NUCLEAR MEDICINE AND RADIATION SAFETY SERVICE GUIDANCE

1. REASON FOR ISSUE: This Veterans Health Administration (VHA) Handbook provides guidance on the administrative structure and management of services and service lines providing Nuclear Medicine in the Department of Veterans Affairs (VA) facilities and its outreach functions; defines VA requirements unique to VA.

2. SUMMARY OF MAJOR CHANGES: This is a new VHA Handbook that describes the administration and functioning of VA-operated Nuclear Medicine laboratories; staffing qualifications and activities; productivity and/or prediction of the technical staffing algorithm; creation, maintenance, accreditation and/or regulation of safe radiation environments; effective communication about radioactivity; relevant committee functions; and quality management mandates.

3. RELATED ISSUES: VHA Handbook 1105.1, VHA Handbook 1106.1, VHA Handbook 1100.19, VHA Handbook 1051, VHA Handbook 1004.1, VA Handbook 7128, and VA Handbook 7700.1.

4. REPORTS: RCS 10-0010.

5. RESPONSIBLE OFFICE: The Office of Patient Care Services (115), Diagnostic Service Strategic Healthcare Group, is responsible for the contents of this Handbook.

6. RESCISSIONS: This Handbook rescinds VHA Directive 98-019, VHA Directive 99-003, and M-2, Part XX.

7. RECERTIFICATION: This document will be recertified on or before the last working day of February 2007.

Frances M. Murphy, M.D., M.P.H.
Acting Under Secretary for Health

DISTRIBUTION: CO: E-mailed 2/19/2002
FLD: VISN, MA, DO, OC, OCRO, and 200 - E-mailed 2/19/2002

CONTENTS

NUCLEAR MEDICINE AND RADIATION SAFETY SERVICE GUIDANCE

PARAGRAPH **PAGE**

NUCLEAR MEDICINE AND RADIATION SAFETY SERVICE GUIDANCE

1. NUCLEAR MEDICINE SERVICE ADMINISTRATION

a. **Purpose.** This Veterans Health Administration (VHA) Handbook is issued to provide direction for the creation, maintenance, and accreditation and/or regulation of safe radiation environments; staffing qualifications and activities; technical staffing productivity and/or 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.

(1) **Definition.** Nuclear medicine is a referral medical specialty whose services are requested by primary and other physicians. 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 and/or physiologic or pathophysiologic conditions, or as a means to assess the success or guide other therapeutic maneuvers. Further, radionuclide therapy can be performed in selected diseases (hyperthyroidism, thyroid cancer, metastatic skeletal cancer (to bone), etc.) with high doses of selected radioisotopes and/or radio-labeled compounds. 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 referring medical physician of the metabolic functions, body constituents, drug levels, and recommendations to the significance of the findings. Nuclear medicine imaging was an early entrant in VHA's telemedicine arena and continues to expand making access to this specialty more available to veteran patients and is a readily adaptable revenue-generating source for excess capacity.

(2) **Equipment.** Nuclear medicine utilizes both clinical nuclear imaging with a variety of devices (gamma cameras and single photon emission computed tomography (SPECT) and positron emission tomography (PET) imaging systems) designed to produce images of the in vivo distribution of administered radioactivity and non-imaging nuclear procedures that employ in vitro, radiobioassay techniques. Gamma cameras operate differently from radiographic radiation-emitting devices (e.g., x-ray, Computed Tomography (CT), Magnetic Resonance Imaging (MRI)). In nuclear medicine, radioactivity is administered to the patient and an imaging system maps the energy emitted from the patient to create images. The time required for the gamma camera to produce an image may be considerably longer than traditional x-ray techniques. 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.

(a) In addition, 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.

(b) Another diagnostic modality 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.

(3) **Imaging Data.** Imaging data produced by gamma cameras can be planar with two-dimensional data obtained from images obtained over selected areas of interest. 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). PET imaging systems are used to image annihilation photons released in the decay of positron emitting radionuclides. Positrons can be imaged with cameras specifically designed or modified to perform PET; and the short physical half-life of many of the positron emitting radionuclides may require that the source of production, typically a cyclotron, to be in close proximity of the imaging facilities. The advantages of many 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.

