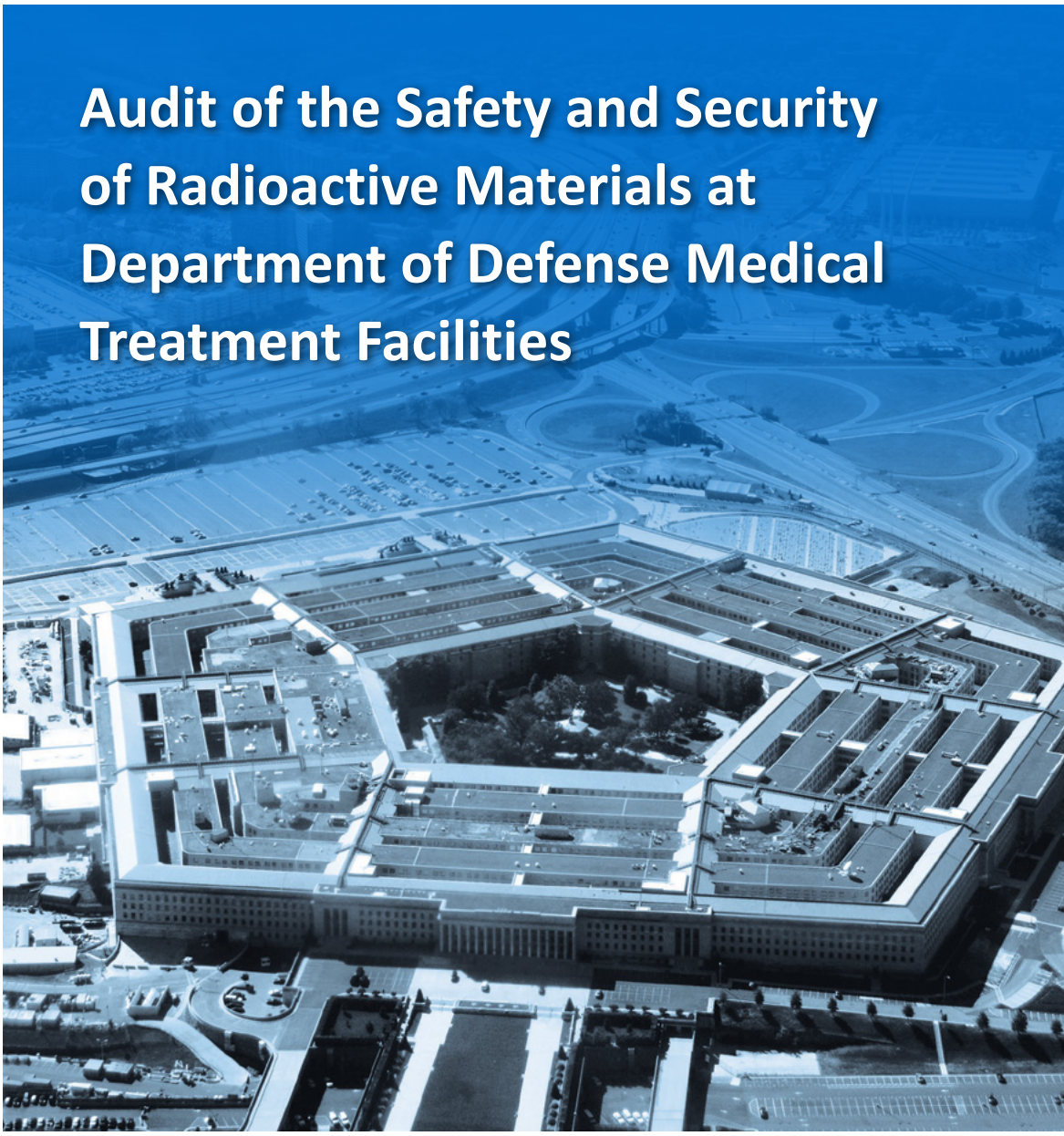
Report No. DODIG-2020-088

INSPECTOR GENERAL

U.S. Department of Defense

JUNE 10, 2020

Audit of the Safety and Security of Radioactive Materials at Department of Defense Medical Treatment Facilities



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Results in Brief

Audit of the Safety and Security of Radioactive Materials at Department of Defense Medical Treatment Facilities

June 10, 2020

Objective

The objective of this audit was to determine whether DoD and military medical treatment facility (medical facility) management properly trained personnel, conducted inspections and program reviews, and accounted for inventory levels for the safety and security of radioactive materials. In addition, Defense Health Agency (DHA) management officials requested that we identify any best practices for their consideration as they assume administration and management responsibility of all medical facilities within the DoD.

We reviewed the safety and security of radioactive materials in the Nuclear Medicine Departments at eight nonstatistically selected DoD medical facilities across the Military Services and National Capital Region–Medical Directorate.

