

ICANL SITE VISITOR'S WORKSHEET

The following must be read before beginning the site visit:

Confidentiality Statement:

"As a participant in this accreditation site visit, I am aware that I have access to accreditation information which shall remain confidential. I agree to respect and protect the confidentiality of all patient and laboratory information, any recommendations, suggestions and discussions prior to, during and following this site visit."

Note: The site visitor does not make the final decision for accreditation. This site visit worksheet will be used, along with the two application reviewer reports, by the ICANL Board of Directors to reach a final decision. If the site visitor observes any deficiency relevant to the *ICANL Standards* not covered by this worksheet, it is appropriate to note these in the general comments section at the end of this document.

You can use the hyperlinks below to jump to any point in the document--just click on the line to go directly to that question. Click on the 'Top' links on the right-hand side of the document to return here.

[Lab Overview](#)

Information about this Application:

Test Lab	Annual Vol.
Quality, MD	RMPI: 150
Application #: 1000	ERNA: 150
Reviewer: Mary Beth Farrell	GNM: 234
# of Sites: 3	PET: 150
First-Time application	
Lab Type: Private Office	
Board Certified Physicians: 1	Med Staff: 1
CBNC Certified Physicians: 1	Tech Staff: 1

Information about this Site:

Site Number: 1
 Test Lab
 123 Accreditation Lane
 Quality, MD 10015

Quality, MD 12345

Areas of Accreditation applying for:

Nuclear cardiology - Myocardial perfusion imaging (MPI)

Nuclear cardiology - Equilibrium radionuclide angiography (ERNA)

Gastrointestinal system imaging

Skeletal system imaging

Pulmonary system imaging

PET Oncologic imaging

Standards	Evaluation of Compliance with Standards	Meets Standard?
		Yes (compliant)
		No (not compliant) - requires site visitor comments
		Partially compliant = requires site visitor comments

Part A: Structure and Organization

I have read and agree to the Conflict of Interest statement above. (If you cannot click 'Agree,' please contact the ICANL staff and return the site visit materials immediately.) Agree Disagree

A1 and A2 Personnel and Supervision

Training

[A1.6](#) Training for technologists or physicians is provided via a formal training program. Yes No NA

[A1.6.1](#) Direct supervision of trainee is provided by qualified staff. Yes No Partially NA

Comments

Trainees, Assistants and Ancillary Personnel

[A1.7](#) Personnel who assist technologists have documented training, experience, and competency. Yes No Partially NA

[A1.7.1](#) A certified/licensed nuclear technologist is identified in writing as the nuclear assistant's supervising technologist. Yes No Partially NA

[A2.1](#) Non-imaging personnel are appropriate for the level of service provided (i.e.: ECG technicians, nurses, exercise physiologist, clerical, administrative). Yes No Partially NA

[A2.1.2](#) Non-imaging personnel are supervised by a qualified individual. Yes No Partially NA

Comments

A3 Physical Facilities

[A3.1](#) Adequate facilities are provided for:

[A3.1.1](#) Waiting, reception, and patient/staff bathrooms Yes No Partially

[A3.1.2](#) Radioactive materials use and storage areas appropriately configured to ensure security and control Yes No Partially

Note: The areas should include adequate shielding based on the use of surrounding areas and type of stored materials. If volatile radionuclides or radionuclide gases are used, appropriate hoods and/or traps are provided.

[A3.1.3](#) Diagnostic imaging and processing areas Yes No Partially

[A3.1.4](#) Patient education, consultation and examination areas Yes No Partially

[A3.1.5](#) Performance of stress procedures within the proximity of the imaging area Yes No Partially

[A3.1.6](#) Emergency transport of patients Yes No Partially

[A3.1.6.1](#) Interpretation areas Yes No Partially

[A3.1.6.2](#) Patient records, reports, and digital data storage Yes No Partially

[A3.1.6.3](#) Administration records and support areas Yes No Partially

- [A3.1.6.4](#) Equipment/supply storage areas Yes No Partially
- [A3.1.6.5](#) Therapeutic procedure areas, if applicable Yes No Partially
- [A3.2](#) Adequate utilities (including water taps, lighting, electrical outlets, emergency power, phones, heating/cooling and ventilation) are available based upon types of procedures and workload. Yes No Partially
- [A3.3](#) Adequate designated space is provided for storage of digital data. Yes No Partially

