

NUCLEAR MEDICINE SERVICE

1. SUMMARY OF MAJOR CHANGES: Major changes are as follows:

a. Paragraph 2: Adds responsibilities for the Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer; Assistant Under Secretary for Health for Patient Care Services/Chief Nursing Officer; Executive Director, National Radiology Program; Executive Director, National Health Physics Program (NHPP); Chair, Institutional Review Board; Department of Veterans Affairs (VA) medical facility Chief of Staff; VA medical facility Associate Director of Patient Care Services; VA medical facility Chief, Healthcare Technology Management; VA medical facility Authorized User; VA medical facility Nuclear Medicine Chief or Lead Technologist; VA medical facility Nuclear Medicine Technologist; and VA medical facility Nuclear Medicine Administrative Officer or Health System Specialist.

b. Paragraph 4: Adds training requirements for all staff whose responsibilities require regular activities within the Nuclear Medicine department and are on the dosimetry program.

c. Converts former supplementary paragraphs and Appendices A-E into the following standard operating procedures (SOPs) on the National Radiology Program SharePoint site:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(1) SOP 1105.02-01: Nuclear Medicine Service/Section Chief Requirements.

(2) SOP 1105.02-02: Regulatory and Accreditation Oversight.

(3) SOP 1105.02-03: Quality Assurance and Improvement Plans.

(4) SOP 1105.02-04: Use of Contract Nuclear Medicine Physicians and Allied Health Staff.

(5) SOP 1105.02-05: Patient Education Regarding Use of Radioactivity in VHA.

(6) SOP 1105.02-06: Off Label Use of Marketed Drugs and Radiopharmaceuticals in VHA.

d. Converts VHA Directive 1187, Administrative Practices for Ensuring Safe Injection of Radio-Labeled Products, dated April 2, 2018, into the following new SOP and rescinds VHA Directive 1187: SOP 1105.02-07: Administrative Practices for Ensuring Safe Injection of Radio-Labeled Blood Products.

e. Creates new SOP 1105.02-08: Management of Extravasation of Radiopharmaceuticals.

2. RELATED ISSUES: VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021; VHA Directive 1105.04, Fluoroscopy Safety, dated June 21, 2018; VHA Directive 1129, Radioactive Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015; VHA Directive 1129.01, Mandatory Reporting of Misadministrations by Therapy Machine Sources of Ionizing Radiation, dated March 21, 2019; and VHA Directive 1050.01(1), VHA Quality and Patient Safety Program, dated March 24, 2023.

3. POLICY OWNER: The Executive Director, National Radiology Program (11DIAG1) and the Executive Director, National Nuclear Medicine and Radiation Safety Program Office (11DIAG3) are responsible for the contents of this directive. Questions may be referred to VHARadiologyProgramOffice@va.gov.

4. LOCAL DOCUMENT REQUIREMENTS: VA medical facilities are required to develop and maintain:

a. Radiation safety SOPs in accordance with this directive; 10 C.F.R. Parts 19, 20, 30, 35, and 71; and the VA medical facility's RAM permit issued by NHPP (see paragraph 2.i.(2)).

b. Written SOPs for the Nuclear Medicine service or section in accordance with the administrative and clinical requirements of this directive, including SOPs for managing consumer (patient) complaints, infection control, quality control and assurance, enhancing quality metrics, results communication and examination of protocols (see paragraph 2.n.(5)).

c. Technical SOPs to ensure patient safety, in particular to verify the patient's identity prior to the start of each procedure (see paragraph 2.r.(3)).

5. RESCISSIONS: VHA Directive 1105.02, Nuclear Medicine and Radiation Safety Administrative Service, dated August 29, 2018, and VHA Directive 1187, Administrative Practices for Ensuring Safe Injection of Radio-Labeled Blood Products, dated April 2, 2018, are rescinded.