Background

On October 1, 2019, the DHA assumed administration and management responsibilities from the Army, Navy, and Air Force for all military hospitals and clinics. The DHA will oversee facilities through a direct support relationship with the Military Medical Departments. The DHA will relieve the Departments of their support during a transition period in which responsibility for specific health care and administrative functions fully transfer to the DHA. The DHA transition has a target completion of September 2021.

Background (cont'd)

About one-third of all patients admitted to hospitals are diagnosed or treated with radiation or radioactive materials, which are referred to as radiopharmaceuticals. This branch of medicine is called nuclear medicine. The most common types of procedures performed by nuclear medicine technicians include brachytherapy, iodine treatment for overactive thyroid, and bone mineral analysis. There are 32 medical facilities and 1 medical training facility within the DoD that have radioactive materials.

The Nuclear Regulatory Commission (NRC) regulates the use of radioactive materials for diagnosing and treating illnesses, and in medical research. The NRC is responsible for ensuring that medical facilities use the materials properly and in a way that protects patients, medical workers, the public, and the environment from radiation contamination and exposure. Furthermore, the NRC oversees medical uses of radioactive materials, issues medical use licenses to medical facilities, authorizes physician users, and develops guidance and regulations for use by licensees.

Finding

DoD medical facility management properly trained personnel, conducted inspections and program reviews, and accounted for inventory levels for the safety and security of radioactive materials at the eight facilities visited. Specifically, DoD management at each medical facility:

- trained Radiation Safety Officers and authorized users regarding the safe use of radioactive materials;
- complied with Federal and DoD requirements for periodic reviews of facility radiation safety programs, ensuring reviews were conducted at least annually, and took corrective actions to address deficiencies identified by the periodic reviews; and
- received, secured, accounted for, and disposed of radioactive materials, and took measures such as conducting surveys and monitoring occupational exposure to ensure patient and employee safety.

Results in Brief

Audit of the Safety and Security of Radioactive Materials at Department of Defense Medical Treatment Facilities

Finding (cont'd)

We identified multiple best practices such as sharing process improvements identified through external audits, improved procedures for survey instrument testing and calibration, and potential cost savings and efficiencies over dosimetry processing for the DHA to consider implementing as it assumes administration and management responsibility of all medical facilities within the DoD. These best practices could help the DHA strengthen controls over the safety and security of radioactive materials and gain potential cost savings.

Recommendations

We recommend that the DHA Director:

- coordinate with Radiation Safety Officers to conduct external audits of other medical facility radiation safety programs to expedite the sharing of best practices across the Military Services and medical facilities,
- implement supplemental guidance to instruct the medical facilities on appropriate steps to take after a failed quality control test,
- conduct a study to determine the benefits and feasibility of directly connecting the medical facilities' nuclear medicine information systems to survey instruments,
- review and revise, as necessary, the dosimetry processing procedures that record and measure radiation exposure to occupational employees, and
- review and revise, as necessary, the occupational dosimetry program to limit monitoring to only those individuals likely to be exposed to radiation.

Management Comments and Our Response

The DHA Director agreed with all recommendations and provided comments that address the specifics for four of the five recommendations. The four recommendations are resolved but will remain open until the DHA Director submits adequate documentation showing that all agreed-upon actions have been completed. However, the DHA Director did not provide comments that addressed the specifics for the recommendation to determine the benefits and feasibility of directly connecting the nuclear medicine information system to survey instruments at the medical facilities. Therefore, the recommendation is unresolved. We request that the DHA Director provide additional comments in response to the final report that resolve the recommendation.

Please see the Recommendations Table on the next page for the status of recommendations.

Recommendations Table

Management	Recommendations Unresolved	Recommendations Resolved	Recommendations Closed
Defense Health Agency	1.c	1.a, 1.b, 1.d, 1.e	None

Please provide Management Comments by July 10, 2020.

Note: The following categories are used to describe agency management's comments to individual recommendations.

- **Unresolved** – Management has not agreed to implement the recommendation or has not proposed actions that will address the recommendation.
- **Resolved** – Management agreed to implement the recommendation or has proposed actions that will address the underlying finding that generated the recommendation.
- **Closed** – OIG verified that the agreed upon corrective actions were implemented.


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4800 MARK CENTER DRIVE
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June 10, 2020

MEMORANDUM FOR DIRECTOR, DEFENSE HEALTH AGENCY
AUDITOR GENERAL, DEPARTMENT OF THE NAVY
AUDITOR GENERAL, DEPARTMENT OF THE ARMY
AUDITOR GENERAL, DEPARTMENT OF THE AIR FORCE

SUBJECT: Audit of the Safety and Security of Radioactive Materials at Department of Defense Medical Treatment Facilities (Report No. DODIG-2020-088)

This final report provides the results of the DoD Office of Inspector General's audit. We previously provided copies of the draft report and requested written comments on the recommendations. We considered management's comments on the draft report when preparing the final report. These comments are included in the report.

