NUCLEAR MEDICINE AND RADIATION SAFETY SERVICE

1. REASON FOR ISSUE. This Veteran Health Administration (VHA) Handbook provides procedures for the administrative structure and management of services and service lines providing Nuclear Medicine in the Department of Veteran Affairs (VA) facilities. This Handbook also defines requirements unique to VA.

2. SUMMARY OF MAJOR CHANGES. This revised Handbook describes the administration and functioning of VA-operated Nuclear Medicine laboratories; staffing qualifications and activities; productivity or prediction of the technical staffing algorithm; creation, maintenance, accreditation, or regulation of safe radiation environments; effective communication regarding radioactivity; relevant committee functions; and performance improvement measures and mandates. The research component has been deleted from this Handbook as other Directives outline the requirements for all research activities.

3. RELATED ISSUES. VHA Handbook 1105.01, VHA Handbook 1051.01, VHA Handbook 1004.01, and VA Handbook 7128. ***NOTE:*** *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 Handbook. In such cases, stakeholders will be notified of these changes, which will be posted on the Nuclear Medicine and Radiation Safety Service internal VA Web site (not available to the public)* *http://vaww.patientcare.va.gov/NuclearMedicine/Nuclear_Medicine_Radiation_Safety_Services.asp* . *Revisions will be made to this Handbook to reflect these changes when the Handbook is revised.*

4. RESPONSIBLE OFFICE. The Office of Patient Care Services, Diagnostic Service (115) is responsible for this Handbook. Questions may be addressed to 734-845-5027

5. RESCISSIONS. VHA Handbook 1105.2, dated February 15, 2002, is rescinded.

6. RECERTIFICATION. This VHA Handbook is scheduled for recertification on or before the last working day of December 2015.

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NUCLEAR MEDICINE AND RADIATION SAFETY SERVICE

1. PURPOSE

This Veterans Health Administration (VHA) Handbook is issued to provide direction for the creation, maintenance, and accreditation and regulation of safe radiation environments; staffing qualifications and activities; technical staffing productivity and prediction algorithm; 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 the Department of Veterans Affairs (VA) facilities or those managed by VHA facilities.

2. BACKGROUND

a. In 1988, Congress passed the Clinical Laboratory Improvement Act (CLIA-88) as part of the Public Health Services Act (Title 42 United States Code (U.S.C.) 263a). This amendment codified into law the requirements for staffing, management, procedures, and oversight of United States (U.S.) laboratories that perform testing used in the diagnosis and treatment of patients. The Department of Health and Human Services (HHS) then published implementing regulations for CLIA-88, Title 42 Code of Federal Regulations (CFR) Part 493. In 1992, Congress passed Public Law (Pub. L.) 102-139 Section10 (a), which exempted VHA from CLIA-88 and stated that the Secretary of Veterans Affairs would, in consultation with Secretary of HHS, publish regulations that would "establish standards equal to that applicable to other medical facilities laboratories in accordance with the requirements of section 353 (f) of the Public Health Services Act." ***NOTE:*** *This requires VHA laboratories, including Nuclear Medicine laboratories, to meet the requirements of CLIA-88. The CLIA-88 regulations (42 CFR Part 493) have been and continue to be modified over time. Rather than revising and publishing VA regulations so that they are consistent with 42 CFR Part 493, this Handbook replaces VA regulations by requiring compliance with 42 CFR Part 493.*

b. Within VA, all laboratory testing utilized for the diagnosis and treatment of patients must meet the requirements of 42 CFR Part 493, (CLIA-88). Laboratory testing, where applicable, must meet the requirements of the following organizations: The Joint Commission (TJC), College of American Pathologists (CAP), Food and Drug Administration (FDA), Occupational Health and Safety Administration (OSHA), and the Nuclear Regulatory Commission (NRC). All laboratory testing, regardless of location, undergoes an on-site inspection to assess whether or not the laboratory is meeting all the requirements of 42 CFR Part 493. The accrediting agency performing the inspection must have deemed status from the Centers for Medicare and Medicaid Services (CMS).

