether the flooring in laboratory satisfactory? | ***YES*** | | 2 | Whether work surface is smooth & covered with adsorbent sheet? | ***YES*** | | 3 | Whether doors & walls painted with smooth and washable paints? | ***YES*** | | 4 | Whether separate rooms are provided for each of the radioactive operations as per guidelines? | ***YES*** | | 5 | Whether sinks are provided in each of the rooms where radioactive material is handled? | ***YES*** | | 6 | Whether sinks are made of non-porous material like SS or Glazed Ceramic? | ***YES*** | | 7 | Whether type of taps fitted at the sinks are elbow-operated? | ***YES*** | | 8 | Whether radiation warning symbols are displayed where required? | ***YES*** | | 9 | Whether emergency procedures for radioactive spillage/mis-administration are pasted at appropriate place in the facility? | ***NO*** | | 10 | Whether ventilation of the radioactive handling rooms is satisfactory? | ***YES*** | | 11 | Whether illumination inside the radioisotope laboratory is satisfactory? | ***YES*** | | 12 | Whether separate drainage system provided for Nuclear Medicine facility? | ***YES*** | | 13 | Whether the delay tank (in case of HDTF) is properly cordoned off? | ***YES*** | | 14 | Whether the delay tank is maintained properly? | ***YES*** | | 15 | Whether any provision is made for indication of radioactive effluent levels in the delay tank? | ***YES*** | | 16 | Any modifications done to the existing approved radiation installation? | ***YES*** | |
| **Observations:**  ***1) Radiation warning symbols are not pasted on all the required places / objects (waste bin syringe carrier delay tank place).2) Emergency procedures for various scenarios are not prepared.*** |

**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?  ***YES***  b) Whether PMD is provided to all radiation workers?  ***YES***  c) Whether PMD is provided to the trainees (if any)?  ***YES***  d) Whether PMDs are being worn by workers appropriately?  ***YES***  e) Whether proper storage of PMDs is available?  ***YES***  f) Whether a control TLD is available and kept at a radiation free Area?  ***YES***  g) Whether radiation workers have access to their personnel monitoring records?  ***YES***  h) Whether PMS was suspended any time during last three years?  ***NO***  If yes, reasons thereof?  i) Whether any excessive exposure was reported during last three years?  ***YES***  If Yes, whether dose recorded was found to be genuine?  ***NA***  Whether adequate measures taken to avoid recurrence of such  excessive exposure?  ***YES***  What are the measures taken?  j) Whether pocket dosimeters are available?  ***YES***  If Yes, whether the dosimeters are used while working?  ***YES***  If Yes, whether dose records are maintained?  ***YES*** |
| **7.2 Radiation Surveillance** |
| a) Whether the following radiation monitoring / measuring instruments are available?   |  |  |  |  |  | | --- | --- | --- | --- | --- | | **S.No.** | **Instrument** | **Available** | **Functional** | **Calibration**  **Valid** | | 1 | RSM | ***YES*** | ***YES*** | ***YES*** | | 2 | Contamination Monitor | ***YES*** | ***YES*** | ***NO*** | | 3 | Dose Calibrator | ***YES*** | ***YES*** | ***YES*** | | 4 | Gamma Zone Monitor (in case HDTF) | ***YES*** | ***YES*** | ***YES*** | | 5 | Direct Reading dosimeters  (not mandatory) | ***YES*** | ***YES*** | ***NO*** |   b) Whether the measuring / monitoring equipment are appropriate for radiation type and energy?  ***YES***  c) Whether periodic radiation protection survey performed?  ***YES*** |
| **Observations:**  ***1) Contamination monitor is not functional acceptably (efficiency is only 6%). 2) Delay tank plumbing control point was found leaky and observed 16 mR/hr at that level. 3) A decontamination shower room is present in the radioactive waste storage room.*** |

**8.0 Management Systems & Records**

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| 1. Whether safe working procedures have been prepared based on OEM instructions?  ***YES*** 2. Whether Local Safety Committee (LSC) to oversee safety of the facility/QA of the  ***YES***   unit is functional & meeting are held quarterly?   1. Whether preventive maintenance schedule has been prepared & implemented based   on OEM Instructions?  ***YES***   1. Whether any modification has been done to the Facility which has a bearing on Safety?  ***YES***   If Yes, whether approval from AERB has been sought before the modification was done?  ***NO***   1. Whether periodic safety status reports are filed in e-LORA?  ***YES***   If no, reasons thereof?   1. Whether emergency working procedures have been prepared for all unusual conditions   and workers are familiar?  ***NO***   1. Whether any unusual occurrence/accidents (e.g. Misadministration,   Excessive Exposure, Lost Source etc.) encountered since last Inspection?  ***NO***  If Yes, whether the same was investigated & reported to AERB?  ***NA***  If no, reasons thereof?   1. Whether corrective actions have been taken by the Facility to prevent   such reoccurrences?  ***YES***   1. Whether periodic QA programme is available and implemented as   required by the AERB Safety Code/ Manufacturer Specified YES  Protocols / Institution QA protocols?  If Yes, please specify details   |  |  | | --- | --- | | Daily Checks | ***YES*** | | Weekly Checks | ***YES*** | | Monthly Checks | ***YES*** | | Annual Checks | ***YES*** | | QA after repair / replacement | ***YES*** |   j) Whether the following records are available?   |  |  |  | | --- | --- | --- | | **S.No.** | **Details of Records** | **Status** | | 1. | Radiation Survey | ***YES*** | | 2. | Personnel Dose Records | ***YES*** | | 3. | Patient Information Records | ***YES*** | | 4. | Activity Procurement & Usage | ***YES*** | | 5. | Disposal of Radioactive Waste | ***YES*** | | 6. | Instruments calibration records | ***YES*** | | 7. | Delay Tank Sample Collection Records | ***YES*** | | 8. | Servicing / Maintenance Records of the Imaging Equipment | ***YES*** | | 9. | QA Test | ***YES*** | |
| **Observations:** |

**9.0 Feedback**

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| ***abc***  I/we was/were briefed by the inspector(s) about the above observations mentioned in this report.    **image**  Name:  ***Dr. RK Venkatasalam*** |
| |  |  | | --- | --- | | **Name of Inspectors** | **Signature with Date** | | ***1. M.Senthil Kumar*** | **image** | | ***2. S.Chockalingam*** | **image** | | ***3.*** |  | |  |  | |