(4) **Regulatory and Accrediting Bodies**

(a) Multiple Federal (including VHA) and state agencies, plus private accrediting bodies regulate the use of ionizing radiation. Failure to adhere to the license and/or permit specifications and regulatory proscriptions can result in the involuntary cessation of operations. These agencies include:

1. Nuclear Regulatory Commission (NRC).

2. Environmental Protection Agency (EPA).

3. Department of Transportation (DOT).

4. Food and Drug Administration (FDA).

5. Occupational Health and Safety Administration (OSHA).

6. Department of Labor (DOL).

7. Joint Commission on Accreditation of Healthcare Organizations (JCAHO).

8. College of American Pathologists (CAP).

9. Society of Nuclear Medicine (SNM).

10. National Council for Radiation Protection (NCRP).

(b) In addition to its primary functions, the Nuclear Medicine, Imaging, and Diagnostic Services (NM,I, and DS) professional staff are a knowledgeable resource for the regulations concerning the clinical and medical research uses of ionizing radiation. NM, I, and DS staff are capable of offering ad hoc counsel and education: the application of radiation safety regulations and employment of centrally directed congressionally mandated methods, as well as local quality improvement methods for nuclear laboratory testing (imaging and radiobioassay) having implications for patient care.

b. **Scope.** The scope of nuclear testing and/or services provided are appropriate for the missions and type of patient services provided at the facility and/or within the Veterans Integrated Service Network (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. Due to the production factors employed in nuclear medicine, the service is also charged with the proper acquisition, receipt, storage, use, distribution, transport and disposal of radioactivity and radioactive contaminated objects to ensure safe environments for patients, staff and others. To ensure comprehensive quality care is seamlessly delivered, if required nuclear medicine services are not available at the local VA facility or within the VISN configuration, these services will be arranged to be performed by a demonstrably accredited laboratory.

c. **Organization**

(1) **Access.** All 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.

(2) **Structure.** 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, diagnostic services, or other named entities.

d. **Functions of Chief or Director, Nuclear Medicine Service Product Lines**

(1) **Missions and Functions.** The Service Chief or Director, Nuclear Medicine, Imaging, and Diagnostic Services (NM, I, and DS) 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 the VISN. The many and diverse functions of this position encompass aspects of patient care, administration, education, research, and counsel during radiation emergencies.

(2) **Credentialing and Privileging.** The Service Chief or Director, NM, I, and DS, identifies in writing appropriate privileging qualifications of staff nuclear physicians to include specific

competencies in: diagnostic testing and/or 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.

(3) **Regulatory Authority.** The Service Chief or Director, NM, I, and DS, must be authorized by the NRC, or be a VHA's Master Material License (MML) permitee 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.

(4) **Congressional Mandate.** The Service Chief or Director, NM, I, and DS, is mandated to annually implement the requirements of the Congressionally-approved Clinical Laboratory Improvement Act of 1988 (CLIA-88). This mandate applies to both the nuclear imaging and radiobioassay products and will be fully delineated in paragraph 2 of this issue.

(5) **Continuing Education.** The Service Chief or Director, NM, I, and DS, must provide continuing educational direction for professional and technical staff; and in affiliated VHA facilities, must ensure that established accredited educational and/or training programs for medical residents and/or fellows and allied health professionals are maintained.

(6) **Research.** The Service Chief or Director, NM, I, and DS, in facilities with research missions, must foster and participate in medical and health systems research. ***NOTE:*** *Publications resulting from research involving VA resources should always acknowledge the researcher's VA affiliation.*

(7) **Administration.** The Service Chief or Director, NM, I, and DS, administers the activities of this product line including: developing a business plan; ensuring adequate staff and equitable assignments; utilizing standard procedures and/or protocols, or developing procedures and/or protocols for all testing; monitoring all quality improvement activities; creating and maintaining safe radiation environments; coordinating and/or overseeing support services to produce a timely quality product; and serving on institutional, cross-institutional, VISN, and national committees, as requested.

(8) **Radiation Emergency Counsel.** The Service Chief, or Director, NM, I, and DS, is expected to provide direction and counsel locally in the event of a radiation emergency according to local policies. 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.