3. DEFINITIONS

a. **Nuclear Medicine.** Nuclear medicine is a referral medical specialty whose services are requested by primary and subspecialty physicians, nurse practitioners, and physician assistants. 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.

(1) Radionuclide therapy can be performed in selected diseases (hyperthyroidism, thyroid cancer, metastatic skeletal cancer (to bone), lymphoma, etc.) with high doses of selected radioisotopes or radio-labeled compounds.

(2) Nuclear medicine evaluations require a wide range of services, encompassing patient consultation and examination, interpretation of images, correlation with other diagnostic methods, the determination of the metabolic functions, body constituents, drug levels, and recommendations to the significance of the findings.

b. **Imaging Data.** Imaging data produced by gamma cameras can be planar with two dimensional data obtained from images obtained over selected areas of interest.

(1) Single photon emission computed tomography (SPECT) imaging systems are 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).

(2) Positron Emission Tomography (PET) imaging systems are used to image annihilation photons released in the decay of positron-emitting radionuclides. Positron emitters can be imaged with cameras specifically designed to perform PET; the short physical half-life of some of the positron emitting radionuclides may require that the source of production, typically a cyclotron, be in close proximity of the imaging facilities.

(3) Combined PET and Computerized Tomography (CT) are both standard imaging tools that allow physicians to pinpoint the location of cancer within the body before making treatment recommendations. The highly sensitive PET scan detects the metabolic signal of actively growing cancer cells in the body and the CT scan provides a detailed picture of the internal anatomy that reveals the location, size, and shape of abnormal cancerous growths. Alone, each imaging test has particular benefits and limitations, but when the results of PET and CT scans are fused, the combined image provides complete information on cancer location and metabolism. Both scans, PET and CT, are done sequentially, with the CT 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-life can markedly decrease radiation exposure, and that the potential for high spatial resolution (5 to 10 millimeter (mm)) images and their use in labeling a broad spectrum of biological compounds can be used in medical diagnosis.

c. **Incident.** An incident is defined as “any instance that causes or has the potential to cause harm to a beneficiary.” An adverse reaction to a radioisotope, or radiopharmaceutical, is an example of an incident for which VA form 10-2633, Report of Special Incident Involving a

Beneficiary, must be made. The terminology "incident" is also used for medical events and other circumstances that must be reported to NRC under 10 CFR Part 20.

d. **Medical Event.** Any event, except for an event that results from patient intervention, in which the administration of byproduct material or radiation from byproduct material results in:

(1) A dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 0.05 Sieverts (Sv) (5 rem) ***Note:*** *Rem is a unit of radiation dosage (such as from X rays) applied to humans. Derived from the phrase roentgen equivalent man, the rem is now defined as the dosage in Radiation Absorbed Dose (rads) that will cause the same amount of biological injury as one rad of X rays or gamma rays)* effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin; and

(a) The total dose delivered differs from the prescribed dose by 20 percent or more;

(b) The total dosage delivered differs from the prescribed dosage by 20 percent or more or falls outside the prescribed dosage range; or

(c) The fractionated dose delivered differs from the prescribed dose, for a single fraction, by 50 percent or more.

(2) A dose that exceeds 0.05 Sv (5 rem) effective dose equivalent, 0.5 Sv (50 rem) to an organ or tissue, or 0.5 Sv (50 rem) shallow dose equivalent to the skin from any of the following:

(a) An administration of a wrong radioactive drug containing byproduct material;

(b) An administration of a radioactive drug containing byproduct material by the wrong route of administration;

(c) An administration of a dose or dosage to the wrong individual or human research subject;

(d) An administration of a dose or dosage delivered by the wrong mode of treatment; or

(e) A leaking sealed source.

(3) A dose to the skin or an organ or tissue other than the treatment site that exceeds by 0.5 Sv (50 rem) to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive (excluding, for permanent implants, seeds that were implanted in the correct site but migrated outside the treatment site).

e. **National Health Physics Program (NHPP).** The NHPP directs the day-to-day implementation of the Master Materials License (MML) and coordinates activities of the National Radiation Safety Committee (NRSC).