6. RECERTIFICATION: This Veterans Health Administration (VHA) directive is scheduled for recertification on or before the last working day of July 2029. This VHA directive will continue to serve as national VHA policy until it is recertified or rescinded.

7. IMPLEMENTATION SCHEDULE: This directive is effective 3 months after the publication date.

July 18, 2024

VHA DIRECTIVE 1105.02

**BY DIRECTION OF THE OFFICE OF THE
UNDER SECRETARY FOR HEALTH:**

/s/ Erica M. Scavella M.D., FACP, FACHE
Assistant Under Secretary for Health
for Clinical Services and Chief Medical
Officer

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

DISTRIBUTION: Emailed to the VHA Publications Distribution List on July 22, 2024.

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NUCLEAR MEDICINE SERVICE

1. POLICY

It is Veterans Health Administration (VHA) policy that all Department of Veterans Affairs (VA) medical facilities that provide Nuclear Medicine services create a culture of safety and maintain a safe environment for VA staff and patients in accordance with all applicable Federal regulatory standards, including requirements for the initiation, maintenance, and regulation of VHA Nuclear Medicine and related Radiation Safety operations. **AUTHORITY:** 38 U.S.C. § 7301(b).

2. RESPONSIBILITIES

a. **Under Secretary for Health.** The Under Secretary for Health is responsible for ensuring overall VHA compliance with this directive.

b. **Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer.** The Assistant Under Secretary for Health for Clinical Services/Chief Medical Officer is responsible for supporting the VHA National Radiology Program (NRP) and the VHA National Nuclear Medicine Program (NMP) with implementation and oversight of this directive.

c. **Assistant Under Secretary for Health for Operations.** The Assistant Under Secretary for Health for Operations is responsible for:

(1) Communicating the contents of this directive to each of the Veterans Integrated Service Networks (VISNs).

(2) Assisting VISN Directors to resolve implementation and compliance challenges in all VA medical facilities within that VISN.

(3) Providing oversight of VISNs to ensure compliance with this directive and its effectiveness.

(4) Reviewing the annual summary report from the Chair, National Radiation Safety Committee (NRSC), which includes a review of any identified safety or compliance issues.

d. **Executive Director, National Radiology Program.** The Executive Director, NRP is responsible for:

(1) Coordinating with the Executive Director, NMP and VA medical facility Director to approve and facilitate on-site or virtual VA medical facility Nuclear Medicine program reviews as appropriate to address quality, safety or regulatory concerns, or as part of a routine audit.

(2) Suspending operations of sites that do not meet the standards of 10 C.F.R. Parts 20 and 35, or programs that have demonstrated ongoing or uncorrected deficiencies, safety, or quality concerns.

e. **Executive Director, National Nuclear Medicine Program.** The Executive Director, NMP is responsible for:

(1) Providing oversight of VA medical facility Nuclear Medicine programs to ensure quality, safety, and compliance with this directive.

(2) Updating this directive and the standard operating procedures (SOPs) as needed based upon best practices and care standards in Nuclear Medicine and Radiation Safety.

(3) Coordinating with the Executive Director, NRP and VA medical facility Director to approve and facilitate on-site or virtual VA medical facility Nuclear Medicine program reviews as appropriate to address quality, safety or regulatory concerns, or as part of a routine audit.

(4) In collaboration with the Executive Director, National Health Physics Program (NHPP), as appropriate, recommending to the Executive Director, NRP suspension of operations of sites that do not meet the standards of 10 C.F.R. Parts 20 and 35, or programs that have demonstrated ongoing or uncorrected deficiencies, safety, or quality concerns.

(5) Providing feedback to the VISN Diagnostic Integrated Clinical Community Lead and VISN leadership as needed regarding compliance, safety, quality, and access for Nuclear Medicine services.

f. **Executive Director, National Health Physics Program.** The Executive Director, NHPP is responsible for:

(1) Overseeing and authorizing the use of radioactive materials within VHA in agreement with the Nuclear Regulatory Commission (NRC) through the administration of VA's Master Materials License (MML). This includes granting radioactive materials (RAM) permits to VA medical facilities with Nuclear Medicine programs for use of radioactive materials, including inspections and enforcement, in accordance with VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021.