This report contains one recommendation that is considered unresolved because management either disagreed with or did not fully address the recommendation, or did not provide a response to the report. Therefore, as discussed in the Recommendations, Management Comments, and Our Response section of this report, this recommendation will remain unresolved until an agreement is reached on the actions to be taken to address the recommendation. Once an agreement is reached, the recommendation will be considered resolved but will remain open until adequate documentation has been submitted showing that the agreed-upon action has been completed. Once we verify that the action is complete, the recommendation will be closed.

This report contains four recommendations that are considered resolved but open because management agreed with and provided comments that fully address the recommendations presented in the report. Therefore, as discussed in the Recommendations, Management Comments, and Our Response section of this report, these recommendations will remain open until adequate documentation has been submitted showing that the agreed-upon action has been completed. Once we verify that the action is complete, the recommendations will be closed.

DoD Instruction 7650.03 requires that recommendations be resolved promptly. Therefore, for the unresolved recommendation, please provide us within 30 days your response concerning specific actions in process or completed on the recommendation or alternative corrective actions proposed. For the resolved recommendations, please provide us within 90 days your response concerning specific actions in process or completed on the recommendations. Your response should be sent as a PDF file to aud-colu@dodig.mil.

We appreciate the cooperation and assistance received during the audit. Please direct questions to me at [redacted].

Theresa S. Hull
Assistant Inspector General for Audit
Acquisition, Contracting, and Sustainment

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Introduction

Objective

The objective of this audit was to determine whether DoD and military medical treatment facility (medical facility) management properly trained personnel, conducted inspections and program reviews, and accounted for inventory levels for the safety and security of radioactive materials. In addition, Defense Health Agency (DHA) management officials requested that we identify best practices for their consideration as they assume administration and management responsibilities of all DoD medical facilities.

We reviewed the safety and security of radioactive materials in the Nuclear Medicine Departments at eight nonstatistically selected DoD medical facilities across the Military Services and National Capital Region–Medical Directorate (NCR-MD).[1]

- William Beaumont Army Medical Center, Texas – Army
- Landstuhl Regional Medical Center, Germany – Army (OCONUS)
- Naval Hospital Pensacola, Florida – Navy
- Naval Hospital Camp Pendleton, California – Navy
- Naval Medical Center Portsmouth, Virginia – Navy
- Eglin Air Force Base Hospital, Florida – Air Force
- Joint Base Elmendorf-Richardson Hospital, Alaska – Air Force (OCONUS)
- Walter Reed National Military Medical Center, Maryland – NCR MD

Background

The Office of the Assistant Secretary of Defense (Health Affairs) oversees all DoD health and force health protection policies, programs, and activities. The DHA is a major element of the Office of the Assistant Secretary of Defense (Health Affairs). The DHA is a joint, integrated combat support agency that enables the Army, Navy, and Air Force medical services to provide a medically ready force. In addition, the DHA ensures that a ready medical force is available for combatant commands in both peace and wartime. The DHA goal is to improve operations across the Military Health System and assist in creating optimal outcomes for health, well-being, and readiness.

[1] We selected these eight locations to ensure coverage of at least two facilities for each Service, two OCONUS locations, one NCR-MD location, and to include Naval Medical Center Portsmouth because it managed a different category of radioactive materials and the DHA specifically requested that we review the facility.

Public Law 114-328, "National Defense Authorization Act for Fiscal Year 2017," December 23, 2016, requires the DHA to manage all military medical treatment facilities. On October 1, 2019, the DHA assumed administration and management responsibilities from the Army, Navy, and Air Force for all military hospitals (medical facilities) and clinics.

Initially, the DHA plans to oversee facilities through a direct support relationship with Military Medical Departments. The DHA will relieve the Military Departments of this support during a transition period in which responsibility for specific health care and administrative functions are fully transferred from the Military Departments to the DHA, with a target completion of September 2021.

There are 32 medical facilities and 1 medical training facility within the DoD that have radioactive materials:

- 15 Army facilities,
- 9 Navy facilities,
- 6 Air Force facilities,
- 2 NCR-MD facilities, and
- the Medical Education and Training Campus.

See Appendix B for the complete list of facilities.

Use of Radioactive Materials in Medical Facilities

According to the U.S. Nuclear Regulatory Commission (NRC), about one-third of all patients admitted to hospitals are diagnosed or treated using radiation or radioactive materials, which are referred to as radiopharmaceuticals. This branch of medicine is called nuclear medicine. The most common types of nuclear medicine procedures performed include brachytherapy, iodine treatment for an overactive thyroid, and bone mineral analysis.