Comments

Copy to Pos. Comments

Copy to Neg. Comments

A4 Equipment and Instrumentation

[A4.1](#)

The following equipment is present and maintained in good working condition (Equipment and instrumentation must be routinely inspected for safety and proper functionality and records kept on file):

- Dose calibrator or decay correction calculation system, as appropriate Yes No Partially NA
- Imaging/counting equipment Yes No Partially NA
- Radiation monitoring devices (portable survey meter required) Yes No Partially NA
- Removeable contamination equipment Yes No Partially NA
- Fixed area survey meter for dose prep/storage areas Yes No Partially NA
- Resuscitation equipment and supplies (appropriate to the types of procedures being performed) Yes No Partially NA
- Exercise equipment (as applicable) Yes No Partially NA
- ECG equipment Yes No Partially NA
- Ancillary monitoring equipment Yes No Partially NA
- Infusion pumps/automated injectors Yes No Partially NA
- Glucometers Yes No Partially NA
- Fume hood Yes No Partially NA
- Xenon gas and dispensing and delivery system Yes No Partially NA
- Medication refrigerators Yes No Partially NA

Is the following equipment readily available for medical emergencies or critically ill patients:

- Oxygen (wall or tank with supplies to use) Yes No Partially NA
- Defibrillator/AED Yes No Partially NA
- Emergency drugs Yes No Partially NA

Note: In reference to B3.3.2, the defibrillator must be routinely checked for functionality and records maintained. Site visitors must confirm all drugs and supplies are within expiration dates by visual inspection.

Verify the method and frequency for checking emergency meds and supplies and the defibrillator checks (should be performed no less than once a month).

Comments

Copy to Pos. Comments

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Part B: Procedures and Protocols

B1 General Protocol Guidelines

[B1.1.1](#)

A complete manual/table of contents is present, appears organized and includes the following:

[B1.1.2](#)

Reviewed and updated at minimum every three years by the Medical Director or an appropriate designee

- Diagnostic imaging protocols Yes No Partially
- Exercise/pharmacologic stress Yes No Partially
- Therapeutic protocols Yes No Partially NA
- Equipment QC Yes No Partially
- Radiation safety Yes No Partially
- Administrative policies/procedures Yes No Partially

Administrative policies/procedures Yes No Partially

Comments

Copy to Pos. Comments

Copy to Neg. Comments

B2 Clinical Procedure Protocols

B2.1 Lab specific protocols are written for all clinical procedures and are performed under conditions that ensure patient and staff safety. Yes No Partially

B2.1.1 Patient Identification -- Policy and implementation assures accurate patient identification prior to initiating the procedure. Yes No Partially

(For dosages of ¹³¹I-sodium iodide > 30 microcuries and any nuclear medicine therapies, the procedure must provide high confidence that the patient will be properly identified.)

B2.1.2 Pregnancy Screening -- Policy and implementation assures that patients who could be pregnant are identified. Yes No Partially

B2.1.2.1 *(For nuclear medicine therapies or diagnostic procedures using ¹³¹I-sodium iodide for thyroid carcinoma, the pregnancy screening protocol must assure that patients who are pregnant are not administered the radiopharmaceutical.*

As mentioned in B2.1.2.1 and B2.1.2.2, if a diagnostic study is needed for a pregnant patient, knowledgeable staff must discuss the potential risks and alternative care (if necessary) with the patient and document the discussion content.)

B2.1.2.3 Determining fetal dose after radiopharmaceutical administration to a pregnant patient (intended or unintended) Yes No Partially

B2.1.3 Breast Feeding Screening -- Policy and implementation assures that patients who are breast feeding are identified. Yes No Partially

(Appropriate guidelines must be available so that breast feeding may be discontinued and, whenever possible, resumed as soon as safe for the child being breast fed.

The staff must be able to instruct the patient regarding timing of pumping breast milk rather than feeding and discard versus storage/use of pumped breast milk.