(2) Approving Authorized Users (AUs) as submitted by the VA medical facility Director for VA medical facilities with limited scope RAM permits.

(3) In collaboration with the Executive Director, NMP, as appropriate, recommending to the Executive Director, NRP suspension of operations of sites that do not meet the standards of 10 C.F.R. Parts 20 and 35, or programs that have demonstrated ongoing or uncorrected deficiencies, safety, or quality concerns.

(4) Notifying VA medical facilities holding RAM permits regarding changes to Federal regulations and other guidance related to Nuclear Medicine and Radiation Safety. Changes affecting the practice of Nuclear Medicine must be communicated through email to the appropriate stakeholders.

g. **Chair, National Radiation Safety Committee.** The Chair, NRSC is responsible for ensuring that the NRSC conducts its duties as required by VHA Directive 1105 and VHA Directive 1129, Radioactive Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015. For the purposes of this directive, the Chair, NRSC is responsible for:

(1) Overseeing the use and administration of radioactive materials across VHA to ensure radiation safety, in accordance with VHA Directive 1105.

(2) Submitting an annual summary report to the Assistant Under Secretary for Health for Operations for review, which includes a review of any identified safety or compliance issues.

h. **Veterans Integrated Service Network Director.** The VISN Director is responsible for:

(1) Ensuring that all VA medical facilities within the VISN comply with this directive and informing leadership when barriers to compliance are identified.

(2) Providing adequate resources to ensure implementation of this directive across VA medical facilities within the VISN.

i. **VA Medical Facility Director.** The VA medical facility Director is responsible for:

(1) Ensuring VA medical facility compliance with this directive and that appropriate corrective action is taken if non-compliance is identified.

(2) Ensuring adequate resources for VA medical facility Nuclear Medicine programs, including space, equipment, and staffing, particularly VA medical facility AU, VA medical facility Nuclear Medicine Technologists, nurses, and support staff as needed to provide high-quality imaging and therapeutic Nuclear Medicine services. **NOTE:** For information regarding the Use of Contract Nuclear Medicine Physicians and Allied Health Staff, see SOP 1105.02-04 at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. This is an internal VA website that is not available to the public.

(3) Coordinating with the Executive Director, NMP and Executive Director, NRP to facilitate onsite or virtual VA medical facility Nuclear Medicine program reviews to address quality, safety, or regulatory concerns or as part of a routine audit. **NOTE:** For information regarding Regulatory and Accreditation Oversight, see SOP 1105.02-02 at: <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA->

[Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx](#). This is an internal VA website that is not available to the public.

(4) If the VA medical facility holds a RAM permit of limited scope, reviewing recommendations for proposed AUs from the VA medical facility Chair, RSC and submitting to the Executive Director, NHPP for approval.

(5) Overseeing the VA medical facility Nuclear Medicine, Imaging, or Radiology Service or Section Chief in overall implementation of precautions for Nuclear Medicine procedures, described in SOP 1105.02-07 at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>, in which blood is drawn from a patient, components are labeled with a radionuclide, and the labeled blood product is reinjected in that patient. **NOTE:** This is an internal VA website that is not available to the public.

j. **VA Medical Facility Chief of Staff.** The VA medical facility Chief of Staff is responsible for providing oversight of VA medical facility Nuclear Medicine, Imaging or Radiology Service or Section Chief compliance with this directive.

k. **VA Medical Facility Associate Director of Patient Care Services.** The VA medical facility Associate Director of Patient Care Services is responsible for supporting the VA medical facility Nuclear Medicine, Imaging, or Radiology service or section in fulfillment of the requirements of this directive.

