

## NUCLEAR MEDICINE AND RADIATION SAFETY ADMINISTRATIVE SERVICES

- 1. REASON FOR ISSUE:** This Veteran Health Administration (VHA) directive establishes policy for the administrative structure and management of services and service lines providing Nuclear Medicine in the Department of Veteran Affairs (VA) facilities.
- 2. SUMMARY OF MAJOR CHANGES:** This directive updates program and operational responsibilities within the Nuclear Medicine and Radiation Safety Service (NMRSS).
- 3. RELATED ISSUES:** VHA Directive 1105, Management of Radioactive Materials, dated February 5, 2015; and VHA Directive 1129, Radioactive Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
- 4. RESPONSIBLE OFFICE:** The National Director, Nuclear Medicine and Radiation Safety Program Office, Diagnostic Service (10P11D) is responsible for this directive. Questions may be addressed to 734-845-5027.
- 5. RESCISSION:** VHA Handbook 1105.02, dated December 10, 2010, is rescinded.
- 6. RECERTIFICATION:** This VHA directive is scheduled for recertification on or before the last working day of August 2023. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

Richard A. Stone. M.D.  
Executive in Charge

**NOTE:** All references herein to VA and VHA documents incorporate by reference subsequent VA and VHA documents on the same or similar subject matter.

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## NUCLEAR MEDICINE AND RADIATION SAFETY ADMINISTRATIVE SERVICES

### 1. PURPOSE

This Veterans Health Administration (VHA) directive establishes requirements for the creation, maintenance, and accreditation and regulation of safe radiation environments; staffing qualifications and activities; system-wide quality management mandates; identification of relevant committee functions; communicating the utilization of radioactivity to minimize adverse consequences; and the administration and functioning of nuclear medicine laboratories in VHA facilities or those managed by VHA facilities.

**AUTHORITY:** Public Law 93-438; Title 38 United States Code (U.S.C.) 7301(b).

### 2. BACKGROUND

a. Within VHA, all Nuclear Medicine Services must meet the requirements of The Joint Commission, Food and Drug Administration (FDA), Occupational Health and Safety Administration (OSHA), National Health Physics Program (NHPP) and the Nuclear Regulatory Commission (NRC). All laboratory testing, regardless of location, undergoes an on-site inspection. The accrediting agency performing the inspection must have deemed status from the Centers for Medicare and Medicaid Services (CMS).

b. When regulations of various inspecting agencies are in conflict the most restrictive, as determined by the National Director, Nuclear Medicine and Radiation Safety Service office, shall apply.

c. Changes to Federal regulations and other guidance related to nuclear medicine and radiation safety may be modified over time affecting the procedures presented in this directive. In such cases, the NHPP and NRC will notify stakeholders of these changes. Changes affecting the practice of nuclear medicine will be communicated through email to the appropriate stakeholders and will be posted on the VHA Nuclear Medicine and Radiation Safety Service Web site at [http://vaww.patientcare.va.gov/NuclearMedicine/Nuclear\\_Medicine\\_Radiation\\_Safety\\_Services.asp](http://vaww.patientcare.va.gov/NuclearMedicine/Nuclear_Medicine_Radiation_Safety_Services.asp). **NOTE:** *This is an internal VA Web site that is not available to the public.*

### 3. DEFINITIONS

a. **Imaging Data.** Nuclear medicine imaging data produced by gamma cameras can be presented as two dimensional planar images (with two-dimensional data obtained over selected areas of anatomic interest) in either static or dynamic format, or presented as three-dimensional imaging datasets (Single photon emission computed tomography (SPECT) or Positron emission tomography (PET). Both SPECT and PET are commonly combined with computed tomography (SPECT/CT or PET/CT) for attenuation correction and anatomic correlation.

(1) A SPECT imaging system is used to collect three-dimensional imaging data by acquiring imaging data from radiation detectors that rotate around the body, (head, thorax, abdomen, or extremity) with the images reconstructed in each of the three primary anatomic projections (coronal, sagittal, transverse). More commonly, SPECT

instrumentation is combined with CT in a single system designed for diagnostic enhancements via attenuation correction and anatomic localization (SPECT/CT).

(2) A PET imaging system is used to image annihilation photons released in the decay of positron-emitting radionuclides. Positron emitting radionuclides are imaged with cameras specifically designed to perform PET and are typically combined with a CT scanning component which is used for attenuation correction and anatomic localization of diagnostic PET images.

