

Reference Guide

Nuclear Medicine Department Survey, Inspection Readiness

| Infection Control | | | | |
|-------------------|----|----|--|----------------------|
| Yes | No | NA | Guidelines | Explain "No" answers |
| | | | Checked for expired stock | |
| | | | Area is clean and free of clutter | |
| | | | Refrigerator temps and blanket warmer temps are recorded as required | |
| | | | Refrigerator thermometer is calibrated | |
| | | | Action taken for temps out of range | |
| | | | Food in refrigerator labeled and dated | |
| | | | Cleaning and defrosting of refrigerator policy in place | |
| | | | Patient food and staff food separated | |
| | | | No food in medical refrigerators | |
| | | | No torn mattresses or position wedges | |
| | | | No cardboard boxes on floor in storage rooms (insects) | |
| | | | No storage in cabinets under sinks | |
| | | | Linen carts covered | |
| | | | Sharps containers not full, not overflowing and secure (not tipping over) (75% full) | |
| | | | Glucometers strips checked for expiration and controls labeled with expiration date and time | |
| | | | No missing, broken, stained ceiling tiles | |
| | | | Staff are performing hand hygiene in/out of room and washing hands when visibly soiled. | |
| | | | Staff know disinfectant wipe "dwell/kill/contact time" (new wipes during shortage) | |
| | | | Any open containers dated, and date of "do not use after" is present | |
| Facility Safety | | | | |
| Yes | No | NA | Guidelines | Explain "No" answers |
| | | | MSDS Info available to staff (binder or digital) | |
| | | | Annual site specific safety training (fire, active shooter, mass casualty, tornado, earthquake etc.) Completed | |
| | | | Staff know location of fire alarms and fire extinguishers | |
| | | | Fire extinguishers checked periodically | |
| | | | Storage or utility rooms: items on top shelf at least 18 inches from sprinkler | |
| | | | Staff can locate oxygen shut-off valves and can verbalize policy for shut-off | |
| | | | No propped doors, fire escape doors and stairwells are unobstructed. | |

Facility Safety (continued)

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Unobstructed electrical panels (36" clearance). | |
| | | | Oxygen tanks secured (in holder / caddy). Full/in use cylinders separated. | |
| | | | Ensure hallways are clear and egress is met | |
| | | | Eyewash stations checked and in appropriate areas | |

Patient Safety

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Process in place to verify correct patient, exam, parameters, etc. | |
| | | | Pediatric vs adult protocols in place (pediatric dose) | |
| | | | Alcohol gel present in all designated locations (no empty or expired containers) | |
| | | | Verbal orders / telephone orders authenticated per policy. | |
| | | | Patient information at desk covered, no open patient information left unattended | |
| | | | Consents are completed prior to procedures. Physician, patient, witness entries signed, date and scanned into media manager. | |
| | | | H&P present and within timeframe (30 days with update w/in 24 hrs. of procedure). | |
| | | | Time outs performed | |

Equipment

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Daily crash cart checks and logs | |
| | | | PM schedules and records on all equipment available | |
| | | | Equipment tagged so staff know PM has been completed | |
| | | | Medication carts and drawers locked up properly | |
| | | | Manufacturers cleaning requirements available | |

Staff

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Annual competencies on file (procedural, venipuncture, equipment) | |
| | | | All techs licenses and credentials are current and primary source verification completed | |
| | | | Job descriptions approved by medical staff | |
| | | | Color blind testing for areas that require it (E.G. Some quality control depends on color. Tech must be able to evaluate the proper color) | |
| | | | Credentials of person performing evaluations. Must be competent in the field they are evaluating staff member in. No lateral (peer) evaluations, must be at a higher level. | |
| | | | New employee orientations completed and on file | |
| | | | Current credentials on file for diagnostic medical physicists who evaluate equipment | |

Nuclear Medicine Specific Guidelines

Organization

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Organizational chart on file (RSC, Senior Management, RSO, Physicist, Med Director) | |
| | | | Annual review of quality management program on file | |
| | | | Quality management program contains ordered amount, assay dose, route of admin, verify patient, and AU signature | |
| | | | Pharmacy review of radiopharmaceutical policy and oversight of medications administered for exams | |
| | | | Ensure USP 825 Compliance | |

Facility

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Shielding design and post-install survey performed for any new construction or changes to equipment requiring this and records on file (SPECT/CT) | |
| | | | Fume hood airflow is checked | |
| | | | For Xenon air flow is checked and negative pressure is maintained (dose limit to members of public) | |
| | | | Hot lab locked or monitored when not | |
| | | | After hours delivery process. Delivery personnel should not have access to the dept. Security should escort and lock dept after delivery or a drop box is in place. | |

NM Staff Records

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Employee HazMat training on file (DOT every 3 years, IATA every 2 years) | |
| | | | List of staff who have access to Nuc Med Dept on file | |
| | | | Annual rad safety training on file | |
| | | | Annual ancillary radiation safety training on file | |

Personnel Monitoring

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Any over exposures and was state notified | |
| | | | Annual dosimetry report distributed or accessible to monitored workers | |
| | | | Staff can access monitoring period dosimetry reports | |
| | | | Dosimetry reports reviewed by RSO | |
| | | | ALARA II investigations on file according to policy | |
| | | | Declared pregnant workers documentation on file | |
| | | | Any public exposures, state notified and records on file | |