l. **VA Medical Facility Radiation Safety Officer.** **NOTE:** The responsibilities of the VA medical facility's Radiation Safety Officer (RSO) are primarily assigned, for radioactive materials, in VHA Directive 1105 and, for machine produced ionizing radiation, in VHA Directive 1129, VHA Directive 1105.04, Fluoroscopy Safety, dated June 21, 2018, and VHA Directive 1129.01, Mandatory Reporting of Misadministrations by Therapy Machine Sources of Ionizing Radiation, dated March 21, 2019. For the purposes of this directive, the VA medical facility RSO is responsible for:

(1) Ensuring compliance with this directive, the VA medical facility RAM permit, and 10 C.F.R. Parts 19, 20, 30, 35, and 71.

(2) Establishing and implementing radiation safety SOP(s) in accordance with this directive; 10 C.F.R. Parts 19, 20, 30, 35, and 71; and the VA medical facility's RAM permit issued by NHPP.

(3) Providing assistance to the VA medical facility Nuclear Medicine, Imaging, or Radiology Service or Section Chief in matters related to radiation safety of patients and personnel, including addressing medical events, any events involving unanticipated exposure of radiation to a patient or staff member, and other adverse incidents involving radioactive material and ionizing radiation.

(4) Working with the VA medical facility Patient Safety Manager and Nuclear Medicine, Imaging, or Radiology Service or Section Chief in the investigation of

identified patient safety events or near misses in alignment with VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.

m. **Chair, VA Medical Facility Radiation Safety Committee.** *NOTE: The responsibilities of the VA medical facility RSC are primarily assigned, for radioactive materials, in VHA Directive 1105 and, for machine produced ionizing radiation, in VHA Directive 1129, VHA Directive 1105.04, and VHA Directive 1129.01. The Chair, VA medical facility RSC is responsible for ensuring that the RSC performs the following functions:*

(1) Providing safety oversight of the VA medical facility Nuclear Medicine program, including any safety events or issues with compliance in the use and administration of radiopharmaceuticals.

(2) Reviewing requests for proposed VA medical facility AUs. If the VA medical facility holds a permit of broad scope, the VA medical facility RSC must approve or disapprove the request. If the VA medical facility holds a permit of limited scope, then the VA medical facility RSC must forward the recommendation to the VA medical facility Director for submission to the Executive Director, NHPP for approval.

(3) Reviewing and approving or disapproving Institutional Review Board (IRB) proposals involving use of radiopharmaceuticals.

(4) Monitoring compliance with SOP 1105.02-07 at:
<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. *NOTE: This is an internal VA website that is not available to the public.*

n. **VA Medical Facility Nuclear Medicine, Imaging or Radiology Service or Section Chief.** *NOTE: For Nuclear Medicine Service/Section Chief Requirements, see SOP 1105.02-01 at:*
<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. *This is an internal VA website that is not available to the public.* Depending on the VA medical facility structure, the VA medical facility Nuclear Medicine, Imaging or Radiology Service or Section Chief is responsible for:

(1) Overseeing the VA medical facility Nuclear Medicine program conduct in compliance with 10 C.F.R Parts 19, 20, 30, 35, and 71.

(2) Managing Nuclear Medicine infrastructure, including space planning, equipment life-cycle management (in collaboration with the VA medical facility Chief, Healthcare Technology Management (HTM) and VA medical facility Nuclear Medicine Chief or Lead Technologist), conducting market research, and participating on technical panels for capital equipment selection.

(3) Taking necessary action to address known Nuclear Medicine-related equipment failures (in collaboration with the VA medical facility Chief, HTM and the VA medical

facility Nuclear Medicine Chief or Lead Technologist) or commercially prepared radiopharmaceutical concerns that pose dangers to patients, including ensuring that the VA medical facility RSO and Patient Safety Manager are notified, and disseminating patient safety information based upon the nature and urgency of the event.