(3) Combined PET and CT (PET/CT) is a standard imaging tool that allows physicians to pinpoint the location of cancer and other pathology within the body for an accurate diagnosis. The most common application of PET/CT utilizes a Fluorine-18 labelled glucose analogue (FDG) which mimics normal glucose metabolism but, because of the Fluorine-18 substitution, concentrates in cells proportional to their glucose metabolism. The highly sensitive PET/CT scan detects the metabolic signal of actively growing cancer cells in the body with the CT component, providing a detailed picture of the internal anatomy that reveals the location, size, and shape of abnormal cancerous growths. Alone, each imaging test has specific benefits and limitations, but when the results of PET and CT scans are fused, the combined image provides significantly more complete information on cancer location and metabolism. Both scans, PET and CT, are done sequentially, with the CT typically being done first during the same procedural session.

(4) The advantages of many, but not all, positron-emitting radionuclides is that their short (minutes to seconds depending upon the isotope) half-lives can markedly decrease radiation exposure. In addition, the coincidence detection offered with the PET modality allows for improved spatial resolution (~5 millimeter (mm) compared to ~8 mm) with SPECT imaging images and their use in labeling a broad spectrum of biological compounds can be used in medical diagnosis.

b. **Incident.** An incident is defined as any instance that causes or has the potential to cause harm to a beneficiary or staff. The terminology “incident” is also used for radiation-related events and other circumstances that must be reported to the NRC under Title 10 Code of Federal Regulations (CFR) Part 20. If an incident results in an injury to an employee, the incident is to be reported in the Automated Safety Incident Surveillance and Tracking System (ASISTS). (See VHA Handbook Directive 2011-020, Automated Safety Incident and Tracking System (ASISTS), dated April 19, 2011, or subsequent policy).

c. **Medical Event.** Any incident, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in a reportable medical event per 10 CFR 35.3045

d. **National Health Physics Program (NHPP).** The NHPP provides oversight for and implementation of the VA’s Master Materials License (MML) for use of radioactive materials, including permitting, inspections and enforcement. The NHPP directs the implementation of the NRC Master Materials Licenses (MMLs) and coordinates

activities of the National Radiation Safety Committee (NRSC). The NHPP grants permits to VA medical facilities, identifies who are the authorized users, and whether the program includes research, interventional, or just diagnostic services.

e. **Nuclear Medicine.** Nuclear medicine is a referral medical specialty whose services are requested by primary and subspecialty physicians, nurse practitioners, and physician assistants, for the purpose of diagnosis and/or therapeutic nuclear medicine intervention. Radionuclides, either alone or bound to compounds (biological and other) with known metabolism (i.e., distribution and clearance), are administered, either orally, by inhalation, intravenously, or in selected instances by direct injection (intraperitoneal, intrathecal, intracystic, intradermal, or other) to obtain diagnostic evaluation(s) of anatomic, physiologic, or pathophysiologic conditions, or as a means to assess the success of, or guide to, other therapeutic interventions.

#### 4. POLICY

It is VHA policy that each VA medical facility which has or manages a Nuclear Medicine and Imaging (NM&I) Service must meet all applicable accreditation and Federal regulatory standards, and create and maintain a safe radiation environment and a culture of radiation safety. **NOTE:** For policies specific to safety culture see VHA Directive 1105, *Management of Radioactive Materials*, dated February 5, 2015, and VHA Directive 1129, *Radiation Protection for Machine Sources of Ionizing Radiation*, dated February 5, 2015, or subsequent policies.

#### 5. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for overall compliance with this directive and serving as the named master materials license official (see VHA Directive 1105).

b. **Deputy Under Secretary for Health for Operations and Management.** The Deputy Under Secretary for Health for Operations and Management is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Services Networks (VISN);

(2) Ensuring that each VISN Director has the resources required to support the fulfillment of the terms of this directive in all VA medical facilities within that VISN; and

(3) Confirming that each VISN has and utilizes on an ongoing basis a means for ensuring the terms of this directive are fulfilled in all the VA medical facilities of the VISN.

c. **National Director, Nuclear Medicine and Radiation Safety Program.** The National Director of the Nuclear Medicine and Radiation Safety (NMRS) Program provides national guidance to VHA's NMRS Program and is responsible for:

(1) Providing direct oversight of the National Radiation Safety Committee (NRSC).