When used for diagnosis, a small amount of radioactive material is injected, inhaled, or swallowed by the patient, and the material collects in the area being studied, allowing the organ's function and composition to be seen by a gamma camera. For therapy, radioactive materials are used to kill cancerous tissue, shrink a tumor, or reduce pain. There are three main types of therapy in nuclear medicine:

- **Teletherapy** targets cancerous tissue with an intense beam of radiation.
- **Brachytherapy** includes high-dose and low-dose rate radiation:
    - high dose rate uses a machine and tubes to deliver the dose temporarily to the patient; and

    - low dose rate uses lower-activity sources sealed in seeds (capsules) that are placed close to or within cancerous tissue, such as in the breast, prostate, or cervix.
- **Therapeutic Nuclear Medicine** uses high doses of radiation from materials that are injected into or ingested by the patient; for example, radioactive iodine to destroy or shrink a diseased thyroid.

Other procedures may use radiation or perform functions similar to those of radioisotopes, but do not involve radioactive materials, such as x-ray, magnetic resonance imaging, chemotherapy, and mammograms. We did not assess the controls over these procedures in our review.

Types of Radioactive Materials in Medical Facilities

Medical facilities use two categories of radioactive materials: unsealed byproduct material, or patient doses, and sealed sources.

Patient Doses

Patient doses include the radioactive materials that is provided to the patient for either therapeutic procedures or diagnostic imaging. Metastable Technetium-99 is the most common radiopharmaceutical, and it is used as a medical diagnostic tool. The radiopharmaceutical is injected into the patient and then a gamma camera is used to detect disease and study organ function.

Sealed Sources

A sealed source is any radioactive materials or byproduct encased in a capsule designed to prevent leakage or escape of the material.[2] The medical facilities use sealed sources for many different functions. For example, medical facility personnel may use sealed sources for instrument calibration and brachytherapy.[3]

[2] Byproduct material is any radioactive material except enriched uranium or plutonium that is produced by a nuclear reactor and is used in calibration sources, radioactive drugs, imaging devices, brachytherapy sources and devices, and teletherapy units.

[3] Brachytherapy is a nuclear medicine procedure during which a sealed radioactive source is implanted directly into a patient being treated for cancer, either temporary or permanent, and the radiation attacks the tumor for as long as the device remains in place.

Potential Health Risks Associated With Radioactive Material Exposure

Radioactive contamination and radiation exposure could occur if radioactive materials are released into the environment as the result of an accident, an event of nature, or an act of terrorism. Such a release could expose people and contaminate their surroundings and personal property. According to the Centers for Disease Control and Prevention, types of radiation exposure and contamination include:

- **Internal contamination** occurs when a person swallows or inhales radioactive materials, or when radioactive materials enter the body through an open wound or are absorbed through the skin.
- **External contamination** occurs when radioactive material, in the form of dust, powder, or liquid, comes into contact with a person's skin, hair, or clothing.
- **Radioactive contamination** occurs when radioactive material is deposited on or in an object or a person. Radioactive materials released into the environment can cause air, water, surfaces, soil, plants, buildings, people, or animals to become contaminated.
- **Radiation exposure** occurs when the energy released from radioactive materials penetrates a person's body.

There are many health risks that can arise from a patient's exposure to radiation. Exposure to very high levels of radiation over a short period of time can cause acute short-term health effects, such as radiation sickness. It can also result in long-term effects, such as cancer and cardiovascular disease. Exposure to low levels of radiation does not cause immediate health effects, but it can increase the risk of developing cancer over a lifetime.

Radioactive Material Licensing and Permits

U.S. Nuclear Regulatory Commission Licenses and Permits

The NRC regulates the use of radioactive materials to diagnose and treat illnesses, and in medical research. The NRC is responsible for ensuring that medical facilities use radioactive materials properly and in a way that protects patients, medical workers, the public, and the environment from radioactive contamination and radiation exposure. The NRC is responsible for ensuring the common defense and security of nuclear materials and for licensing all Federal facilities.

The NRC oversees medical uses of radioactive materials through licensing, inspection, and enforcement programs. It issues medical use licenses to medical facilities, authorizes physician users, develops guidance and regulations for use by licensees, and maintains a committee of medical experts to obtain advice about the use of byproduct materials in medicine.

The NRC issues multiple types of licenses, including master materials licenses and broad scope licenses.[4] Within the DoD the NRC issued materials licenses to each of the Army medical facilities in the United States, master materials licenses to the Navy and Air Force, and a broad scope license to the DHA. Under the authority of the master materials licenses, the Navy and Air Force issued permits to the individual medical facilities. As of October 1, 2019, individual medical facilities were realigned under the DHA broad scope license.