B2.1.3.1 For nuclear medicine therapies or diagnostic procedures for thyroid carcinoma using ¹³¹I-sodium iodide, the breast feeding screening protocol assures that any patient who is breast feeding is not administered the radiopharmaceutical. Yes No Partially NA

B2.1.4 Warning signs are present to prevent the inadvertent administration of radiopharmaceuticals to breast-feeding or pregnant patients. Yes No Partially

Note: At a minimum, warning signs must be easily seen by the patient (and in a language understandable by most patients) in the area where initial radiopharmaceutical administration is performed.

B2.2 Do the diagnostic imaging protocols and their implementation result in an accurate depiction of the distribution of the pharmaceuticals and provide data that is interpretable by the responsible physician? Yes No Partially

Imaging procedures are performed as written. Yes No Partially

Stress/pharmacologic procedures are performed as written. Yes No Partially

Therapy procedures are performed as written. Yes No Partially

Comments

Copy to Pos. Comments

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B3.2 Imaging Equipment QC

B3.2 Site specific protocols are present for imaging equipment QC. Yes No Partially

Imaging equipment is maintained in good working condition. Yes No Partially

QC is performed per written standards. Yes No Partially

Protocol includes QC record retention for comparison. Yes No Partially

Protocol includes that results are reviewed and actions taken/documentated. Yes No Partially

Protocols and documentation include:

Energy Peaking (daily, prior to use; documentation not required) Yes No Partially

Intrinsic or extrinsic uniformity (daily, prior to use; approx. 2-5 million counts) Yes No Partially

Resolution and linearity (weekly, bar phantom) Yes No Partially

High count calibration floods (monthly, or per manufacturers recommendations; %gt; or = 30 million count) Yes No Partially

Flood stored for different isotopes used (if applicable) Yes No Partially NA

- Center of rotation (monthly, SPECT) Yes No Partially
- Collimator integrity (annually) Yes No Partially
- Uniformity calibration (monthly or per manufacturer's recommendations) Yes No Partially NA
- Preventative maintenance (every six months) Yes No Partially NA

Comments _____

Copy to Pos. Comments

Copy to Neg. Comments

B3.2 PET QC

- Blank Scan (daily) Yes No Partially NA
- Normalization (after hardware change or per manufacturer's recommendation) Yes No Partially NA
- Absolute activity calibration (after hardware change or per manufacturer's recommendation) Yes No Partially NA
- Preventative maintenance (every six months or per manufacturer's recommendation) Yes No Partially NA

Note: If equipment is physically moved (other than planar mobile gamma cameras or non-PMT mobile systems used within a building) the above camera QC procedures must be repeated after each move and prior to use.

If frequency varies from standards listed above, justification must be based on published scientific data and documented. Any initial acceptance results should be retained for comparison. On-site visitors should review 6-12 months of QC records.

Comments _____

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B3.3 Non-imaging Equipment QC

B3.3.1

Protocols are present for and include:

B3.3.3

A radiation monitoring device (especially a portable survey meter) on site which has been calibrated upon initial acquisition, annually, and after any repairs that might effect calibration. Yes No Partially NA

B3.3.4

- Routine inspection/test for all non-imaging equipment using appropriate reference standards Yes No Partially NA
- Dose calibrator constancy (daily) Yes No Partially NA
- Dose calibrator linearity (quarterly) Yes No Partially NA
- Dose calibrator accuracy (annually) Yes No Partially NA
- Survey meter calibration (annually) Yes No Partially NA
- Glucometer accuracy (daily) Yes No Partially NA

Comments _____

Copy to Pos. Comments

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B3 Equipment Quality Control Protocols

B3.1

Equipment Quality Control -- imaging and non-imaging equipment:

QC records maintained Yes No Partially

Service and maintenance records maintained Yes No Partially

Comments _____

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B4 Radiation Safety and Radioactive Materials Handling Protocols

B4.1

Radiation safety and radioactive materials handling protocols are present and include, as appropriate:

B4.1.1

Annual review verified by initial or signature by the Medical Director or a designee. Review should include program changes, noted deficiencies, and actions taken (or a statement that none are needed). Yes No Partially

B4.1.2

Written designation of the Radiation Safety Officer (RSO), who has agreed in writing to assume responsibility for the radiation protection program. Yes No Partially

B4.2

Note: Facility operations must be in compliance with accepted federal, state and local standards. The facility must retain copies of inspections/surveys as well as evidence of

corrections for deficiencies found.