(9) **Data Timeliness and Accuracy.** The Service Chief, or Director, NM, I, and DS, is responsible for ensuring that all statistical information representing the activities of the service (Report Control Number (RCN) 10-0010, PET Registry, Current Procedural Terminology (CPT) codes, etc.) is accurate and submitted in a timely fashion.

(10) **Delegation.** The Service Chief or Director, NM, I, and DS, need not personally perform all responsibilities. Selected administrative responsibilities may be delegated to appropriate supervisory staff such as 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, and DS, however, remains responsible for the operation and administration of the service.

e. **Categorization of Specific Nuclear Imaging Procedures and Radiobioassay Tests**

(1) **Categorization of Workload.** 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 the Centers for Medicare and Medicaid Services (CMS).

(2) **Review of CPT Codes.** Since CPT codes may be modified annually by the AMA, a field representative Ad Hoc Committee directed by the Program Director, Nuclear Medicine and Radiation Safety Service, VHA Central Office, will review changes at least annually and provide guidance to the field regarding changes.

(3) **Field Service Chief or Director, NM, I, and DS's Responsibility.** It is the Field Service Chief or Director, NM, I, and DS's responsibility to ensure that CPT code changes, and recommendations of the Ad Hoc Committee are communicated to the accountable support staff.

f. **Management Data and Trend Analysis.** The Chief or Director, NM, I, and DS 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, Nuclear Medicine and Radiation Safety Services, Diagnostic Services Strategic Healthcare Group (DSSHG), 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 the 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.

g. **Qualifications and Knowledge Required for the Role of Service Chief, Director, NM, I, and DS**

(1) **Qualifications.** The Service Chief, or Director, NM, I, and DS, must possess a broad knowledge of clinical medicine, ideally be board certified by the American Board of Nuclear Medicine or possess a Nuclear Medicine certificate with board certification from the American College of Radiology. 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/or applications of ionizing radiation to meet the requirements of Title 10 Code of Federal Register (CFR) Chapter 1, Parts 0 through 199, 21 CFR Part 361.1,40

CFR, Chapter 1, Part 261, 10 CFR Part 61, Subpart I, EPA 520 1-89-003, 29 CFR 1910.1096, 49 CFR and 42 CFR Part 493, in order to be able to discharge those responsibilities appropriately.

(2) **Use of Contract Physician for Service Chief or Director**

(a) Contract board certified and/or eligible Nuclear Physicians and/or Radiologists with nuclear medicine certification, or an otherwise well qualified physician, may be retained as Chief where a nuclear physician or radiologist with nuclear medicine certification cannot be successfully recruited, or where there is insufficient workload volume to warrant a full-time physician.

(b) Responsibilities. Contract physicians are expected to fully participate on a prorated time basis in the institution's educational programs and/or requirements, quality improvement, patient safety programs, and other responsibilities as assigned.

***NOTE**: VHA Directive 2001-001 defines what processes must be considered in appointing an otherwise well-qualified physician and the recruitment actions that must be undertaken.*

h. **Other Human Resources**

(1) **Staff Nuclear Physicians**

(a) Provide consultation to clinical referring physicians regarding the appropriateness of the diagnostic nuclear testing requested, the clinical ramifications of the imaging findings and provide consultation and therapy with unsealed radioactive sources. They are expected to:

1. Be knowledgeable and provide counsel regarding the regulatory requirements of creating and maintaining safe radiation environments, and

2. Provide direction in the management of radiation emergencies.

(b) Participate in the Service's mandated quality improvement, patient safety programs, and educational mandates are considered an essential part of the staff nuclear physicians professional responsibilities.

(c) Contract staff Nuclear Physicians. Contract Nuclear Physicians and/or Radiologists with nuclear medicine certification are expected to function with the same esponsibilities and expectations as are stated.