Radioactive Material Licenses in Foreign Countries

DoD medical facilities in foreign countries do not fall under the authority of the NRC. For example, the Landstuhl Regional Medical Center operates under an Army Radiation Authorization issued by the U.S. Army Medical Command, rather than an individual license issued by the NRC.[5] The Landstuhl Regional Medical Center follows the same Code of Federal Regulations (CFR) requirements as any other Army facility, even though the NRC does not govern it. In addition, Landstuhl Regional Medical Center must follow German guidelines that are more stringent than NRC regulations, according to facility personnel. For example, unlike United States facilities, German guidelines require Landstuhl Regional Medical Center personnel to collect urine from patients who receive Iodine-131 to treat overactive thyroids or thyroid cancer, and decay it before disposal.[6] In addition, the acceptable radiation level emitting from a patient before release from the facility is lower and more restrictive according to German guidelines.

Oversight of Radioactive Materials in Medical Facilities

The NRC provides oversight of the DoD medical facilities with radioactive materials in the United States. However, the Navy and Marine Corps Public Health Center and Air Force Inspection Agency perform inspections at their respective facilities because the Navy and Air Force have master materials licenses. The U.S. Army Medical Command performs inspections at Army facilities, including Army facilities located in other countries.

[4] A master materials license is a material (byproduct, source, and/or special nuclear material) license issued to a Federal organization, authorizing the use of radioactive material at multiple sites. A broad scope license typically authorizes the possession and use of a wide range of byproduct radioactive materials.

[5] An Army Radiation Authorization is required for a facility to possess linear accelerators and radioactive materials not under the jurisdiction of the NRC (overseas), and is issued by the U.S. Army Medical Command to Army medical facilities.

[6] Decay means the spontaneous transformation of one radioisotope into one or more different isotopes, accompanied by a decrease in radioactivity.

Nuclear Regulatory Commission

The NRC has oversight of the DoD medical facilities to include inspections of licensed activities, investigations of incidents or allegations of potential wrongdoing committed by persons or entities within NRC jurisdiction, and enforcement programs to ensure the safe use of radioactive materials. Violations of regulations and licenses are assigned a severity level that reflects their seriousness and safety significance, which determines how the violations should be dispositioned.

Army Inspector General

The Army Inspector General conducts radiation safety inspections and license compliance audits of the Army Radiation Safety Program. The Army Inspector General also establishes standard inspection policies, procedures, and techniques for the conduct of inspections and audits.

Navy and Marine Corps Public Health Center

The Navy and Marine Corps Public Health Center performs inspections to assess compliance with current Navy and Federal regulations and facility permits.[7] The Bureau of Medicine and Surgery instruction applies to all naval medical department activities engaged in training, calibration, diagnostic, or therapeutic procedures using NRC regulated radioactive byproduct material.

Air Force Inspection Agency

The Air Force Inspection Agency inspects radioactive material permits issued to authorized Air Force users.[8] The authority of Air Force activities to acquire, receive, use, store, transfer, transport, distribute, or dispose of radioactive materials regulated by the NRC is granted through the Air Force master materials license.

DoD Medical Facility Management and Personnel Responsible for Radioactive Materials

The management and oversight of radioactive materials within the medical facilities is the responsibility of the Radiation Safety Committee, Radiation Safety Officer (RSO), and authorized users. Additionally, occupational employees interact with radioactive materials on a regular basis.

[7] Bureau of Medicine and Surgery Instruction 6470.20A, "Radioactive Material Permit Program for Medical Use," July 21, 2015.

[8] Air Force Instruction 40-201, "Radioactive Materials (RAM) Management," November 14, 2017.

Radiation Safety Committee

According to the CFR, licensees that are authorized for two or more different types of uses of byproduct material specified by the CFR shall establish a Radiation Safety Committee to oversee all uses of byproduct material permitted by the license.[9] The Committee must include an authorized user of each type of use permitted by the license, the RSO, a representative of the nursing service, and a representative of management who is neither an authorized user nor an RSO.

Radiation Safety Officer

According to the CFR, a licensee's management shall appoint an RSO, who agrees in writing, to be responsible for implementing the radiation protection program.[10] The RSO must ensure that the licensee's radioactive materials are used and stored safely and securely according to approved policies and procedures, and that all regulatory requirements are met. A licensee shall establish the authority, duties, and responsibilities of the RSO in writing.

A licensee shall provide the RSO sufficient authority, organizational freedom, time, resources, and management prerogative to:

- identify radiation safety problems;
- initiate, recommend, or provide corrective actions;
- stop unsafe operations; and
- verify implementation of corrective actions.