[B4.3.1.1](#) Provision for a safe working environment, including an ALARA policy. Yes No Partially

[B4.3.1.4](#) Radiation safety instruction upon hire and annually thereafter for all personnel handling, or potentially exposed to, radioactive materials, including all authorized users. Records of training must be retained. Yes No Partially

[B4.3.1.5](#) Monitoring of staff radiation exposure Yes No Partially

[B4.3.1.7](#) Proper use of shielding, radiation protection devices (e.g., syringe shields), and protective clothing as well as refraining from eating or drinking in radiation use areas Yes No Partially

Note: Verify that crosstalk and the use of shielding are addressed. For site visitors, confirm that staff members are wearing lab coats.

[B4.3.1.9](#) Spill confinement/decontamination procedures that include having guidelines posted in the facility (with the RSO's phone number for regular and after hours contact) and having documentation requirements for reporting spills/decontamination Yes No Partially

[B4.3.1.10](#) All personnel that inject or come into contact with radioactive materials or patients wear (ing) monitoring devices Yes No Partially

[B4.3.1.11](#) Periodic area surveys and wipe tests including tolerance limits and response to trigger levels Yes No Partially

Note: For facilities performing only routine diagnostic nuclear cardiology, unless there is a more stringent state or local requirement, area surveys and wipe tests may be performed weekly or even less frequently

if site experience shows that the extended interval is appropriate based on historical data at the site. Alternatively, at facilities where there is a greater risk of contamination such as training sites, more frequent monitoring may be appropriate.

The facility protocol must document the frequency.

Site visitors should check 6-12 months of survey/wipe records.

[B4.3.1.11.1](#) Sites performing nuclear medicine therapies or using dosages greater than 30 microcuries of ¹³¹I-sodium iodide, area surveys are performed daily in areas of dosage prep or administration. Yes No Partially NA

[B4.3.1.12](#) Sealed sources wipe/leak testing protocol and documentation including identity, activity, and location of all sources, name of person conducting the inventory, and results of testing is present. Yes No Partially NA

Note: The frequency of the sealed source wipe/leak test is a minimum of every six months.

[B4.3.1.13](#) Protocol for reporting theft or loss of radioactive materials based on types and amounts of materials and risk to public Yes No Partially

[B4.3.1.15](#) Instruction of patients, family members and, as needed, hospital staff (e.g., nursing personnel) regarding radiation precautions for all therapeutic procedures and/or when appropriate for diagnostic procedures Yes No Partially NA

[B4.3.1.16](#) Protocols establishing, defining and explaining specific procedures for following and adhering to the 'written directive' policy for all personnel involved in administration of nuclear medicine therapies or diagnostic dosages of ¹³¹I-sodium iodide, area surveys are performed daily in areas of dosage prep or administration. Yes No Partially

[B4.3.2](#) Receipt of radioactive materials policy Yes No Partially

[B4.3.2.1](#) Designation of a specific secured area for placing shipments of radionuclides Yes No Partially

[B4.3.2.2](#) Recording of receipt of all shipments of radionuclides Yes No Partially

[B4.3.2.3](#) Survey of shipments of radionuclides, prior to opening, including tolerance limits and response to triggers (including proper notification of damage or leak) Yes No Partially

[B4.3.3](#) Preparation of radiopharmaceuticals as applicable (if only unit doses are used, no protocols are needed since this is done by supplier.) Yes No Partially NA

[B4.3.3.1](#) Assay of generator eluate for total activity Yes No Partially NA

[B4.3.3.2](#) Assay of generator eluate for breakthrough of parent radionuclide Yes No Partially NA

Preparation of radiopharmaceuticals according to product insert or other written protocol Yes No Partially

[B4.3.3.4](#) Verification of radiochemical purity of radiopharmaceuticals Yes No Partially NA

[B4.3.3.5](#) Documentation of lot or batch numbers of components used in radiopharmaceutical preparation Yes No Partially NA

[B4.3.3.6](#) Verification of pH of radiopharmaceuticals preparations when appropriate Yes No Partially NA