4. REGULATORY AND ACCREDITING BODIES

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. These agencies include:

a. NRC.

b. Environmental Protection Agency (EPA).

c. Department of Transportation (DOT).

d. FDA.

e. OSHA.

f. Department of Labor (DOL).

g. TJC.

h. CAP.

i. NRSC.

j. National Health Physics Program (NHPP) (see subpar. 3d).

k. Society of Nuclear Medicine (SNM).

l. National Council for Radiation Protection and Measurements (NCRP).

5. ACCESS

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

6 STRUCTURE

Nuclear Medicine services may be organized in a variety of forms at the discretion of the facility Director or Veterans Integrated Service Network (VISN) Director. It can be either an autonomous medical entity or combined with other medical services to create imaging, diagnostic services, or other named entities.

7. EQUIPMENT

Nuclear medicine utilizes both clinical imaging with a variety of devices (gamma cameras and SPECT, and gamma cameras capable of SPECT CT, PET imaging systems and positron PET CT), and cardiac Computed Tomography Angiography (CTA), which are designed to produce images of the in vivo distribution of administered radioactivity, and non-imaging nuclear procedures that employ in vivo, radiobioassay techniques.

a. Gamma cameras operate differently from radiographic radiation-emitting devices (e.g., plain radiographs, CT, magnetic resonance imaging (MRI), SPECT). Nuclear medicine radioactivity is administered to the patient and an imaging system maps the energy emitted from the patient to create images.

(1) The time required for the gamma camera to produce an image may be considerably longer than traditional x-ray techniques.

(2) Nuclear medicine imaging may require multiple patient positions and gamma camera exposures at different times, occasionally up to a week following the administration of radioactivity. In this regard, each imaging procedure is tailored to a specific patient and to the medical problem(s) and question(s) to be addressed.

b. External hand-held radiation detecting probes can be used to identify collections of radioactivity during surgical procedures to aid in the localization of tumors or in the identification of sentinel lymph nodes as potential sites for metastases of malignant melanoma, breast, and other cancers. With these specialized and unique characteristics of nuclear medicine imaging and the metabolic information obtained from these examinations, the volume of workload that can be produced is more limited than that of other imaging techniques.

c. Another diagnostic modality that may be used in nuclear medicine is bone densitometry, a device designed to measure body composition and the density of bone for diagnosis and following therapy for osteoporosis.

8. EQUIPMENT FAILURE OR RADIOPHARMACEUTICAL CONCERNS

In the event of known nuclear or nuclear-related equipment failures, or commercially prepared radiopharmaceutical concerns that pose dangers to patients, the facility Director must ensure all current VHA communication media is utilized in disseminating patient safety information based upon the nature and urgency of the information needing to be shared (see subpar. 12e).

9. SCOPE

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.

a. Due to the production factors employed in nuclear medicine, the Nuclear Medicine and Radiation Safety Service (NM RSS) is charged with the proper acquisition, receipt, storage, use, distribution, transport, and disposal of radioactive contaminated objects to ensure safe environments for patients, staff, and others. To ensure 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, arrangements must be made to ensure these services are performed by a demonstrably-accredited laboratory.

b. 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 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), i.e., the NRC on-site representative.

(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).

c. NM RSS professional staff are capable of offering 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 radiobioassay) having implications for patient care.

10. RESPONSIBILITIES OF THE NATIONAL RADIATION SAFETY DIRECTOR

In addition to providing national guidance to VHA's Nuclear Medicine program, the National Radiation Safety Director is responsible for oversight for the:

a. **Facility RSC.** The RSC ensures the safe use of all forms of ionizing radiation in accordance with applicable regulations (NRC, EPA, DOT, FDA, and VHA) and VHA Directive 1105.01. The RSC creates and maintains records, minutes, and files using the prescriptive guidelines established by the NRSC and NHPP.

b. **NRSC.** The NRSC, the principal VA Central Office-level organizational element to implement the MML, operates under a committee charter and delegation of authority approved by the Under Secretary for Health, and is responsible for maintaining and implementing the MML through the NHPP.