Authorized Users

An authorized user is a physician, dentist, or podiatrist who is identified as an authorized user on a license or permit that authorizes the medical use of byproduct material or that is authorized to permit the medical use of byproduct material. A person named as an authorized user on an NRC license is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations.

Occupational Employees

Occupational employees are individuals within the medical facilities who interact with radioactive materials on a regular basis, and may have their exposure tracked by the Army, Navy, or Air Force dosimetry centers.[11] Occupational employees are not named on a license or permit.

[9] Title 10 CFR section 35.24 (2018).

[10] 10 CFR sec. 35.24 (2018).

[11] Dosimetry is the measurement and recording of doses of ionizing radiation.

Radiation Monitoring and Reporting

The CFR requires licensees to control the occupational dose to individual adults to certain prescribed limits.[12] The CFR further requires licensees to maintain records of doses received by all individuals for whom monitoring is required and records of doses received during planned special exposures, accidents, and emergency conditions.[13] At a minimum, each licensee shall monitor occupational exposure of adults likely to receive, in 1 year, from radiation sources external to the body, a dose in excess of 10 percent of the limits in the CFR and all individuals entering a high or very high radiation area.[14]

There are four different, but interrelated, units for measuring radioactivity, exposure, absorbed dose, and dose equivalent:

1. **Radioactivity** is the amount of ionizing radiation released by a material.
2. **Exposure** is the amount of radiation traveling through the air.
3. **Absorbed Dose** is the amount of radiation absorbed by an object or person.
4. **Dose Equivalent or Effective Dose** is the amount of radiation absorbed and the medical effects of that type of radiation.

Review of Internal Controls

DoD Instruction 5010.40 requires DoD organizations to implement a comprehensive system of internal controls that provides reasonable assurance that programs are operating as intended and to evaluate the effectiveness of the controls.[15] DoD medical facility management controls over the safety and security of radioactive materials were effective as they applied to the audit objectives; however, we identified some best practices and additional controls to further strengthen the safety and security of radioactive materials. We will provide a copy of the final report to the senior officials responsible for internal controls in the DHA.

[12] 10 CFR sec. 20.1201 (2007).
[13] 10 CFR sec. 20.2106 (1998).
[14] 10 CFR sec. 20.1502 (1998).
[15] DoD Instruction 5010.40, "Managers' Internal Control Program Procedures," May 30, 2013.

Finding

DoD Medical Facility Management Maintained Programs to Ensure the Safety and Security of Radioactive Materials

DoD medical facility management properly trained personnel, conducted inspections and program reviews, and accounted for inventory levels for the safety and security of radioactive materials at the eight medical facilities we reviewed. Specifically, DoD management at each medical facility:

- trained RSOs and authorized users regarding safe handling and use of radioactive materials, and RSOs implemented radiation safety training programs and ensured required employees received radiation safety training and hazardous material employee training.
- complied with Federal and DoD requirements for periodic reviews of facility radiation safety programs and ensured reviews were conducted at least annually, and took corrective actions to address deficiencies identified by the periodic reviews.
- received, secured, accounted for, and disposed of radioactive materials, and took measures such as conducting surveys and monitoring occupational exposure to ensure patient and employee safety.

DHA management officials requested that we identify best practices for their consideration as they assume administration and management responsibility of all medical facilities. Through facility walk-throughs, interviews with medical facility personnel, and review of pertinent documentation, we identified some areas where DHA management could implement process changes and improvements to further strengthen controls over the safety and security of radioactive materials and gain potential cost savings and resource efficiencies. Specifically, we identified best practices related to sharing process improvements identified through external audits, improved procedures for survey instrument testing and calibration, and potential cost savings and efficiencies over dosimetry processing.

Medical Facility Management Conducted Effective Oversight of Radioactive Materials at DoD Medical Facilities

DoD medical facility management oversight of radioactive materials at the eight medical facilities we visited complied with Federal and DoD regulations.[16] Specifically, DoD and medical facility management provided the required training; conducted reviews and took corrective actions; implemented controls to ensure the safety and security of radioactive materials; and limited radiation exposure to the general public, patients, and occupational employees.

Medical Facility Personnel Responsible for Radioactive Materials Received Required Training

DoD medical facility personnel properly trained RSOs and authorized users in accordance with the CFR.[17] In addition, the RSOs at the eight facilities implemented radiation safety training programs and ensured all required occupational employees received radiation safety training and hazardous material employee training in accordance with the CFR.[18]

Radiation Safety Officers and Authorized Users Met Federal Training Standards

Medical facility RSOs and authorized users received the required training and had the proper prior work experience.