[B4.3.3.7](#) Performance of sterility testing on radiopharmaceuticals prepared using non-commercial kits Yes No Partially NA

[B4.3.3.8](#) Performance of endotoxin testing on radiopharmaceuticals prepared using non-commercial kits Yes No Partially NA

[B4.3.3.9](#) Proper storage of kits and prepared radiopharmaceuticals Yes No Partially NA
 Comments

B4.3.4 Administration of Radiopharmaceuticals

[B4.3.4](#) Policy containing all required components for administration of radiopharmaceuticals to patients is present. Yes No Partially

[B4.3.4.1.1](#) Determination of patient dosages using standardized protocols approved by the Medical Director, or by individually written prescriptions Yes No Partially

[B4.3.4.1.2](#) Individual determination of doses for pediatric patients prior to administration Yes No Partially NA

[B4.3.4.2](#) Assay of patient dosages of radiopharmaceuticals (using a dose calibrator) on-site prior to administration Yes No Partially NA

Note: For sites using unit doses, the dosages may be determined based on decay correction of the unit dose. Sites using other than unit doses may determine the dosages being administered using a combination of measurement and mathematical calculations or a combination of volumetric measurements and mathematical calculations based on measurements done by an appropriate preparer (radiopharmacy/supplier). On-site visitors should check 6-12 months of dose calibration records as well as the radioactive waste and disposal records as listed in B4.3.5.

[B4.3.4.3](#) Recording of specific patient dosages prior to administration. Yes No Partially

[B4.3.4.4](#) Verification of patient identity prior to radiopharmaceutical administration as well as pregnancy/breast feeding status (as described in B.2.1). Yes No Partially

[B4.3.4.5](#) Verification of the radiopharmaceutical identity and dosage immediately prior to administration by the prescribed route. Yes No Partially

[B4.3.4.6](#) Verification of the expiration date/time of the radiopharmaceutical and assurance it is administered prior to its expiration date. Yes No Partially

[B4.3.4.7](#) Clear documentation of the administration of radiopharmaceuticals (substance, amount, route, site, date, time and identity of person administering) Yes No Partially

Comments _____

B4.3.5 Radioactive Materials Storage and Disposal

[B4.3.5](#) Policy containing all required components for radioactive materials storage and disposal is present. Yes No Partially

[B4.3.5.1](#) Proper handling of radioactive wastes. Radioactive trash (wipes, syringes, alcohol swabs, etc.) is kept separate from normal trash, stored and appropriately discarded. Yes No Partially

[B4.3.5.2](#) Security (e.g., locking) of areas containing radioactive materials (including hot lab, other radioactive use and storage/decay areas) when not under supervision of clinic personnel Yes No Partially

Note: Labs must ensure that non-authorized personnel (including visitors, patients and non-authorized staff) cannot access any radioactive materials (refer also to facility requirements in A3.1).

[B4.3.5.3](#) Adequate shielding of radioactive materials storage areas based on the types and amounts of radionuclides as well as the types of use of surrounding areas Yes No Partially

Comments _____

B5 Administrative and Other Protocols

Written protocols are present for and include appropriate documentation for the following:

[B5.1](#) Procedure availability (Hours and services provided must be appropriate for the institutional setting.) Yes No Partially

[B5.2](#) Request for services Yes No Partially

Note: Site visitors must review the written policy for requesting clinical nuclear medicine procedures. The documentation of a request, including the identity of the patient, the referring health care provider and clinical information that indicates the rationale for the procedure must be present prior to performing any

procedure.