(2) Ensuring the proper acquisition, receipt, storage, use, distribution, transport, and disposal of radioactive contaminated objects to ensure safe environments for patients, staff, and others.

(3) Ensuring that comprehensive quality care is seamlessly delivered. If required nuclear medicine services are not available at the local VA facility or within the VISN configuration, Community or Choice arrangements must be made to ensure these services are performed by a comparable non-VA setting

(4) Reviewing changes, at least annually, to the American Medical Association's (AMA) Current Procedural Terminology (CPT) Code and providing guidance to VHA facilities. (For purposes of uniformity, accuracy, and inter-institutional reliability, the activities of Nuclear Medicine Service lines are categorized according to the AMA CPT codes; VHA employs the complexity index of each CPT code as weighted by CMS. The CPT codes may be modified annually by the AMA.) CPT code changes are posted on the NMRSS Web site at

[http://vaww.patientcare.va.gov/NuclearMedicine/Nuclear\\_Medicine\\_Radiation\\_Safety\\_Services.asp](http://vaww.patientcare.va.gov/NuclearMedicine/Nuclear_Medicine_Radiation_Safety_Services.asp) **NOTE:** *This is an internal VA Web site and is not available to the public.*

(5) Providing informal oversight of the facility Radiation Safety Committees (RSC). The National Director, as needed and as dictated by the goals of the VA, provides consultation suggestions, review, and guidance regarding radiation safety standards and implementation to facility RSCs.

(6) Providing oversight to NMRS professional staff providing ad hoc counsel and education, such as the application of radiation safety regulations and employment of centrally-directed congressionally mandated methods, as well as local performance improvement methods for nuclear laboratory testing (imaging and radio-bioassay) having implications for patient care (See Appendix C).

d. **National Radiation Safety Committee.** The NRSC is the principal VA Central Office (VACO)-level organizational element to implement the MML, and operates under a committee charter and delegation of authority approved by the Under Secretary for Health. (See VHA Directive 1105 and VHA Directive 1129).

e. **Veterans Integrated Service Network Director.** The Veterans Integrated Service Network (VISN) Director is responsible for:

(1) Ensuring appropriate allocation and deployment of resources for nuclear medicine services across VISN medical facilities.

(2) Ensuring all laboratories and individuals performing radiobioassay used for the diagnosis of, or guiding the treatment of, patients are in compliance with 42 CFR Part 493.

f. **VA Medical Facility Director.** Each VA medical facility Director is responsible for:

(1) Acting as, or designating, the facility-level licensee or permittee.

(2) Ensuring the Service Chief or Director, NM&I is appropriately qualified: See Appendix A: Service Chief Qualifications

(3) Ensuring that the Service Chief/Director, NM&I establishes and maintains a comprehensive and systematic Performance Improvement Program that follows the requirements provided in Appendix C.

(4) Assuring establishment and maintenance of a patient-safety culture in NM&I. (See VHA Directive 1105 and VHA Directive 1129).

(5) Ensuring a radiation-safe environment in NM&I Service that promotes the "ALARA" principle, i.e., maintaining radiation dose exposure as low as reasonably achievable.

(6) Ensuring management representation on the facility RSC, compliance with VHA Directive 1105 and creation and maintenance of records, minutes, and files using the prescriptive guidelines established by the NRSC and NHPP.

(7) In the event of known nuclear medicine -related equipment failures, or commercially prepared radiopharmaceutical concerns that pose dangers to patients, ensuring that the facility patient safety manager is notified, and is responsible for disseminating patient safety information based upon the nature and urgency of the information needing to be shared.

(8) Ensuring that any incident is promptly investigated.

(9) Reporting to the NHPP any incident that meets the definition of a medical event (See VHA Directive 1105).

(10) Ensuring that the Service/Section Chief/Director, NM&I establishes and maintains a comprehensive and systematic Performance Improvement Program that follows the requirements provided in Appendix C.