Medical facility RSOs and authorized users received the required training and had the proper prior work experience. The CFR outlines specific training and experience requirements for individuals to be authorized as an RSO or an authorized user on a facility's permit or license.[19] The CFR requires the training and experience to be obtained within 7 years preceding the date of application or the individual must have had related continuing education and experience since the required training and experience was completed. In addition, the CFR requires RSOs and authorized users to receive written attestation that the individual has satisfactorily completed all training and experience requirements by a preceptor RSO or authorized user.[20]

16 See Appendix A, Criteria.

17 10 CFR sec. 35.50, 35.51, 35.55 (2018), and 35.59 (2006).

18 10 CFR sec. 19.12 (1995).

19 10 CFR sec. 35.50, 35.51, 35.55 (2018), and 35.59 (2006).

20 A preceptor is an individual who provides, directs, or verifies training and experience required for an individual to become an authorized user, authorized medical physicist, authorized nuclear pharmacist, or Radiation Safety Officer.

RSOs and authorized users complete either an NRC Form 313A (RSO) or NRC Form 313A (AUD) to demonstrate that they have the training and experience required to be authorized as an RSO or authorized user on a facility's permit or license.[21] The forms require proposed RSOs and authorized users to either obtain board certification or complete a structured educational program, which includes classroom and laboratory training in addition to supervised work experience.

When the NRC approves an RSO or authorized user, the existing license satisfies the NRC Form 313A requirement for subsequent facilities. For the eight medical facilities, all RSOs and authorized users completed NRC Forms 313A or provided a previous permit or license identifying that they were already authorized as an RSO or authorized user at another facility. In addition, RSOs and authorized users completed all training and experience identified on the NRC Forms 313A within 7 years of application, or the individuals provided proof of related continuing education and experience since the required training and experience were completed. Lastly, RSOs and authorized users received written attestation by a preceptor RSO or authorized user on an NRC Form 313A.

Radiation Safety Officers Implemented Radiation Safety Training Programs

The RSOs implemented radiation safety training programs and ensured that all required occupational employees received radiation safety training and hazardous material employee training. The CFR requires all individuals who are likely to be exposed to 100 millirem in a year to receive radiation safety training.[22] The CFR also requires employees who either offer radioactive materials for transportation, or transport the materials, to receive hazardous material employee training at least once every 3 years.

The RSOs implemented radiation safety training programs and ensured that all required occupational employees received radiation safety training and hazardous material employee training.

RSOs at the eight facilities considered nuclear medicine department personnel as individuals likely to exceed 100 millirem exposure in a year. RSOs at the eight facilities provided radiation safety training to all nuclear medicine department personnel, and hazardous material employee training at least

[21] NRC Form 313A (RSO), "Radiation Safety Officer Training and Experience and Preceptor Attestation" June 2016, or NRC Form 313A (AUD), "Authorized User Training and Experience and Preceptor Attestation," June 2016.

[22] 10 CFR sec. 19.12 (1995) and 71.5 (2004).
49 CFR sec. 172.702 (1996) and 172.704 (2015).
A millirem is a dose of radiation equal to one thousandth of a rem.

once every 3 years to all individuals they identified as having the potential to prepare radioactive materials for shipment in accordance with Department of Transportation regulations.[23]

Medical Facilities Implemented Radiation Safety Programs, Conducted Periodic Reviews, and Took Corrective Actions

DoD medical facility personnel at each of the eight facilities complied with Federal requirements for periodic reviews of facility radiation safety programs.[24] Specifically, the medical facility personnel:

- implemented a radiation safety program,
- appointed an RSO responsible for the radiation safety program,
- conducted periodic reviews at least annually, and
- implemented corrective actions to address deficiencies identified during the reviews.

In addition, 6 of the 8 medical facilities established Radiation Safety Committees to oversee all uses of byproduct material permitted by the license, in accordance with the CFR. The other two medical facilities, Eglin Air Force Base Hospital and Joint Base Elmendorf–Richardson Hospital, were not required to have Radiation Safety Committees based on their radioactive material permits.[25]

Medical Facility Management Implemented Radiation Safety Programs

DoD medical facility personnel implemented radiation safety programs and appointed RSOs to oversee the programs. According to the CFR, licensees should develop and implement radiation safety programs commensurate with the scope and extent of licensed activities and sufficient to ensure compliance with applicable regulations.[26] Additionally, the CFR states that licensee management should appoint an RSO to be responsible for implementing the radiation safety program and ensuring radiation safety activities are performed in accordance with

[23] 49 CFR sec. 172.702 (1996) and 172.704 (2015).

[24] 10 CFR sec. 20.1101 (1998) and 35.24 (2018).

The CFR primarily uses the term Radiation Protection Program to refer to the program in place to ensure compliance with applicable requirements ensuring protection against radiation. However, the medical facilities also refer to this program as the Radiation Safety Program.