Scope of RML

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | RSO named on RML | |
| | | | AUs current | |
| | | | RSO duties and agreement on file | |
| | | | Use and storage areas identified and current | |
| | | | RSO and storage locations were approved by the state | |
| | | | If doing Human Research does your RML allow this | |
| | | | You have current RML on file for any vendors from which you order sources and your radiopharmacy. | |
| | | | Doses are assayed or decay calculations are performed prior to administration | |
| | | | Review RAM License. Know what radioactive material and maximum quantity your license authorizes you to use. | |
| | | | Verify that your license and amendments are correct. | |
| | | | Has anything on license changed? Was amendment sent to state requesting change. (i.e. company name, address, new storage location, termination of storage location, etc.) | |
| | | | Read and be familiar with your operating, safety and emergency procedures. | |
| | | | RSC in place if required | |
| | | | RSC Membership List current | |
| | | | RSC composed of member for each use, RSO, Nursing, management | |
| | | | Meets the required number of times within a time frame | |
| | | | Quorum present during meeting | |
| | | | Signed copies of past RSC meeting minutes | |
| | | | Meeting agenda and supporting documentation on file | |
| | | | Radiation safety program is available | |
| | | | Radiation safety program is reviewed annually by the RSO | |

Mobile Unit

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Whose RML are they operating under | |
| | | | Do you have letters on file authorizing use of RAM at the facility by mobile service if not does license have authorizing possession of the RAM | |
| | | | Is all RAM removed from facility prior to leaving | |

Equipment QC

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---------------------------------------|----------------------|
| | | | Survey meters are calibrated annually | |

| Well Counter/Thyroid Probe | | | |
|---|--|--|---|
| | | | Efficiency |
| | | | MDA |
| | | | NMIS updated with new efficiency |
| | | | Daily calibrations and weekly chi square |
| Dose Calibrator | | | |
| | | | Linearity install and quarterly \pm 10% accuracy |
| | | | Constancy each day \pm 10% accuracy |
| | | | Geometry install and after repair or move or adjusted \pm 10% accuracy |
| | | | Accuracy-install and annually \pm 10% accuracy |
| Annual Equipment testing by diagnostic medical physicist is performed | | | |
| | | | Image and system uniformity (NM and PET) |
| | | | High contrast resolution/system spatial Resolution (NM and PET) |
| | | | Artifact evaluation (NM and PET) |
| | | | Image acquisition display monitor performance evaluation (NM and PET) (SMPTE Pattern installed on workstations) |
| | | | Max and min luminance |
| | | | Luminance uniformity |
| | | | Resolution |
| | | | Spatial accuracy |
| | | | Sensitivity (NM only) |
| | | | Energy resolution (NM only) |
| | | | Count rate performance (NM only) |
| | | | Low contrast resolution or detectability (PET Only) |
| Gamma Camera QC | | | |
| | | | Xenon alarm monitor is tested and recorded (mfg recommendations) |
| | | | Xenon filters are exchanged or decayed accordingly (charcoal trap rotation) |
| | | | Floods daily, |
| | | | Bars weekly (if applicable) |
| | | | COR monthly, |
| | | | Hi count Uniformity correction floods monthly. |
| | | | SPECT QC (phantoms if req) |

PET/CT QC

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Daily blank scan | |
| | | | Weekly/quarterly calibrations (mfg specific) | |
| | | | Daily tube warm Up (CT) | |
| | | | Daily fast calibration (CT) | |
| | | | Daily/weekly phantom scan (CT) (mfg specific) | |
| | | | Phantom testing for ACR | |

Written Directives

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Written directive policies in place and followed | |
| | | | Release of therapy patient's paperwork on file. Met release levels | |
| | | | Were written instructions given to patients to keep dose to others low | |
| | | | Were breast feeding instructions given if dose to child could exceed 100 mRem | |
| | | | Were documents signed by patient and AU | |
| | | | Are necessary pregnancy tests performed or documentation on file (I-131 proof of hysterectomy or negative pregnancy test) | |
| | | | Was state notified for doses which differ from the prescribed by 20%, regulation specific (Y-90 Theraspheres) | |

Notifications and Posting

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|--|----------------------|
| | | | Previous violations posted and addressed. Will be focus of next inspection | |
| | | | Notice to employees | |
| | | | Hot lab posted properly "Caution Radioactive Materials" | |
| | | | Any stolen or lost sources reported to the state | |
| | | | Any medical events reported | |
| | | | Emergency contact info posted for the RSO and state dept | |

Surveys and Contamination Control

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Daily surveys and weekly wipes if applicable | |
| | | | Area survey and wipe map on file | |
| | | | Wipe results reported in dpm/100 cm ² | |
| | | | Packages received and opened properly (inspector may observe process) | |
| | | | Sources in transport such as dose to cardio for stress tests are appropriately shielded, labeled, and secured | |

Sealed Sources and Leak Tests

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Sealed source list on file and current | |
| | | | Any disposed sources documentation on file | |
| | | | Sealed source list checked every 6 months and signed by RSO | |
| | | | Leak tests performed and on file | |
| | | | Any sources that failed leak test disposed of | |

Waste Management

| Yes | No | NA | Guidelines | Explain "No" answers |
|-----|----|----|---|----------------------|
| | | | Records of receipt, transfer, and disposal of RAM maintained | |
| | | | DIS is less than 120 days unless authorized for greater (Lutathera)(Lu-177m 161 days) | |
| | | | Trash is surveyed daily so nothing radioactive is sent to landfill | |
| | | | Waste storage areas are labeled, secured and surveyed (storage areas outside of dept) | |
| | | | Long lived RAM and Short Lived RAM are segregated to ensure it is stored for minimum of 10 half lives | |
| | | | Waste down sink is monitored if applicable | |
| | | | RAM containers shipped back to the pharmacy are surveyed and wiped (if applicable) and records maintained | |
| | | | Labels for return containers are appropriate | |
| | | | LLRW forms completed and submitted to state | |

Disclaimer: This information is intended to assist you in developing your internal audit. It should be considered a template for creating a similar checklist more specific to the operations of your facility. The use of this information does not guarantee there will be no findings or deficiencies during an inspection or survey.