(11) Providing appropriate delegation; selected administrative responsibilities may be delegated to appropriate supervisory staff. **NOTE:** *Medical care responsibilities may only be delegated to physicians, and technical responsibilities to qualified technical personnel, as appropriate. The Medical Facility Director, however, remains responsible for the operation and administration of the service.*

g. **Service/Section Chief, Nuclear Medicine and Imaging.** The Service/Section Chief, NM&I is responsible for planning, directing, coordinating, and evaluating the nuclear medicine services based upon the missions, special needs, size, and organizational structure of the facility and VISN. The many and diverse functions of this position encompass aspects of patient care, administration, education, research, and counsel during radiation emergencies, to include:

(1) Establishing, directing, and maintaining a comprehensive systematic Performance Improvement Program that follows the requirements provided in Appendix C.

(2) Documenting actions and defining any changes in operations that result from the Performance Improvement Program.

(3) Enacting follow-up recommendations per the evaluation of NM&I service results for any National Performance Measures.

(4) Credentialing and privileging appropriate staff; identifying, in writing, appropriate privileging qualifications of staff nuclear physicians to include: specific competencies in diagnostic testing, procedures, and therapy; coordination with other imaging and laboratory findings; consultation; and examination according to the procedures identified in VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012, or subsequent policy.

(5) Providing Continuing Education direction for professional and technical staff; and, in affiliated VHA facilities, ensuring that established accredited educational and training programs for medical residents, fellows, and allied health professionals are maintained.

(6) Fostering research in facilities with a research mission; encouraging participation in medical and health systems research.

(7) Developing metrics as needed, that supplement National Performance Measures for local NM&I quality and safety assurance.

(8) Determining and initiating necessary action, as needed, particularly regarding known nuclear or nuclear-related equipment failures.

(9) In collaboration with the facility RSO and the facility RSC, monitoring activity to ensure and maintain a safe radiation environment. (See VHA Directive 1105).

(10) Appointing and overseeing a patient safety monitor to address “close call” or “near miss” situations and informed consent. (See VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 4, 2009, or subsequent policy.)

(11) Ensuring a smooth administration of the facility nuclear medicine program by:

(a) Developing a business plan;

(b) Ensuring adequate staff and equitable assignments;

(c) Utilizing standard procedures and protocols, or developing procedures and protocols for all testing;

(d) Monitoring all performance improvement activities;

(e) Creating and maintaining safe radiation environments;

(f) Consulting and overseeing support services to produce a timely quality product; and

(g) Serving on institutional, cross-institutional, VISN, and national committees, as requested.

(12) Ensuring each VA medical facility or accredited laboratory performing nuclear services with VHA patients has, as applicable, at a minimum, the following elements:

(a) Standardized protocols for performing each nuclear medicine imaging and therapeutic procedure that are reviewed/revised and approved annually.

(b) An appropriateness monitor for requested nuclear imaging studies that includes follow-up with referring physicians.

(c) A monitor that evaluates the accuracy of the physicians' diagnostic impressions (also known as double reading of scans) of a representative sample of nuclear imaging studies performed.

(d) Provision for and implementation of Ongoing Professional Practice Evaluation (OPPE) for all providers.

(13) Providing radiation emergency counsel and direction locally, according to facility procedures and manuals, in the event of a radiation emergency. **NOTE:** *This responsibility may be shared with the facility Radiation Safety Officer (RSO) and may be subordinate in authority to VHA's Medical Emergency Radiation Reaction Team (MERRT) in the event of a major radiation emergency.* The patient must be given a description of any precautions that are necessary for the patient, or patient's family.

(14) Providing appropriate delegation; selected administrative responsibilities may be delegated to appropriate supervisory staff, such as an administrative officer or supervisory nuclear technologist. **NOTE:** *Medical care responsibilities may only be delegated to physicians, and technical responsibilities to qualified technical personnel, as appropriate. The Service Chief or Director, NM&I, however, remains responsible for the operation and administration of the service.*

(15) Ensuring accurate and timely data and trend analysis as follows:

(a) Utilizing the existing electronic health record and VA databases for clinical data and aggregate management information.

(b) Submitting workload and other data as requested annually by the Program Director, NMRSS, Patient Care Services, and VHA Central Office.

(c) Providing accurate information, reviewing the output and promptly addressing errors in the Decision Support System (DSS). As DSS is VA's major financial

instrument to assess the inputs and outputs of production upon which management decisions are predicated, it is essential to provide of accurate data.

(d) Ensuring that all statistical information representing the activities of the service (CPT codes, etc.) is accurate and submitted in a timely fashion.