(2) **Allied Health Staff**

(a) Nuclear technical staff, nuclear pharmacists, nurses, exercise physiologists and radiation safety staff may be assigned to NM, I, and DS. Ideally the Radiation Safety Officer (RSO) or technical staff in a segmented role with some portion of the Full-time Equivalent (FTE) 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 correct and/or take corrective action against the immediate supervisor. 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 proscriptions of relevant regulatory and/or accrediting agencies. ***NOTE:*** *VHA Qualification Standards apply to the hiring and retention of nuclear technical staff.*

(b) Contract Allied Health Staff. Contract nuclear technical and radiation safety staff are expected to meet the existing Qualification Standards, position descriptions, and responsibilities for the role they are occupying, including the proscriptions of the regulatory and accrediting bodies.

(3) **Clerical and/or Support Staff.** Clerical and/or support staff who receive patients; arrange appointments, follow-up on patients' missing appointments, etc., and other responsibilities, as defined by local policy, are necessary for operation of the unit and ensuring that some accrediting standards are addressed.

2. QUALITY MANAGEMENT

a. Scope. Each VHA medical facility must establish and maintain a comprehensive systematic Quality Management Program under the direction of the Service Chief or Director, NM, I, and DS, that includes:

(1) Employment of quality control for gamma cameras and other equipment.

(2) Policy, 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 and/or disabilities) and protocols that describe operations which provide the highest quality of nuclear imaging and radiobioassay testing.

(3) Ensuring the availability, appropriateness of the requested study, 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) Addressing a patient-safety focus.

(6) Providing a radiation-safe environment.

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

(8) Incorporating congressionally mandated (CLIA) annual nuclear imaging and radiobioassay laboratory testing.

b. **Required Elements for Quality Management.** 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 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 timeliness of first available appointment and of 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 "near miss" situations, and informed consent.

(9) CLIA mandated imaging and radiobioassay proficiency.

c. **Radiation Safety Inspection and Accreditation**

(1) **Regulatory Authority.** VHA facilities, per Public Law (Pub. L.) 93-438, are either under the authority of the NRC or VHA's MML authority to regulate Byproduct, Source and Special Nuclear Materials. These authorities grant licenses and/or permits for use of such nuclear materials and oversee that the license and/or permit conditions and regulatory proscriptions are followed. It is the Service Chief or Director's NM, I, and DS's responsibility, working with the facility RSO and the facility Radiation Safety Committee (RSC) to monitor activity to ensure radiation safe environments.

***NOTE**: Naturally-occurring and Accelerator-produced Radioactive Materials (NARM), while not regulated by the NRC, are regulated by VHA's National Radiation Safety Committee (NRSC). Since NRC and/or MML regulations have been and continue to be modified over time, rather than revising and publishing VA regulations so that they are equal to 10 CFR, Chapter 1,*

Parts 0 through 199, this Handbook substitutes 10 CFR Chapter 1, Parts 0 through 199 for VA regulations. This Handbook does not apply to the nuclear reactor facility at the VA Medical Center, Omaha, NE.

(2) **Counsel and Education**

(a) The Radiation Safety Center for Inquiry (RSCI), organizationally part of the of the Nuclear Medicine and Radiation Safety Services Office, was established to provide ad hoc counsel and education via teleconference or electronic media.

(b) Staff for RSCI 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.

(c) They are 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.

d. **External Proficiency Testing Program**

(1) **Radiobioassay Testing Proficiency**

(a) Background. In 1988, Congress passed the 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/or treatment of patients. The Department of Health and Human Services (HHS) then published implementing regulations for CLIA, 42 CFR Part 493. In 1992, the Congress passed Pub. L. 102-139 Sec.101. (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, in essence, requires VHA laboratories, including Nuclear Medicine laboratories, to meet the requirements of CLIA. The CLIA 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 equal to 42 CFR Part 493, this Handbook substitutes 42 CFR Part 493 for VA regulations.*

(b) Scope. Within VA, all laboratory testing utilized for the diagnosis and/or 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: JCAHO, CAP, FDA, OSHA, and NRC. All laboratory testing, regardless of location, must undergo 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 CMS.

1. Radiobioassay. Service and/or product lines that perform 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, meet the regulations implementing the CLIA 88, (42 CFR, Part 493) to maintain accreditation. All laboratory testing comes under the oversight of the clinical laboratory.