c. **Current Procedural Terminology (CPT) Code Review.** For purposes of uniformity, accuracy, and inter-institutional reliability, the products of Nuclear Medicine's service lines are categorized according to the American Medical Association's (AMA) CPT codes. VHA

employs the complexity index of each CPT code as weighted by CMS. Since CPT codes may be modified annually by the AMA, the National Radiation Safety Director reviews changes, at least annually, and provides guidance to the field regarding changes. These changes are posted on the NM RSS Web site at: http://vaww1.va.gov/nuclearmedicineservice. ***NOTE:*** *This is an internal Web site and is not available to the public.*

11. RESPONSIBILITIES OF THE VISN DIRECTOR

Each VISN Director is responsible for oversight of the CLIA-88 mandate by ensuring all laboratories and individuals performing radiobioassay used for the diagnosis of, or guiding the treatment of, patients are in compliance with the policies of 42 CFR Part 493.

12. RESPONSIBILITIES OF THE FACILTY DIRECTOR

Each facility Director is responsible for:

a. Ensuring the Service Chief or Director, Nuclear Medicine and Imaging (NM&I) possesses a broad knowledge of clinical medicine, is board certified by the American Board of Nuclear Medicine, or possesses Nuclear Radiology certification from the American Board of Radiology.

(1) The Service Chief or Director, NM&I, must be authorized by the NHPP, or be a VHA's 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.

(2) As an alternative, the 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. 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; 29 CFR 1910.1096; and 42 CFR Part 493 in order to be able to discharge those responsibilities appropriately.

b. Establishing and maintaining a comprehensive systematic Performance Improvement Program under the direction of the Service Chief or Director, NM&I, that includes:

(1) Employing quality control for gamma cameras and other equipment according to accepted standards.

(2) Publishing policies, procedures (including age-specific criteria: hearing, vision, understanding as influenced by the speed of instructions, positioning changes necessitated by aging, and those patients with special needs or disabilities), and protocols that describe operations, which provide the highest quality of nuclear imaging and radiobioassay testing.

(3) Ensuring the availability and appropriateness of the requested study, and the accuracy and timeliness of nuclear medicine test results.

(4) Recognizing the importance and varied attributes of patient satisfaction, including waiting times for an appointment and courtesy of the staff, etc.

(5) Participating in the ongoing evaluation of service results for National Performance Measures related to NM&I programs.

(6) Assessing and addressing a patient-safety focus.

(7) Providing a radiation-safe environment.

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

(9) Incorporating congressionally-mandated annual nuclear imaging and radiobioassay laboratory testing (see CLIA-88).

c. Mandating the required elements for performance improvement. Each VHA medical facility or accredited laboratory performing nuclear services with VHA patients is expected to have, as a minimum, the following elements:

(1) Quality control procedures for equipment according to manufacturers' specifications.

(2) Standardized protocols for performing each nuclear medicine imaging and therapeutic procedure.

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

(4) 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.

(5) An evaluation of patient satisfaction, including interaction (also known as "waiting time" compared to scheduled appointment time), physical comfort, and attributes of the social interaction, i.e., courtesy.

(6) An indicator that addresses effectiveness of patient education.

(7) The creation and maintenance of a safe radiation environment.

(8) A patient safety monitor, addressing "close call" or "near miss" situations and informed consent.

(9) CLIA-88-mandated imaging radiobioassay proficiency.

d. Recognizing this program as being congressionally mandated, and that this exercise is a demonstration of quality of services provided in-house, or those provided by contractual vendors.

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

f. Discussing the published productivity and prediction information with the responsible Service Chief or Director, NM&I, and acting upon the findings.

g. Ensuring management representation on the RSC, compliance with VHA Directive 1105.01, and creation and maintenance of records, minutes, and files using the prescriptive guidelines established by the NRSC and NHPP.

h. Being, or designating, the facility-level licensee or permittee.

i. Reporting to the NHPP any of the following (see VHA Directive 1105.01):

(1) Medical events (require immediate notification to the NHPP). ***NOTE:*** *Medical events also need to be reported immediately to the facility patient safety manager who is responsible for reporting to the VHA National Center for Patient Safety.*

(2) Any incident exceeding dose limits (occupational worker or member of the public).