(e) Categorizing workload and ensuring CPT code changes and recommendations of the Program Director, NMRSS, are communicated to the accountable support staff.

(16) Establishing a Technical Quality Assurance Program for monitoring the performance of imaging and counting equipment.

h. **Facility Nuclear Medicine Physician.** Physicians providing nuclear medicine care must be approved by NHPP according to 10 CFR Part 35, and are responsible for:

(1) Providing consultation to clinical referring physicians regarding the appropriateness of:

- (a) The diagnostic nuclear testing requested;
- (b) The clinical ramifications of the imaging findings; and
- (c) Therapy with unsealed radioactive sources.

(2) Providing direction in the management of radiation emergencies. Please refer to the National Radiation Safety Committee (NRSC) SOP 05 <http://nhpp.med.va.gov/Top/2VAspecific/12Procedures/SOPs/SOP5.pdf> which describes procedures for responding to incidents involving radioactive material that occur at facilities holding VHA Master Material License (MML) permits.

(3) Participating in NM&I service's mandated quality improvement, patient safety programs, and educational mandates, which are considered an essential part of the staff nuclear physicians' professional responsibilities. **NOTE:** *Participation in patient safety programs includes reporting medical events and close calls to the facility patient safety manager.*

(4) Maintaining current knowledge and providing counsel regarding the regulatory requirements of creating and maintaining safe radiation environments.

i. **Radiation Safety Committee and Radiation Safety Officer.** The RSC and the RSO are responsible for supporting the VA medical facility Director and taking all actions necessary to ensure the safe use of radioactive materials and regulatory compliance. In the usual organizational arrangements, the RSO completes day-to-day actions and functions as a member of the RSC. (See VHA Directive 1105). Ideally, the RSO or technical staff in a segmented role with some portion of the Full-time Equivalent (FTE) employee dedicated to RSO responsibilities, is organizationally aligned with facility management so that the individual RSO is not placed in the position of potentially having to censure or take corrective action against their immediate supervisor.

## 6. REGULATORY AND ACCREDITATION OVERSIGHT

There are multiple Federal (including VA) and state agencies, plus private accrediting bodies, which regulate the use of ionizing radiation. Failure to adhere to the license or permit specifications and regulatory proscriptions can result in the involuntary cessation of operations. VHA facilities, based on Pub. L. 93-438, are under the authority of the NRC and VHA's MML authority to regulate byproduct, source, and special nuclear materials which is accomplished through the NHPP as the regulator for the VHA's MML. These authorities grant and permit for use of nuclear materials and oversee that the license or permit conditions and the regulatory proscriptions are followed. (See Appendix B).

## 7. NUCLEAR MEDICINE SERVICES AND RADIATION SAFETY IN VA MEDICAL FACILITIES

a. Depending upon the facility's mission, potential workload, and availability of the service within proximity for Veteran patients, some facilities may not provide nuclear medicine services or comprehensive nuclear medicine services.

b. Nuclear medicine services may be organized in a variety of forms at the discretion of the facility Director or VISN Director. It can be either an autonomous medical entity or combined with other medical services to create imaging and diagnostic services.

c. The scope of nuclear testing and services provided are appropriate for the missions and type of patient services provided at the facility and within the VISN configuration. Services may include the acquisition, processing, and interpretation of nuclear imaging and radiobioassay laboratory diagnostic testing; telemedicine nuclear image interpretation of scans acquired at other sites; and therapy with unsealed sources.

d. Facilities that utilize radioactive materials in the conduct of clinical practice or medical research are required by various Federal agencies to establish and utilize intra- and extra-VHA committees to regulate and oversee local activities; these are for:

(1) **Clinical Practice.** A VA medical facility that limits its involvement with radioactive materials to clinical practice is mandated by the NRC and MML to constitute and conduct a facility Radiation Safety Committee (RSC).

(2) **Research.** Facilities that are engaged in the use of radioactive materials in human research, no matter how small the amount of radioactivity, must establish, convene, and conduct committees that ensure compliance with the Federal Policy for the Protection of Human Subjects (see 10 CFR 35.6).

## 8. PERFORMANCE IMPROVEMENT PLAN

Each VA medical facility with NM&I must have a performance improvement plan. For detailed requirements see Appendix C.