2. Organizational Placement of Radiobioassay.

a. 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.

b. All VA laboratories doing radiobioassay testing are required to be inspected by CAP as the CMS deemed body. This can be accomplished by either applying to CAP as an independent laboratory, necessitating considerably more administrative paper work, or declaring the radiobioassay portion of the product line as an ancillary testing site (ATS) of the facility's main P&LMS laboratory. In the latter option, collaboration with the P&LMS to create some collaborative policies and procedures will involve considerably less administration. In either option, the radiobioassay component must be on-site inspected by CAP (see VHA Handbook 1106.1).

3. Oversight of CLIA Mandate. Each VISN must ensure that all laboratories and individuals performing radiobioassay used for the diagnosis and/or guiding treatment of patients are in compliance with the policies of 42 CFR, Part 493.

4. Cost for Radiobioassay Proficiency. Cost of radiobioassay testing is borne by the involved facility.

(2) **Nuclear Imaging Proficiency Testing**

(a) CLIA Imaging Proficiency. Similarly, CLIA 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 Nuclear Medicine and Radiation Safety Service Office contracts with the appropriate accrediting body, the SNM, to:

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

2. Address any questions from the field;

3. Evaluate the responses, report those findings to the individual facilities; and

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

(b) Inadequate Performance. Facilities that fail to adequately perform on the exercise are contacted by the VA Central Office Program Director, Nuclear Medicine and Radiation Safety Service to submit the "bar flood" acquired on the gamma camera which was used the day of the proficiency testing, to determine if poor performance was related to inadequately performing technology. If so, the facility is to be informed in order to correct the technological problem. 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, Nuclear Medicine and Radiation Safety Service and suggestions offered for improvement. Poor performance on a single phantom exercise, while it will be followed up, does not constitute incompetence. It indicates that interpretation of images of a particular organ system needs to be reviewed. Inadequate performance is entered into an aggregate and per provider database to trend 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 mentor or a formal educational program would be recommended. ***NOTE:*** *Continued poor performance would necessitate facility action.*

(c) Costs. The cost for a single image proficiency test per 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 VHA Central Office, may do so at their own cost.

(d) Continuing Education Units (CEUs). Continuing medical education and technical continuing education units are granted to those staff who apply, participate, and submit the completed materials.

(e) Feedback. VISN Directors receive the annual summary of system-wide results. Facilities that demonstrate consistent erroneous interpretations, or poor camera-quality control, will be identified and receive the remedial action(s) recommended by the Program Director, Nuclear Medicine and Radiation Safety Office.

(f) Non-compliant Facilities. Facilities that fail to participate, after several reminders, will be identified to their respective VISN for assistance with compliance.

(g) Facility Director's Responsibilities. Facility Directors, recognizing this program as being congressionally mandated, also recognize that this exercise is a demonstration of quality of services provided in-house, or those provided by contractual vendors. Facility Directors must initiate actions based upon the recommendations of the Program Director, Nuclear Medicine and Radiation Safety Service.

3. DISSEMINATION OF INFORMATION REGARDING USE OF RADIOACTIVITY IN VHA

a. **Scope**

(1) **Rights, Responsibilities and Practices.** Many competing and compelling rights (the patient's right to know), regulations (NRC and/or MML), common practices (reporting to one's supervisor), and concerns (fear of retribution) enter into the individual's judgment of what, when and to whom to report when there appears to be an improper use of radioactivity.

(2) **Expert Resources.** The understanding of the dangers and the allowable use, quantities, time and distance from exposure for each radioactive element constitute a science of its own with relatively few persons competently knowledgeable. Facilities using radioactivity 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.

b. **Authorities**

(1) **Routine Diagnostic Imaging.** Patients must be informed that the diagnostic study and/or examination utilizes a low dosage of radioactivity. Describe any precautions (usually none) that are necessary for the patient and/or family post study. Use language that is readily understandable and non-contributory to further radio phobia.

(2) **Therapeutic Intervention.** The facility RSO is contacted 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.

(3) **Informing Patients about Adverse Events.** VHA is obligated to inform patients and their families about injuries resulting from adverse events 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 will advise the patient and/or family with accurate information.