(4) Recommending appropriate staffing of sub-sections of Nuclear Medicine to the VA medical facility Director, such as the Nuclear Cardiac Stress Lab, Nuclear Medicine Therapy Infusion Facility and Nuclear Medicine Radiopharmacy, as well as considerations for both outpatient and inpatient care settings with related access needs, as applicable.

(5) Ensuring that the Nuclear Medicine service or section has written SOPs in accordance with the administrative and clinical requirements of this directive, including SOPs for managing consumer (patient) complaints, infection control, quality control and assurance, enhancing quality metrics, results communication, and examination of protocols. The SOPs must be current, reflect actual practice and be readily available to program staff.

(6) Establishing, directing and maintaining a comprehensive, systematic Quality Assurance (QA)/Performance Monitoring and Improvement Program that follows the requirements provided in SOP 1105.02-03, Quality Assurance and Improvement Plans, at: <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>, and documenting actions and defining any changes in operations that result from the QA/Performance Improvement Program. **NOTE:** *This is an internal VA website that is not available to the public.*

(7) Ensuring that performance on QA measures is reported to the appropriate radiology and VA medical facility-level quality improvement committees.

(8) Appointing a Nuclear Medicine Chief or Lead Technologist for the service or section who reports to the VA medical facility Nuclear Medicine, Imaging or Radiology Service Chief or Section Chief and oversees technical operations.

(9) Appointing an Administrative Officer (AO) or Health Systems Specialist (HSS) for the Nuclear Medicine service or section, developing a functional alternative within available staffing or working with available AO or HSS support within a larger or umbrella Imaging Service line to ensure administrative operations are appropriately performed.

(10) Facilitating Nuclear Medicine research when applicable, including participation in collaborative VA trials.

(11) Ensuring all therapeutic extravasations are reviewed and reported according to SOP 1105.02-08: Management of Extravasation of Radiopharmaceuticals at: <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

(12) Ensuring staff appropriately utilize radiation dose monitoring devices.

(13) Ensuring that precautions, described in SOP 1105.02-07 at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>, are implemented within their service or section for Nuclear Medicine procedures in which blood is drawn from a patient, components are labeled with a radionuclide, and the labeled blood product is reinjected in that patient. **NOTE:** *This is an internal VA website that is not available to the public. This SOP requires, when the blood is drawn from the patient and again when the labeled blood product is reinjected into the patient, verification by two clinical staff members of the patient's identity using at least two identifiers, and that these identifiers match the identifiers listed on the vial or syringe of blood or labeled blood product. Two-person checks are also required during the radiolabeling process. These requirements apply when the radiolabeling is performed at a VA medical facility and at a commercial radiopharmacy.*

(14) Appointing a Nuclear Medicine AU physician to serve as a member of the VA medical facility RSC. **NOTE:** *The VA medical facility Nuclear Medicine, Imaging or Radiology Service or Section Chief can also serve in this capacity. It is strongly recommended that the Nuclear Medicine Chief Technologist or Lead Technologist be appointed to the RSC.*

(15) Ensuring that procedures are in place to optimize radiation doses to patients from Computerized Tomography (CT) imaging and that periodic review of CT protocols are performed in accordance with VHA Directive 1129.

(16) Ensuring any event involving unanticipated exposure of radiation to a patient or staff member is reported to the VA medical facility RSO.

(17) Ensuring that any medical events, as defined by 10 C.F.R. § 35.3045, are reported promptly to the VA medical facility RSO. Such medical events must also be reported using the VA medical facility's patient event reporting mechanism, such as the Joint Patient Safety Reporting System (JPSR), within 24 hours.

(18) Working with the VA medical facility RSO and Patient Safety Manager in the investigation of identified patient safety events or near misses in alignment with VHA Directive 1050.01(1).