## 9. THE PATIENT'S "RIGHT TO KNOW" REGARDING USE OF RADIOACTIVITY IN VHA

Patients' right to know, including understanding the dangers of using radiation, the allowable use of radiation, quantities used, and time and distance from exposure from radioactive elements, constitutes a science of its own with relatively few persons competently knowledgeable. Facilities using radiation must have expert RSOs on staff or access to them; RSOs are the staff most qualified to address patient concerns regarding radiation. The availability of these expert RSOs allows for the alleviation of patient concerns and enactment of appropriate actions, including avoiding any widespread contamination, in a timely fashion.

a. **Routine Diagnostic Imaging.** Language that provides education and addresses nuclear medicine fears need to be used when discussing issues with the patient or the patient's family. **NOTE:** *VHA Handbook 1120.04, Veterans Health Education and Information Program Requirements, dated September 24, 2015, or subsequent policy, provides direction for Veteran education.*

b. **Therapeutic Intervention.** The facility RSO must be contacted by the Chief, NM&I prior to the therapeutic procedure to assist in decisions and preparing the proper post-therapy environment. In certain circumstances (dosage, condition of the patient, etc.) it may be desirable to arrange an in-patient stay until the radioactivity administered is at a sufficiently low level that it is not harmful to others. Applicable consents should be obtained per VHA Handbook 1004.01, Informed Consent for Clinical Treatments and Procedures, dated August 14, 2009, or subsequent policy.

c. **Informing Patients about Adverse Events.** VHA is obligated to inform patients and their families about injuries resulting from adverse events (full disclosure) and the options available to them. Once it is established, through the RSO's counsel, that an adverse event involving a patient has occurred, the attending physician must advise the patient, or patient's family, with accurate information (For detailed information regarding disclosure of adverse events to patients, see VHA Handbook 1004.08.) **NOTE:** *10 CFR Part 35.3045 requires specific notification for patients and referring physicians if a medical event occurs.*

d. **Distinguishing Practice from Research.** Occasionally, there are questions or confusion regarding the scope of medical practice that includes the clinical use of radioisotopes and how that differs from the research use of radionuclides. It is vital that the medical facility address these questions and engage the appropriate facility oversight committee (e.g., Radiation Safety Committee, Research and Development Committee, Institutional Review Board and the facility-level Radioactive Drug Research Committee) as needed. The facility must fully adhere to the Federal Policy for the Protection of Human Subjects. **NOTE:** *VHA Handbook 1004.01; 10 CFR Parts 19, 20, 30, 33 and 35; and 21 CFR Parts 50, 56, 207, 211, 310, 312, 314, and 361 provide direction.*

e. **Suspected Improper Behavior.** Staff suspected of violating rules related to or activity during the conduct of research, e.g., lack of informed consent, must promptly be reported to the facility IRB or research service and the facility RSO.

## 10. "OFF LABEL USE"

a. Both FDA (Title 21 of the CFR) and NRC acknowledge that there are clinical circumstances where deviations from approved uses (i.e., "off label" uses) of radiopharmaceuticals are necessary in the routine management of patients. It is understood that allowing for routine use, not specified on the package insert, may represent commonly accepted industry-wide practice that aligns with existing guidelines and is considered within the standard of care in nuclear medicine practice.

b. Criteria for exempting an "off label" use of an approved radioactive drug from Investigational New Drug (IND) requirements are:

(1) No significant increase in patient risk. The prescribing physician must determine the risks and benefits of the intended off-label use.

(2) No intention to develop a new indication(s) for the use of the radioactive drug (e.g., a clinical research project).

c. These standards allow for changes to be made in the preparation, route of administration, or indication(s) for use of a radiopharmaceutical that deviate from approved methods of preparation, route of administration, or indication(s) in the course of individual patient medical management.

(1) The intent of the deviation(s), from an approved method of radiopharmaceutical, is to obtain information important in the clinical management of a patient. **NOTE:** *The use of these "off label" uses is not to conduct a clinical research trial.*

(2) Deviations from an approved use of a radiopharmaceutical occur after consultation between a referring physician and a nuclear medicine or radiology physician. A written requisition to perform an imaging procedure must be submitted by a credentialed and privileged referring physician to a credentialed and privileged nuclear medicine or radiology physician for the expressed purpose of obtaining information necessary in clinical management. This is broadly defined as the scope of clinical practice.

## 11. TRAINING REQUIREMENTS

There are no training requirements associated with this directive.