- [B5.3](#) Duties and Responsibilities for each staff position Yes No Partially
- [B5.4](#) Safety/Security for Staff and Patients (policy to include a written procedure for responding to disasters or other threats to staff or patient safety/security) Yes No Partially
- [B5.5](#) Confidentiality and HIPAA compliance Yes No Partially
- [B5.6](#) Informed Consent (as required, required for therapeutic procedures) Yes No Partially NA
- [B5.7](#) Investigational Radiopharmaceuticals (if used) Yes No Partially NA
- [B5.8](#) Infection Control Yes No Partially
- [B5.9](#) Communicable Diseases Yes No Partially
- [B5.10](#) Hazardous Materials Yes No Partially
- [B5.11](#) Medical Emergencies Yes No Partially
- [B5.12](#) Special Needs Patient Care Yes No Partially
- [B5.13](#) Handling of Non-radioactive Pharmaceuticals Protocol is present and contains all of the required components. Yes No Partially
- [B5.13.1](#) and [B5.13.2](#) Non-radioactive pharmaceuticals are properly stored and prepared (controlled substances must be locked with controlled access if kept on site). Yes No Partially
- [B5.13.3](#) Patient dosages are determined using standard protocols approved by the Medical Director, or individually written prescriptions. Pediatric dosages are determined individually (if applicable). Yes No Partially
- [B5.13.4](#) The health care provider responsible for prescribing the pharmaceutical must be clearly identified for each patient dose(via prescription or protocol) and properly recorded. Yes No Partially
- [B5.13.5](#) The patient's identity is verified prior to pharmaceutical administration. Yes No Partially
- [B5.13.6](#) The identity and dosage of each pharmaceutical are identified immediately prior to administration by the prescribed route. Yes No Partially
- [B5.13.7](#) The expiration date of the pharmaceutical is checked and the dosage is administered prior to the expiration. Yes No Partially
- [B5.13.8](#) There is clear documentation of the administration of pharmaceuticals(substance, amount, route, site, time and identity of person administering). Yes No Partially
- [B5.14](#) Adverse Drug Events Yes No Partially
- [B5.15](#) Drug Administration Errors Yes No Partially

Comments

B6 Image interpretation and reporting protocols

Case Study Review

Site visitor note: Review a random sample of 5-10 case studies. Be sure to include at least one case from each of the following group, as appropriate, if applying for multiple accreditation categories.

In each comment box for each case type list the patient initials and dates of the studies, along with your comments about the cases.

Scoring legend: NA=Not applicable; MS=Meets the standards; SD=Some deficiency; U=Unacceptable

(Score for all cases combined.)

Nuclear Cardiology Cases

- Quality of data MS U SD NA
- Motion artifact MS U SD NA
- Count density MS U SD NA
- Processing/filtering MS U SD NA
- Data display MS U SD NA
- Line up of slices/normalization (nuclear cardiology) MS U SD NA
- Appropriate color (if applicable) MS U SD NA
- Appropriate hard copy (if applicable) MS U SD NA
- Standardization MS U SD NA
- Description and interpretation (images, quantitation, stress) MS U SD NA

Conclusion/summary MS U SD

Patient Initials, Dates of Studies, Comments

Nuclear Medicine Cases

Quality of data MS U SD NA
 Motion artifact MS U SD NA
 Count density MS U SD NA
 Processing/filtering MS U SD NA
 Data display MS U SD NA
 Appropriate color (if applicable) MS U SD NA
 Appropriate hard copy (if applicable) MS U SD NA
 Standardization MS U SD NA
 Description and interpretation (images, quantitation, stress) MS U SD NA
 Conclusion/summary MS U SD

Patient Initials, Dates of Studies, Comments

PET Cases

Quality of data MS U SD NA
 Motion artifact MS U SD NA
 Count density MS U SD NA
 Processing/filtering MS U SD NA
 Data display MS U SD NA
 Line up of slices/normalization (nuclear cardiology) MS U SD NA
 Appropriate color (if applicable) MS U SD NA
 Appropriate hard copy (if applicable) MS U SD NA
 Standardization MS U SD NA
 Description and interpretation (images, quantitation, stress) MS U SD NA
 Conclusion/summary MS U SD

Patient Initials, Dates of Studies, Comments

Final Interpretation

- [B6.1](#) Final interpretation is provided by the Medical Director or a member of the interpreting staff. Yes No Partially
- [B6.1.1](#) The following studies are interpreted from computer screen as applicable:
 - All cardiac studies Yes No Partially NA
 - All PET/SPECT images Yes No Partially NA
 - All dynamic studies Yes No Partially NA
 Exams are interpreted within two working day. Yes No Partially
- [B6.1.2](#) Results of examinations with critical results are communicated to the referring physician as quickly as clinically indicated. A record of the communication should be maintained. Yes No Partially
- [B6.1.3](#) Exams are signed and forwarded to the referring physician or health care provider within four working days. Yes No Partially
- [B6.1.4](#) All final reports are reviewed and signed manually or electronically (with password protection) by the responsible physician. Yes No Partially

protection) by the responsible physician. Yes No Partially

Stamped signatures or signing by non-physician staff is unacceptable.