(4) **Questions and/or Confusion Regarding Practice or Research.** Occasionally, there are questions and/or confusion regarding the scope of medical practice that includes the clinical use of radioisotopes and how that differs from the research uses of radionuclides. Issues of informed consent and adherence to the Federal Policy for the Protection of Human Subjects which addresses the appropriate medical facility committee, i.e., Radiation Safety Committee, Research and Development Committee, Subcommittee on Human Experimentation (also known as the Institutional Review Board (IRB)), and the Radioactive Drug Research Committee, etc., are vital in these circumstances.

***NOTE**: VHA Handbook 1004.1,Informed Consent and 10 CFR 19,20,30,33,35,49 and 21 CFR 50,56,207,211,310,312,314 and 361 provide direction.*

(5) **Suspected Improper Use.** Staff suspected of improper use and/or activity must promptly be reported to the facility RSO. If for some reason the RSO is not available or amenable to prompt discussion, the Service Chief or Director, NM, I, and DS, should be capable of addressing the issue or refer it to the proper authorities. All staff has the right to directly contact the NRC and/or National Health Physics Program (NHPP) staff that monitor VHA's MML without facility administration's permission or fear of retribution.

***NOTE**: If unable to contact NHPP staff, the NRC may be contacted.*

(6) **Equipment Failure and/or Radio pharmaceutical Concerns.** In the event of known nuclear and/or nuclear related equipment failures, or commercially prepared radio pharmaceutical concerns that pose dangers to patients, all current VHA communication media is to be utilized in disseminating patient safety information based upon the nature and urgency of the information needing to be shared.

(7) **Media Overtures. Under NO circumstances is one to personally respond to news media.** Even though you think you can resolve the confusion, do NOT personally respond to news media or unknown person(s) calling to seek information or to clarify information already possessed regarding incidents involving the use of radioactivity, past or present, that have occurred in the local facility, or in the VHA system. Refer all inquires to the local public relations staff. In all cases the local facility management and facility public relations are to be contacted immediately. ***NOTE:** Given the nature of the information, VISN and VHA Central Office public relations should be contacted by the facility Director, or designee.*

4. ALGORITHM FOR TECHNICAL STAFF PRODUCTIVITY AND/OR PREDICTING STAFFING REQUIREMENTS

a. **Background.** The business approach of controlling costs, while maintaining quality and quantity, is responsible for attempts to establish methods for determining the number of technical staff necessary to produce a measurable amount of nuclear imaging workload or predicting how many technical staff are needed if a certain amount of nuclear imaging workload is projected. Within the nuclear and related professional communities, either private or public, there have been no valid and accepted measures to employ since there were so many confounding production variables (number of cameras, age of cameras, planar and/or Single Photon Emission Computed Tomography (SPECT) capacity, missions of the facility, number of technologists and/or technicians, lack of standardized protocols) that entered into the process.

b. **Process.** The statistical significance of each variable was identified and those found not or minimally significant were eliminated. Deducting paid hours of annual and sick leave, authorized and/or military absences, and holiday time, calculated actual productive hours. This step is often not considered with simplistic ratio measures such as " number of procedures to number of technicians." In an employment system that rewards employee longevity, unproductive paid hours can be substantial. Workload is converted from the number of a given nuclear imaging procedure, as identified by CPT, into weighted workload using the technical practice (not malpractice) Medicare Relative Value Units (RVUs). The tables to locate individual facility's productivity in the appropriate comparable facility grouping and to predict

future technical need with the appropriate Medicare RVUs, are supplied annually with the Service's annual report.

(1) **Productivity.** To determine the efficacy of production, facilities are annually placed into statistically similar groups based upon ranges of the Medicare weighted RVUs per productive technical hour produced, compared with those facilities with the same number, types, and ages of cameras and technical staff. Benchmark facilities are readily identified, as are those that need to scrutinize and to modify their operations in order to become more productive.

(2) **Prediction.** To determine the number of technical staff needed to produce a given amount of weighted workload, one needs to determine the projected volume of each CPT code and calculate the projected technical component RVUs by using the provided Medicare table. Once the summed total projected weighted workload is calculated, use the staffing tables provided annually, locate the grouping in which the facility would be placed according to projected workload, and the number and age of cameras in the facility. ***NOTE:*** *Some simple calculations to deduct anticipated unproductive technical hours needs to be made for accuracy.*

c. **Responsibility.** Facility Directors are responsible for discussing the published productivity and prediction information with the responsible Service Chief or Director, NM, I, and DS, and acting upon the findings.