## 12. RECORDS MANAGEMENT

All records regardless of format (paper, electronic, electronic systems) created by this directive shall be managed per the National Archives and Records Administration (NARA) approved records schedules found in VA Records Control Schedule 10-1. If

you have any question to the regarding any aspect of records management you should contact your facility Records Manager or your Records Liaison. **NOTE:** *When possible you may add a broad location of possible records schedules of interest pertaining to the records within the VHA directive. For example, if the subject of the directive is employee training, provide the location in RCS 101 of employee training records.*

### 13. REFERENCES

- a. Pub. L. 93-438, Energy Reorganization Act of 1974.
- b. 10 CFR Part 20, Nuclear Regulatory Commission, Standards for Protection Against Radiation.
- c. 10 CFR Part 35, Medical Use of Byproduct Material.
- d. 10 CFR Part 61. Licensing Requirements for Land Disposal of Radioactive Waste.
- e. 21 CFR 361.1, Food and Drug Administration, Radioactive Drugs for Certain Research Use.
- f. 29 CFR 1910.1096, Occupational Safety and Health Administration, Ionizing Radiation Standards.
- g. 40 CFR Part 261, Environmental Protection Agency, Identification and Listing of Hazardous Waste.
- h. 42 CFR Part 493, Public Health (Department of Health and Human Services), Laboratory Requirements.
- i. 49 CFR Parts 107, 171 through 180, and 390 through 397, Department of Transportation), Regulation of Hazardous Materials.
- j. VHA Directive 1105. Management of Radioactive Materials, dated February 5, 2015
- k. VHA Directive 1129. Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
- l. VHA Handbook 2011-020. Automated Safety Incident Surveillance and Tracking System (ASISTS), dated April 19, 2011.
- m. VHA Handbook 1004.01 Informed Consent for Clinical Treatments and Procedures, dated August 4, 2009.
- n. VHA Handbook 1004.08, Disclosure of Adverse Events to Patients, dated October 2, 2012, or subsequent policy.
- o. VHA Handbook 1100.19, Credentialing and Privileging, dated October 15, 2012.

p. VHA Handbook 1105.04, Fluoroscopy Safety, dated July 6, 2012, or subsequent policy

q. VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research, dated November 12, 2014.

r. EPA-402-R-10003. Federal Guidance Report No. 14 “Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures”;  
<https://www.epa.gov/radiation/federal-guidance-report-no-14-radiation-protection-guidance-diagnostic-and-interventional>.

s. EPA 520/ 1-89-002, 1-89-003. A Guide for Determining Compliance with the Clean Air Act Standards for Radionuclide Emissions from NRC-Licensed and Non-DOE Federal Facilities; User’s Guide for the Comply Code;  
<https://www.epa.gov/sites/production/files/2015-05/documents/520-1-89-002.pdf>.

t. <http://nhpp.med.va.gov/Top/2VAspecific/12Procedures/SOPs/SOP5.pdf>

**NUCLEAR MEDICINE SERVICE/SECTION CHIEF REQUIREMENTS**

1. Possess a broad knowledge of clinical medicine and is preferably board certified by the American Board of Nuclear Medicine or certified in Nuclear Radiology by the American Board of Radiology.
2. As an alternative to board certification, the VA medical facility Director and Chief of Staff must ensure that any non-board certified physician, or physician not eligible for board certification, is otherwise well qualified and fully capable of providing high-quality care in the role of Service Chief or Director, NM&I. This includes understanding and training in the principles and applications of ionizing radiation to meet the requirements of 10 CFR Chapter 1; 21 CFR 361.1; 40 CFR Part 261; 10 CFR Part 61, Subpart I; EPA 520/1-89-003; and 29 CFR 1910.1096 in order to discharge those responsibilities appropriately.
3. As authorized by the NHPP, be a VHA MML permittee as a user of radioactive materials within the premises of the VA facility or VISN structure to which the license or permit has been issued.