(3) Any unauthorized disposals or missing radioactive materials.

(4) Packages containing radioactive materials being received and determined to have exceeded surface contamination limits (require immediate notification to the NHPP).

(5) Any significant radiation safety program deficiencies.

(6) When the medical center is inspected, or otherwise contacted by the NRC.

(7) When the medical center is contacted by a regulatory authority regarding the use of radioactive materials.

(8) Any incidents involving beneficiaries (VA patients or research subjects) that occur at a medical facility.

j. Investigating, promptly, any incident.

13. RESPONSIBILITIES OF THE SERVICE CHIEF, NUCLEAR MEDICINE AND IMAGING (NM&I)

The Service Chief, NM&I, is responsible for:

a. **Missions and Functions.** The Service 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.

b. **Credentialing and Privileging of Appropriate Staff.** The Service Chief, NM&I, must identify, 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.

c. **Providing Continuing Education.** The Service Chief NM&I, must provide continuing educational direction for professional and technical staff; and, in affiliated VHA facilities, must ensure that established accredited educational and training programs for medical residents, fellows, and allied health professionals are maintained.

d. **Fostering Research.** In facilities with research missions, the Service Chief, NM&I, is to encourage fostering and participation in medical and health systems research.

e. **Program Administration.** The Service Chief, NM&I, administers the facility nuclear medicine program by:

(1) Developing a business plan;

(2) Ensuring adequate staff and equitable assignments;

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

(4) Monitoring all performance improvement activities;

(5) Creating and maintaining safe radiation environments;

(6) Coordinating and overseeing support services to produce a timely quality product; and

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

f. **Providing Radiation Emergency Counsel.** The Service Chief, NM&I, is expected to provide direction and counsel locally, according to local policies, 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.*

g. **Submitting Data with Timeliness and Accuracy**. The Service Chief, NM&I is responsible for ensuring that all statistical information representing the activities of the service (CPT codes, etc.) is accurate and submitted in a timely fashion.

h. **Providing Appropriate Delegation.** The Service Chief, NM&I, need not personally perform all responsibilities. 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.*

i. **Categorizing Workload.** The Service Chief, NM&I, has the responsibility to ensure that CPT code changes, and recommendations of the Program Director, NM RSS, are communicated to the accountable support staff.

j. **Managing Data and Trend Analysis.** The Service Chief, NM&I, is responsible for:

(1) Utilizing the existing Veterans Health Information Systems and Technology Architecture (VistA) for clinical data and aggregate management information.

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

(3) Providing accurate information, reviewing the output and promptly addressing errors in the Decision Support System (DSS). As VA's major financial instrument to assess the inputs and outputs of production upon which management decisions are predicated, provision of accurate data is essential.

k. **Technical Quality Assurance Program.** The Service Chief, NM&I needs to establish a technical quality assurance program for monitoring the performance of imaging and counting equipment.

14. USE OF CONTRACT NUCLEAR PHYSICIANS

a. **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.

b. **Use of Staff Nuclear Physicians.** Physicians providing nuclear medicine care must be approved by NHPP according to 10 CFR Part 35. All contract physicians 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.

(1) Each is responsible for:

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

1. The diagnostic nuclear testing requested;

2. The clinical ramifications of the imaging findings; and

3. Therapy with unsealed radioactive sources.

(b) Providing direction in the management of radiation emergencies.

(c) 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.*

(2) They are expected to be knowledgeable and provide counsel regarding the regulatory requirements of creating and maintaining safe radiation environments.

15. 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 proscriptions of relevant regulatory and accrediting agencies. ***NOTE:*** *VHA qualification standards apply to the hiring and retention of nuclear technical staff.*

a. **Radiation Safety Officer (RSO).** 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 the immediate supervisor.

b. **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.

c. **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 and to ensure that accrediting standards are addressed.