(19) Sending requests for proposed VA medical facility AUs to the VA medical facility RSC for review.

o. VA Medical Facility Chief, Healthcare Technology Management. The VA medical facility Chief, HTM is responsible for:

(1) Collaborating with the VA medical facility Nuclear Medicine, Imaging, or Radiology Service or Section Chief and Nuclear Medicine Chief or Lead Technologist on the procurement and life-cycle management of nuclear medicine equipment,

including conducting market research and participating on technical panels for capital equipment selection.

(2) Collaborating with the VA medical facility Nuclear Medicine, Imaging, or Radiology Service or Section Chief and Nuclear Medicine Chief or Lead Technologist to take necessary action to address known Nuclear Medicine-related equipment failures or commercially prepared radiopharmaceutical concerns that pose dangers to patients, including ensuring that the VA medical facility RSO and Patient Safety Manager are notified, and disseminating patient safety information based upon the nature and urgency of the event.

(3) Managing the contract for preventive maintenance.

(4) Assessing, or working with the vendor to assess, all imaging equipment after installation, annually, and any major repairs that may affect image quality or patient exposure.

(5) Ensuring proper procedures for disposal and removal of equipment at the end of its life.

p. **VA Medical Facility Patient Safety Manager.** The VA medical facility Patient Safety Manager is responsible for working with the VA medical facility RSO and Nuclear Medicine, Imaging, or Radiology Service or Section Chief in the investigation of identified patient safety events or near misses in alignment with VHA Directive 1050.01(1).

q. **VA Medical Facility Authorized User.** A VA medical facility Nuclear Medicine Physician, Radiologist, or other physician named as an AU is responsible for:

(1) Ensuring that radioactive materials are handled and used safely in accordance with NRC regulations, VHA Directive 1105, and the terms and conditions of the VA medical facility RAM permit.

(2) Evaluating medical necessity to ensure that a patient who has been referred for care receives the appropriate nuclear procedure, and providing consultation to the clinical referring physician regarding appropriateness of care. **NOTE:** *For information regarding Patient Education Regarding Use of Radioactivity in VHA, see SOP 1105.02-05 at:*

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. This is an internal VA website that is not available to the public.

(3) Providing supervision of the use of radioactive material in accordance with 10 C.F.R. 35.27.

(4) Supervising the administration of radioactive pharmaceuticals and adjunct medications.

(5) Serving as a member of the VA medical facility RSC, as appointed by the VA medical facility Nuclear Medicine, Imaging or Radiology Service or Section Chief.

r. **VA Medical Facility Nuclear Medicine Chief Technologist or Lead Technologist.** Each VA medical facility that provides clinical Nuclear Medicine patient care must have a designated Nuclear Medicine Chief or Lead Technologist. The VA medical facility Nuclear Medicine Chief or Lead Technologist operates under the supervision of a VA medical facility AU as defined in paragraph 2.s. Depending on the VA medical facility structure, the VA medical facility Nuclear Medicine Chief or Lead Technologist, in support of the VA medical facility Nuclear Medicine, Imaging, or Radiology Service or Section Chief, is responsible for:

(1) Overseeing technical and Radiation Safety operations within Nuclear Medicine and ensuring compliance with all regulations and accrediting body guidance.

(2) Collaborating with the VA medical facility Nuclear Medicine, Imaging or Radiology Service or Section Chief and the Chief, HTM on market research, service maintenance and life-cycle management of all Nuclear Medicine equipment, and overseeing the equipment quality control program for Nuclear Medicine.

(3) Establishing and maintaining technical SOPs to ensure patient safety, in particular to verify the patient's identity by confirming at least two patient identifiers prior to the start of each procedure. For information on acceptable patient identifiers, see VHA Directive 1907.09, Identity Authentication for Health Care Services, dated June 6, 2019.

(4) Participating in the QA/Performance Monitoring and Improvement Program for monitoring the performance of imaging, non-imaging, and therapeutic procedures.

(5) Entering orders for radiopharmaceuticals for human use, under the supervision of the VA medical facility AU named on the VA medical facility RAM permit.