B6.1.6 Retention of Records -- All patient records are confidentially maintained and retained and accessible for the appropriate period of time as prescribed by state, institution or other rules/regulations. Yes No Partially

B6.1.6.1 Retained hard copy is of high quality and reflects the findings described in the final interpretation. Yes No Partially

B6.1.6.2 The raw digital image data is retained for a minimum of three years. Yes No Partially NA

B6.1.6.3 Technical data that are not part of the final report are maintained as part of the facility records. Yes No Partially

B6.1.6.4 Specific worksheets for non-imaging studies are maintained as part of the facility records. Yes No Partially NA

B6.1.8 Remote interpretation -- If images are transmitted to another location for interpretation, a method of validating the quality of the transmitted images is done to assure that it is of comparable diagnostic quality. (Recommended, not required.) Yes No Partially NA

B6.2 Final interpretation of examinations include consideration of relevant clinical and imaging data. Yes No Partially

This includes, but is not limited to:

-Written or electronic request from the referring physician

-Clinical information and clinical indication/question

-Radionuclide images

-Stress or pharmacologic and quantitative data (when appropriate)

-Other imaging modalities (i.e. echo/ultrasound, CT, MRI, etc.), if applicable

-Comparison with prior nuclear medicine examinations, if applicable

B6.3 The quality of the reports is acceptable. Yes No Partially

The report is typed or computer generated and accurately reflects the content and results of the study. Yes No Partially

This includes, but is not limited to:

B6.3.1 Patient's name, identification number (if used), gender and age Yes No Partially

B6.3.2 Requesting healthcare provider's name Yes No Partially

B6.3.3 Date of the examination Yes No Partially

B6.3.4 Date of the report Yes No Partially

B6.3.5 Clinical indications leading to the performance of the examination Yes No Partially

B6.3.7 Description of the procedure performed:

Type of the examination(s) Yes No Partially

Type, amount and route of administration of radiopharmaceutical given Yes No Partially

Type, amount and route of administration of any other drugs given Yes No Partially NA

Stress or intervention, if applicable Yes No Partially

B6.3.8 The results of the examination include:

Pertinent positive and negative findings Yes No Partially

B6.3.8.1 Stress test findings, if applicable, including hemodynamic/ECG response Yes No Partially NA

B6.3.8.2 Localization and quantification of abnormal findings, as appropriate Yes No Partially

B6.3.9 The reasons for limited examinations and/or deviation from standard protocols, if applicable Yes No Partially

B6.3.10 An overall succinct impression Yes No Partially

B6.3.11 Any need for additional studies based on the interpretation of the nuclear medicine procedure Yes No Partially

B6.3.12 Identification and manual or electronic signature of responsible physician Yes No Partially

Comments

B7 Therapy performance and reporting protocols

B7.1 Nuclear medicine therapies are performed and a final report provided by the Medical Director or members of the medical staff who are qualified as defined in A1.1.1 and A1.1.3. Yes No Partially NA

The treating physician is an authorized user for the radioisotope administered if it is controlled under the radioactive materials license. Yes No Partially NA