16. RADIATION SAFETY INSPECTION AND ACCREDITATION

a. 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. These authorities grant licenses and permits for use of nuclear materials and oversee that the license or permit conditions and the regulatory proscriptions are followed. The Service Chief or Director, NM&I, has the responsibility, working with the facility RSO and the facility RSC, to monitor activity to ensure safe radiation environments (see VHA Directive 1105.01).

b. The Radiation Safety Center for Inquiry (RSCI), organizationally part of the NM RSS Office, was established to provide, as needed, routine technical assistance and education primarily using teleconference or electronic media. RSCI staff consists of facility RSOs who have:

(1) Volunteered to share their expertise;

(2) Compiled admirable "track records" in their own facility NRC inspections;

(3) Provided timely responses;

(4) Demonstrable verbal and written skills; and

(5) Made themselves available to assist with queries, provide on-site evaluation and counsel to facilities at the request of facility management, and to compile data on areas of educational need for planning general radiation safety educational programs.

17. RADIOBIOASSAY TESTING PROFICIENCY

a. Radiobioassay Service, under the oversight of the clinical laboratory, performs radiobioassay testing, including tests that involve the in-vivo administration of radioactive materials to a patient and the subsequent measurement of radioactivity in body fluids. It must meet the regulations for implementing 42 CFR, Part 493 (CLIA-88) to maintain accreditation.

b. The applicable requirements of 42 CFR Part 493 and appropriate accrediting agencies must be met when any laboratory patient care services are offered, regardless of the location of the Pathology and Laboratory Medicine Service (P&LMS). These requirements are applicable to all other elements that perform patient care tests in a VHA medical facility, regardless of the physical relationship to the main P&LMS, or the administrative service assigned to direct the personnel, research, or technical aspects of the test site.

c. All VA laboratories doing radiobioassay testing are required to be inspected by CAP as the CMS deemed body.

(1) This can be accomplished by either:

(a) Applying to CAP as an independent laboratory ***NOTE***: *This is a labor intensive process*, or

(b) Declaring the radiobioassay portion of the product line as an ancillary testing site (ATS) of the facility's main P&LMS laboratory. ***NOTE:*** *In the latter option, collaboration with the P&LMS to create policies and procedures will reduce administrative paperwork.*

(2) In either option, the radiobioassay component must be inspected by CAP on-site (see VHA Handbook 1106.01).

d. The cost of radiobioassay testing is borne by the involved facility.

18. NUCLEAR IMAGING PROFICIENCY TESTING

a. CLIA-88 requirements mandate annual testing of the nuclear imaging outputs of VHA nuclear laboratories, and those VHA facilities that use contract laboratories for their patient's nuclear imaging. To accomplish this requirement, the NM RSS contracts with the appropriate accrediting body to:

(1) Provide VA Central Office with pre-selected phantom proficiency testing materials;

(2) Address any questions from the field;

(3) Evaluate the responses and report those findings to the individual facilities; and

(4) Summarize the VHA facility results for VA Central Office, including comparing VHA outcome with those of the private health care sector.

b. VISN Directors receive the annual summary of system-wide results. Facilities that demonstrate consistent erroneous interpretations, or poor camera-quality control, are identified and receive the remedial action(s) recommended by the Program Director, NM RSS.

c. The cost for a single image proficiency test each year is assigned to VA Central Office. Those facilities that choose to expand the testing program to include more than the single annual phantom selected by VA Central Office, may do so at their own cost.

19. INADEQUATE PERFORMANCE AND NON-COMPLIANCE

a. **Non-compliant Facilities.** After several reminders, facilities that fail to participate in proficiency testing are identified by the Program Director, NM RSS Office. The appropriate VISN director is notified regarding non-participating facilities.

b. **Inadequate Performance**

(1) In order to determine if inadequate performance was related to poor performing technology, facilities that are unsuccessful on testing are contacted by the Director, NM RSS to submit various images and quality documents related to gamma camera function. If a technological problem is identified, the facility is notified to make appropriate corrections.

(2) Should the concern be with the physician's professional interpretation, a teleconference with the involved physician to determine the root cause must be completed by the Program Director, NM RSS, and suggestions offered for improvement.