## REGULATORY AND ACCREDITATION OVERSIGHT

- 1. NUCLEAR REGULATORY COMMISSION (NRC).** The NRC sets standards for ionizing radiation protection from NRC-licensed radioactive materials (10 CFR 20) and for medical uses of NRC-licensed radioactive materials (10 CFR 35). NRC requirements apply to the total dose to an individual from both licensed and unlicensed sources (e.g. PET/CT) that are under the control of the licensee.
- 2. ENVIRONMENTAL PROTECTION AGENCY (EPA).** Federal Guidance Report No. 14 "Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures" (EPA-402-R-10003) provides guidance for CT radiation doses.
- 3. DEPARTMENT OF TRANSPORTATION (DOT).** Arrangements for delivery of isotopes must adhere to the NRC and DOT regulatory requirements for the use of a licensed carrier, and for the inspection and radiation dosimetry upon delivery to the site of medical use.
- 4. FOOD AND DRUG ADMINISTRATION (FDA).** FDA regulates radioactive drugs used in research, as well as certain medical devices used in nuclear medicine, e.g., CT.
- 5. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION (OSHA).** Outlines the regulation for employee radiation safety through dosimetry monitoring. Standards 29 CFR 1910.1096(d)(3)(i)
- 6. DEPARTMENT OF LABOR (DOL).** The DOL is the oversight body of OSHA which administers the Occupation Safety and Health (OSH) Act.
- 7. THE JOINT COMMISSION.** The Joint Commission defines diagnostic imaging requirements for the hospital and ambulatory care programs. The requirements Appendix B address: imaging equipment testing and maintenance; annual education for staff Use as reference supporting CT and MRI services; minimum qualifications for medical physicists; managing MRI safety risks; data collection on MRI incidents and CT radiation dose data; CT protocol management and documentation of CT radiation dose.
- 8. NATIONAL HEALTH PHYSICS PROGRAM (NHPP).** See Definitions, Paragraph 3.d.
- 9. NATIONAL COUNCIL FOR RADIATION PROTECTION AND MEASUREMENTS (NCRP).** The NCRP formulates and widely disseminates information, guidance and recommendations regarding radiation risk, protection, dosimetry, and other measurement.

### PERFORMANCE IMPROVEMENT PLAN

1. Each VA medical facility with NM&I must have a performance improvement plan which provides the following:
  - a. Quality control procedures for gamma cameras and other equipment according to manufacturer's specifications and accepted standards.
  - b. Assurance of the availability and appropriateness of the requested study, and the accuracy and timeliness of nuclear medicine test results.
  - c. An evaluation of wait time metric.
  - d. Any indicator or metric that has been identified as a performance improvement need such as radiation dose.
2. The Service/Section Chief, NM&I is responsible for planning, directing, coordinating, and evaluating the nuclear medicine Performance Improvement Plan including:
  - a. Establishing, directing, and maintaining a comprehensive systematic Performance Improvement Program that follows the requirements as outlined below.
  - b. Documenting actions and defining any changes in operations that result from the Performance Improvement Program.
  - c. Enacting follow-up recommendations per the evaluation of NM&I service results for any National Performance Measures.

## USE OF CONTRACT NUCLEAR PHYSICIANS

1. **Use of Contract Physicians for Service Chief.** Contract board certified or eligible nuclear physicians or radiologists with nuclear radiology certification, or an otherwise well-qualified physician, may be retained as Chief where a nuclear medicine physician or radiologist with nuclear radiology certification cannot be successfully recruited, or where there is insufficient workload volume to warrant a full-time physician.
2. **Contract Nuclear Medicine Physicians.** All contract physicians board certified or eligible, are expected to fully participate on a prorated time basis in the institution's educational programs and requirements, performance improvement, patient safety programs, and other responsibilities as assigned.

## ALLIED HEALTH STAFF

Nuclear technical staff, nuclear pharmacists, nurses, physicists, exercise physiologists and radiation safety staff may be assigned to NM&I. This ancillary staff provides services, consultation, and direction on technical, pharmacological, patient care, and radiation safety aspects respectively according to local VHA policies, directives, handbooks, and the prescriptions of relevant regulatory and accrediting agencies. **NOTE:** *VHA qualification standards apply to the hiring and retention of nuclear technical staff.*

1. **Contract Allied Health Staff.** Contract nuclear technical and radiation safety staff are expected to meet VHA's existing qualification standards, position descriptions, and responsibilities for the role they are occupying, including the proscriptions of the regulatory and accrediting bodies.
2. **Clerical and Support Staff.** Clerical and support staff who receive patients, arrange appointments, follow-up on patients' missed appointments, etc., must be defined by local policy, as necessary for operation of the unit.