- [B7.1.1](#) The treating physician reviews the pertinent elements of the patient's history, physical findings, laboratory and imaging data to determine that the proposed treatment is appropriate. Yes No Partially NA
- The treating physician is taking responsibility for the proper administration of the therapy and its potential side effects. Yes No Partially NA
- [B7.1.2](#) The treating physician is responsible for assuring that the facility's therapy protocol is followed (B2.4) as well as radiation safety protocols specifically relevant to radionuclide therapies (B4). Yes No Partially NA
- If deviations from the protocols are made, these are documented in the patient's medical record and/or the final report.*
- [B7.1.3](#) Prior to administration of the therapeutic dosage, the treating physician must assure that the patient is fully informed regarding the risks (including side effects), benefits, alternatives and expected outcome (including likelihood of success) of the therapy, written consent is obtained, the patient is not pregnant, and the patient is not lactating or is specifically counseled about the risks of breast feeding (if any) based on the specific treatment. Yes No Partially NA
- [B7.1.4](#) The treating physician must assure that the patient is properly identified prior to radionuclide therapy dosage administration and that the dosage is administered properly. Yes No Partially NA
- [B7.1.5](#) The treating physician must assure that the patient is given appropriate post-therapy instructions and specific information concerning his/her follow-up appointment(s) (with whom, when, and where). Yes No Partially NA
- [B7.1.6](#) The treating physician is responsible for post-therapy care unless coordinated with and transitioned to the referring physician or other healthcare provider (including providing any specific subject-area information needed for proper care following the the therapy). Yes No Partially NA
- [B7.2](#) The report of the therapy must be typed or computer generated and must accurately reflect the treatment performed. This must include, but is not limited to: Yes No Partially NA
- [B7.2.1](#) Patient's name, gender, age (or date of birth) and identification number, if applicable Yes No Partially NA
- [B7.2.2](#) Requesting healthcare provider's name Yes No Partially NA
- [B7.2.3](#) Date of the examination Yes No Partially NA
- [B7.2.4](#) Date of the report Yes No Partially NA
- [B7.2.5](#) Patient's diagnosis including a summary of relevant history, physical findings, laboratory and imaging data to confirm the diagnosis Yes No Partially NA
- [B7.2.6](#) Justification for therapy including alternatives, risk (including side effects), benefits and expected outcomes (including likelihood of success) Yes No Partially NA
- [B7.2.7](#) That the patient was informed of the B7.2.6 above and consent obtained Yes No Partially NA
- [B7.2.8](#) When applicable, evidence that the patient is not pregnant Yes No Partially NA
- [B7.2.9](#) When applicable, that the patient is not breast feeding or has been properly counseled regarding risks of breast feeding (if any) Yes No Partially NA
- [B7.2.10](#) The specific radiopharmaceutical administered including identity, amount and route, and any other relevant procedures that were part of the therapy Yes No Partially NA
- [B7.2.11](#) Post-therapy instructions given to the patient including planned follow-up (with whom, when and where or how to arrange the appointment) Yes No Partially NA
- [B7.2.12](#) Any unusual occurrences or variations from clinic protocols Yes No Partially NA
- [B7.2.13](#) Identification and manual or password-protected electronic signature of the responsible physician. Stamped signatures or signing by non-physician staff is unacceptable. (The treating physician must be qualified as noted in B7.1). Yes No Partially NA

Comments

Part C: Outcome and Quality Assessment

Section 1 Quality assessment protocols

Site Visitor/Auditor note: The following QA components may be contained in a single QA plan.

- [C1.1](#) The facility conducts internal quality assessment at regular time intervals. Yes No Partially
- [C2.1](#) The program contains administrative quality assessment (i.e., appropriateness, backlog, wait times etc.). Yes No Partially
- [C2.1.2](#) The program contains technical quality assessment (image quality, reproducibility, etc.). Yes No Partially
- [C2.1.3](#) The program contains interpretative quality assessment program (peer review, correlation Yes No Partially

with other studies, etc.). Yes No Partially

C3.1 Periodic meetings to provide in-service education and to discuss and disseminate information are held with laboratory staff. Yes No Partially

Comments

Form input area for comments

Copy to Pos. Comments
Copy to Neg. Comments

In addition, please provide a brief commentary that may be communicated to this laboratory. Be specific and constructive with ways to improve the operation of the laboratory. Please also provide any positive comments that should be passed onto the laboratory.

Comments and Recommendations

General/positive comments:

Form input area for general/positive comments

Deficiencies and suggested remediation:

Form input area for deficiencies and suggested remediation

- include standard reference number and/or item description. (If explained in detail previously please copy and paste here.)
Comments for ICANL only. Will not be provided to laboratory.

Form input area for ICANL comments

Recommendation for final decision: Accredited Delay Provisional Grant

Recommend staff from this laboratory to become site visitors (must have undergone an exemplary site visit): Yes No

This is the end of the form.