(3) Poor performance by the physician interpreting results on a single phantom exercise, will be followed up according to guidelines; however, it does not constitute a competency problem. Instead, it indicates that acquisition and interpretation of images of a particular organ system needs to be reviewed. Inadequate performances are entered into a database, by provider and in the aggregate, to trend the subsequent year's performance in order to determine if poor performance is confined to a specific organ system, or if it is more generalized. In the latter

scenario, facility management would be contacted and a review by a qualified physicist, mentoring program, or a formal educational exercise would be recommended. ***NOTE:*** *Continued poor performance necessitates facility action.*

(4) The Office of the Inspector General (OIG) mandates that the Nuclear Medicine Program Office follow up on a performance that is unacceptable to determine root causes and make recommendations for any performance improvement plans. Content expert staff from the Program Office perform a focused analysis of the equipment, acquisition parameters, processing techniques, imaging data, and responses to questions concerning the case materials. An expert in content utilizes uniform criteria to assess the procedures involved in producing the images and interpretation of the scans.

(a) Once the National Program Office receives summary results data from the Society of Nuclear Medicine (SNM), individual facilities failing the exercise are contacted to resubmit results, sometimes requiring multiple imaging attempts to discern the cause(s) for failing the exercise. This is followed by subsequent analysis, trending of data, and contacts with the management of the involved facilities.

(b) Focused review determines the factors that resulted in failure to achieve acceptable performance. When important problems are identified, these issues are communicated to site facility and VISN management so that appropriate corrective actions are taken.

(5) Educational materials and "lessons learned" are posted on the NM RSS Web site at: http://vaww.va.gov/nuclearmedicineservice/ . ***NOTE:*** *This is an internal Web site and is not available to the public.*

(6) Subsequent results are monitored by the Program Office, with a goal of identifying and correcting deficiencies in a learning environment, and improving the performance of individual sites compared with national standards.

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

Patients' right to know, including understanding the dangers of radioactivity, the allowable use of radioactivity, 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 radioactivity must have expert RSOs on staff or access to them. RSOs are the staff most qualified to address concerns regarding radioactivity. The issue of timeliness is urgent to allay concerns and take appropriate action, including avoiding more widespread contamination.

a. **Routine Diagnostic Imaging.** The patient must also be given a description of any precautions that are necessary for the patient, or patient's family. Language that provides education and addresses nuclear medicine fears needs to be used when discussing issues with the patient or the patient's family.

b. **Therapeutic Intervention.** The facility RSO must be contacted by the Chief, NM&I or designee, 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.

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 (see current VHA policy for additional details about disclosure to patients). ***NOTE:*** *10 CFR Part 35 requires specific notification for patients and referring physicians if a medical event occurs.*

d. **Regarding Practice or 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. Issues of informed consent and adherence to the Federal Policy for the Protection of Human Subjects, which addresses the appropriate medical facility oversight committee, (i.e., Radiation Safety Committee, Research and Development Committee, Institutional Review Board (IRB) [formerly known as the Subcommittee on Human Studies], and the Radioactive Drug Research Committee (RDRC), etc.) are vital in these circumstances. ***NOTE:*** *VHA Handbook 1004.01; 10 CFR Parts 19, 20, 30, 33 and35; and 21 CFR Parts 50, 56, 207, 211, 310, 312, 314, and 361 provide direction.*

e. **Suspected Improper Use.** Staff suspected of improper use or activity must promptly be reported to the facility RSO.

21. "OFF LABEL USE"

a. Both FDA and NRC acknowledge that there are clinical circumstances where deviations (i.e., "off label") from approved uses of radiopharmaceuticals are necessary in the routine management of patients. 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.

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

b. 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.

(3) The proposed alternative procedure is discussed with the patient and oral informed consent is obtained.

(4) Deviations from approved uses are documented in the medical records prescription section for the radiopharmaceuticals initiated by the nuclear medicine or radiology physician. A formal description of the indication(s) for the alternate procedure; reason(s) for deviation(s); methods (preparation, dose and route of administration); description of the images; scan interpretation; and recommendations, as a result of the procedure, become part of the permanent electronic medical record of the patient.