5. RELEVANT COMMITTEES

a. **Scope.** Facilities that utilize radioactive materials in the conduct of clinical practice and/or medical research are required by various Federal agencies to establish and utilize intra- and extra- VHA committees to regulate and oversee local activities.

(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 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 (10 CFR 35.6). Such committees include the facility Research and Development (R&D) Committee, Subcommittee on Human Experimentation (IRB), the RSC, and under some circumstances the Radioactive Drug Research Committee (RDRC). Approval by the appropriate committee is mandatory before initiating research involving human subjects. In addition, all nuclear medicine research activity must be in full compliance with VA's Office of Research and Compliance Assurance (ORCA) regulations, and must provide documentation demonstrating such compliance at any audit.

NOTE*: In addition to the project's review and approval by the appropriate facility committees, informed consent from individual research subjects must also be obtained before initiating the project. See Handbook 1100, Informed Consent for specific guidance.*

b. **Responsibilities**

(1) **Under Secretary for Health.** The Under Secretary for Health has charged the individual researcher with the responsibility for scrupulously following the proper approval processes.

(2) **Facility Director.** The regulatory bodies (NRC and MML) specify that the ultimate responsibility be vested in the facility level licensee or permitee, usually the facility Director. The facility Director ensures administrative representation on these committees and reviews and approves of the meeting minutes.

c. **Committee Charge, Membership, and Functions**

(1) **RSC.** This committee ensures the safe use of all forms of ionizing radiation in accordance with applicable regulations (NRC, EPA, DOT, FDA, and VHA, including MML). Membership includes a chair (usually a nuclear medicine specialist, radiologist, senior medical staff member, or research staff member with experience in the use of radioactivity for clinical and research applications), the RSO, a representative from facility administration, research, patient care, and other user clinical services (nuclear medicine, radiology, radiation oncology, internal medicine, cardiology, pulmonary, or gastroenterology). The RSC chair and RSO are specifically named in each medical facility's NRC license and/or MML permit. The basic elements reviewed by the RSC for research projects are the:

(a) Training and experience of the investigator.

(b) Training and experience of all individuals handling radioisotopes or ionizing radiation.

(c) Physical form and amount of radioisotope, or form of ionizing radiation.

(d) Physical space for the use of the radioisotope, or ionizing radiation.

(e) Proposed use of the radioisotope or ionizing radiation.

(f) Safety precautions for the safe use of the radioisotope or ionizing radiation.

(g) Physical form and the amount of waste to be generated.

(2) **R&D Committee.** The R&D Committee is charged with the responsibility to review scientific, administrative, and budgetary aspects of all VHA facility generated research proposals. Membership is usually broad, including various medical specialties, other clinical staff, and facility administration. The basic elements reviewed for research projects include:

(a) A brief description of the research project (abstract).

(b) A budget.

(c) The rationale for the research project.

(d) The research problem or question to be answered by the research project.

(e) Specific aims or objective of the research project.

(f) Background information pertinent to the research project.

(g) The preliminary data by investigator.

(h) The general methods to be used in the research project.

(i) An experimental plan of the research project.

(j) A data analysis or interpretation.

(3) **IRB (or any other named entity with the equivalent charge).** ***NOTE:*** *Sometimes referred to as the Subcommittee on Human Experimentation.* Every VHA medical facility that performs any research must have an IRB. The IRB is charged with reviewing proposed human research in terms of medical facility commitments and policies, applicable law, and standards of professional conduct and practice. This is fundamentally a risk versus benefit assessment. Membership must include a broad range of staff and laypersons knowledgeable in the previously mentioned arenas. The basic elements reviewed by an IRB for all proposed research projects are:

(a) Rationale of the proposed research project.

(b) Minimization of risk.

(c) Reasonable risk and/or benefit ratio.

(d) Equitable selection of subjects.

(e) Securing and documenting informed consent.

(f) Monitoring safety of research subjects.

(g) Privacy and confidentiality of research subjects.

(h) Protection of vulnerable research subjects.

(i) Documentation of all the preceding by an appropriate method of informed consent.