(6) Overseeing the radiopharmaceutical purchase orders, safe package receipt, and handling of radioactive materials within Nuclear Medicine.

(7) Overseeing equipment calibration and QA procedures set by the manufacturer.

(8) Overseeing security of radioactive materials, storage of radioactive materials, and disposal of radioactive waste.

(9) Tracking all radiopharmaceutical utilization within Nuclear Medicine through an electronic tracking system (e.g., a local SharePoint site or Commercial Off the Shelf (COTS) tracking system) and maintaining AU Written Directive records in accordance with NRC regulations and NHPP requirements. **NOTE:** For additional information, see SOP 1105.02-06: Off Label Use of Marketed Drugs and Radiopharmaceuticals in VHA, at <https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. This is an internal VA website that is not available to the public.

(10) Implementing Nuclear Medicine education and technical training programs.

(11) Supporting and collaborating with principal investigators in the conduct of approved protocols for Nuclear Medicine research programs. For additional information, see VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019.

(12) Monitoring compliance with SOP 1105.02-07 and reporting metrics for completed procedures and VA Form 10-0130, Administration of Radio-Labeled Blood Products, at each VA medical facility RSC meeting. **NOTE:** SOP 1105.02-07 can be found at:

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. This is an internal VA website that is not available to the public.

s. **VA Medical Facility Nuclear Medicine Technologist.** VA medical facility Nuclear Medicine Technologists are responsible for:

(1) Safe handling and administration of radionuclides, radiopharmaceuticals, and adjunct medications under the supervision of a VA medical facility AU.

(2) Operating radiation detectors, scanning apparatuses, and related equipment for patients having General Nuclear Medicine, Nuclear Cardiology, Positron Emission Tomography and CT (PET/CT), and PET and Magnetic Resonance Imaging (PET/MRI) exams.

(3) Performing equipment calibration and QA procedures set by the manufacturer.

t. **VA Medical Facility Nuclear Medicine Administrative Officer or Health Systems Specialist.** **NOTE:** In lieu of a dedicated VA medical facility AO or HSS, the VA medical facility may utilize alternative staffing when available or work with available AO or HSS support within a larger or umbrella Imaging service line. The VA medical facility Nuclear Medicine AO or HSS is responsible for overseeing administrative operations for the VA medical facility Nuclear Medicine service or section, including orders management, access tracking and resource utilization, strategic and business planning, cost-benefit analysis for lease vs. own and community care vs. within VHA, Contracting Officer's Representative function, radiopharmaceutical supply invoice management, overall program development, and supervising administrative staff when assigned.

3. REGULATORY REQUIREMENTS

a. Within VHA, all Nuclear Medicine services or sections must meet the requirements of The Joint Commission, NRC, Food and Drug Administration, the Occupational Safety and Health Administration (OSHA), Department of Transportation, and NHPP.

b. When regulations of various agencies are in conflict, the most restrictive regulation must apply, as determined by the Executive Director, NMP in consultation with the Executive Director, NHPP.

c. Federal regulations and guidance related to Nuclear Medicine and Radiation Safety may be modified over time, affecting the requirements presented in this directive. In such cases, NHPP must notify stakeholders of these changes. Changes affecting the practice of Nuclear Medicine must be communicated to the appropriate stakeholders and be posted on the VHA Nuclear Medicine and Radiation Safety Service SharePoint site at

<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NNMP/SitePages/Home.aspx>. **NOTE:** This is an internal VA website that is not available to the public.

4. TRAINING

Initial and annual radiation safety training is required for all staff (does not include health professions trainees (HPTs)) whose responsibilities require regular activities within the Nuclear Medicine department and are on the dosimetry program. Training is provided by the VA medical facility and must also satisfy the requirements of 10 C.F.R. §§ 19.12 and 35.27. It is the responsibility of the VA medical facility RSO to ensure that appropriate radiation safety training takes place in a timely manner (see VHA Directive 1105 for additional details).

5. RECORDS MANAGEMENT

a. All records regardless of format (for example, paper, electronic, electronic systems) required by this directive must be managed as required by the National Archives and Records Administration (NARA) approved records schedules found in VHA Records Control Schedule 10-1, unless Federal regulations by OSHA or NRC require a longer retention period. Questions regarding any aspect of records management can be addressed to the appropriate Records Officer.

b. Written Directives by a VA medical facility AU must be retained in accordance with 10 C.F.R. § 35.240.

6. DEFINITIONS

a. **Dosimetry.** Dosimetry is the science by which the absorbed radiation dose to personnel or a patient is measured and calculated. This is tracked routinely for staff and can be assessed for target and non-target dose limiting tissues in patients undergoing radiation-based therapy.

b. **Electronic Health Record.** EHR is the digital collection of patient health information resulting from clinical patient care, medical testing and other care-related activities. Authorized VA health care providers may access EHR to facilitate and document medical care. EHR comprises existing and forthcoming VA software including Computerized Patient Record System (CPRS), Veterans Information Systems and Technology Architecture (VistA), and Oracle Health platforms. **NOTE:** The purpose of

this definition is to adopt a short, general term (EHR) to use in VHA national policy in place of software-specific terms while VA transitions platforms.

c. **Medical Event.** A medical event is any incident, except for an event that results from patient intervention, in which administration of byproduct material or radiation from byproduct material to a patient or human research subject results in a reportable medical event as defined in 10 C.F.R. § 35.3045(a) or (b).

d. **Nuclear Medicine.** Nuclear Medicine is a specialty and subspecialty whose services are requested by primary and subspecialty physicians, nurse practitioners and physician assistants for the purpose of diagnosis or therapeutic Nuclear Medicine intervention. Radionuclides, either alone or bound to compounds (biological and other) with known metabolism/binding (i.e., distribution and clearance) are administered either orally, by inhalation, intravenously or, in selected instances, by direct injection (intraperitoneal, intrathecal, intra-arterial, intracystic, intradermal or other) to obtain diagnostic evaluations/treatment of pathophysiologic conditions, or as a means to assess the success of, or guide, other therapeutic interventions. The Nuclear Medicine specialty is comprised of General Nuclear Medicine, Nuclear Cardiology, Nuclear Oncology/Theranostics, Molecular Imaging with PET/CT, PET/MRI, and in some instances may include Bone Densitometry.

7. REFERENCES

- a. 38 U.S.C. § 7301(b).
- b. 10 C.F.R. Parts 20, 30, 35, and 71.
- c. VHA Directive 1050.01(1), VHA Quality and Patient Safety Programs, dated March 24, 2023.
- d. VHA Directive 1105, Management of Radioactive Materials, dated February 24, 2021.
- e. VHA Directive 1105.04, Fluoroscopy Safety, dated June 21, 2018.
- f. VHA Directive 1129, Radiation Protection for Machine Sources of Ionizing Radiation, dated February 5, 2015.
- g. VHA Directive 1129.01, Mandatory Reporting of Misadministrations by Therapy Machine Sources of Ionizing Radiation, dated March 21, 2019.
- h. VHA Directive 1200.08(1), Safety of Personnel and Security of Laboratories Involved in VA Research, dated April 24, 2019.
- i. VHA Directive 1907.09, Identity Authentication for Health Care Services, dated June 6, 2019.
- j. VA Form 10-0130, Administration of Radio-Labeled Blood Products.

k. National Radiology Program SharePoint site:
<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NRP2/SitePages/VHA-Directive-1105.02-Nuclear-Medicine-and-Radiation-Safety-Services.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*

l. Nuclear Medicine and Radiation Safety Service SharePoint site:
<https://dvagov.sharepoint.com/sites/VHADiagnosticservices/NNMP/SitePages/Home.aspx>. **NOTE:** *This is an internal VA website that is not available to the public.*