(4) **RDRC.** The RDRC reviews all research uses of radioactive drugs in humans that have not been previously approved by the FDA. The proposed use of radioactive drug(s) or any x-ray procedures used in conjunction with the study must be in accordance with FDA regulations (21 CFR Part 361.1). RDRC membership is specified in 21 CFR 361 and is to include a chair with experience in the research applications of radiopharmaceuticals, facility RSO, a biologist or chemist familiar with drug formulation and

representatives from facility administration and user services. The FDA approves the credentials of each member. The RDRC is the local representative of the FDA at the facility. The facility is subject to unannounced inspections of the RDRC activities. The elements reviewed by RDRC for research projects are:

(a) Investigator qualifications.

(b) Licensure for the use of the radioisotope.

(c) Intent to pursue research (defined in 21 CFR Part 361.1).

(d) Lack of pharmacologic effects(s).

(e) Selection of research subjects.

(f) Provisions for the reporting of adverse reactions.

(g) Radiation dosimetry.

(h) Quality control of the radioactive drug.

(i) Concurrence of approval by IRB.

d. **Reporting Requirements**

(1) **FDA.** The FDA requires the following reports**:**

(a) Annual Report. Radioactive drugs used for research purposes in humans as described in 21 CFR Part 361 are approved on a per project basis by the RDRC. Each RDRC must submit an annual report to FDA on or before January 31st. The annual report must include the names and qualifications of the committee members and any consultants used by the RDRC (use FDA Form 2914, Report on Research Use of Radioactive Drug Membership Summary). The annual report to the FDA also includes a summary report for each project conducted during the preceding year (use FDA Form 2915, Report on Research Use of Radioactive Drug Study Summary). The RDRC chairperson is responsible for the timely review of annual membership and research study summaries to the FDA.

(b) Adverse Reactions. Adverse reactions, or effects associated with the use of a radioactive drug in a research study, must be reported to the RDRC (if the study is under RDRC aegis), the Radiation Safety Committee, and the local Chief, Research Service. If applicable, the chairperson of the RDRC is responsible for notifying FDA. Since radioactivity is involved, the Radiation Safety Committee chairperson, the RSO, and the local subcommittee on human experimentation (local Investigational Review Board) should also be notified of any adverse reactions.

(2) **NRC.** The NRC requires a report on **"**Misadministrations and Recordable Events." Human research studies are subject to NRC regulation regarding the misadministration of

ionizing radiation. Specific notification, reporting and documentation of misadministrations and recordable events must be followed (10 CFR Part 35.33).

(3) **VA.** VA requires an incident report on incidents involving beneficiaries (VA patients and/orresearch subjects) that occur at a medical facility; the incident must be promptly reported and investigated. 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.

FIGURE 1

COMMITTEE REPORTING REQUIREMENTS (HUMAN RESEARCH)

Committee	Meets	Report(local)	Report(national)	Inspections
R&D	monthly	CEB[1] TQI program[2] (JCAHO)	VA	Medical facility
IRB	monthly	R&D (CEB)	VA	FDA (announced)
RSC	quarterly annually	CEB		NHPP (NRC) (unannounced)
RDRC	quarterly	RSC (CEB)	FDA	FDA[3], NRC[3] (unannounced)

[1]Clinical Executive Board or equivalent committee
[2]Total Quality Improvement or equivalent program
[3]Misadministration or adverse reaction

(4) **Clinical Scope of Practice versus Clinical Research**

(a) Off Label Use

1. 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:

a. No significant increase in patient risk.

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

2. These provisions 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 medical management of a

patient deemed necessary for patient care.

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

b. Deviations from an approved use of a radiopharmaceutical occurs 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.

c. The proposed procedure is discussed with the patient (oral informed consent).

d. Deviations from approved uses are documented in the prescription for the radiopharmaceutical that is initiated by the nuclear medicine or radiology physician. A formal description of the indication(s) for the 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 medical record of the patient.

e. Conversely, an IND application would need to be submitted to FDA for new radiopharmaceuticals or alternative uses of established radioactive drugs used for clinical research purposes as a prelude to medical facility IRB, RSC, and R&D committees' approvals.