[25] The authority for the Eglin Air Force Base Hospital and Joint Base Elmendorf–Richardson permits is the NRC master materials license issued to the Air Force and managed by the Air Force Radioisotope Committee and Air Force Instruction 40-201, "Radioactive Materials (RAM) Management," November 14, 2017. The instruction states that a permit Radiation Safety Committee is required if specified as a permit condition. Neither of the two medical facility permits identified a requirement for a Radiation Safety Committee.

[26] 10 CFR sec. 20.1101 (1998).

licensee-approved procedures and regulatory requirements. The CFR further states that licensees who meet specific requirements should establish a Radiation Safety Committee that works with facility management and the RSO in implementing radiation safety programs.[27]

Medical facility management at all facilities visited developed radiation safety programs to ensure compliance with NRC and Department of Transportation regulations and the terms and conditions of the licenses. Facility management also appointed RSOs to implement those programs. Medical facility management and the RSOs ensured compliance through various functions, such as developing local radiation safety policies, publishing standard operating procedures, overseeing required radiation safety activities, and conducting internal audits.

Medical facility management and the RSOs ensured compliance through various functions.

Furthermore, facility management established Radiation Safety Committees, when required, to oversee the use of radioactive materials and work with medical facility management and the RSOs in implementing the radiation safety program. Medical facility management ensured the Radiation Safety Committees were composed of the required personnel, such as the RSO, an authorized user of each type of use permitted by the license, a representative of the nursing service, and a representative of management who is neither an authorized user nor the RSO. The Radiation Safety Committees also conducted quarterly meetings to oversee the radiation safety program and related activities.

For example, Landstuhl Regional Medical Center management and the RSO developed a detailed policy memorandum and various standard operating procedures to support and manage the facility's radiation safety program. The RSO oversaw required radiation safety activities, such as area surveys, leak tests, and occupational employee monitoring and related radiation exposure investigations. The RSO also conducted internal audits of the radiation safety program, and Landstuhl Regional Medical Center management and the RSO corrected identified deficiencies. In addition, the Landstuhl Regional Medical Center Radiation Safety Committee held meetings each quarter to review and discuss radiation safety program activities. During the meetings, the Radiation Safety Committee discussed proposed license changes, nuclear medicine quality management reports, radioactive material accountability and use, occupational monitoring, radiation safety training, and radiation safety inspections.

[27] 10 CFR sec. 35.24 (2018), Nuclear Regulatory Commission Regulation (NUREG) 1556, Volume 9, Revision 3, "Program-Specific Guidance About Medical Use Licenses," November 2016, and NUREG 1556, Volume 11, Revision 1, "Program-Specific Guidance about Licenses of Broad Scope," February 2017.

Medical Facility Management Ensured Periodic Reviews of Radiation Safety Programs

DoD medical facility personnel ensured that periodic reviews of their radiation safety programs occurred and maintained related documentation. According to the CFR, each licensee is required, at least annually, to perform a review of their radiation safety program and maintain records of the reviews.[28] Each review should ensure that the radiation safety program complies with NRC regulations and the terms and conditions of the license, in addition to ensuring occupational doses and doses to members of the public are as low as reasonably achievable.[29]

Periodic reviews of medical facility radiation safety programs include both internal and external reviews. Medical facility RSOs or other radiation safety personnel conduct internal reviews, while the NRC and DoD-level agencies, such as the U.S. Army Medical Command, the Navy and Marine Corps Public Health Center, and the Air Force Inspection Agency, conduct external reviews of medical facility radiation safety programs. All of the medical facilities met the periodic review requirement by receiving either annual internal reviews, external reviews, or a combination of both at least annually during the scope of the audit.

The Navy implemented a potential best practice to more effectively share lessons learned and recommended process improvements throughout its medical facilities. Specifically, in addition to ensuring medical facilities complied with the CFR requirements for periodic reviews, the Navy also implemented an external audit procedure in which RSOs from other Navy medical facilities performed inspections annually. This process allowed the inspecting RSO to provide input and best practices to the RSO in charge of the radiation safety program reviewed, and to obtain possible best practices from the medical facility inspected that the RSO could implement at their own facility. Therefore, the DHA should coordinate external audits among DoD medical facility RSOs, which would expedite the sharing of best practices across the Military Services and individual medical facilities. Additionally, the DHA should consider developing a database or repository for inspecting RSOs to input information on best practices and lessons learned through external audits for medical facility personnel to review for potential best practices or process improvements that may be implemented.

[28] 10 CFR sec. 20.1101 (1998) and 20.2102 (1991).

[29] NUREG 1556, Volume 9, Revision 3.

Medical Facility Management Took Corrective Actions to Address Deficiencies Identified During Reviews

Medical facility management and the RSOs took corrective actions in response to the deficiencies identified during the periodic reviews and maintained the related documentation. Examples of deficiencies identified during reviews include:

- missing or incomplete records related to radiation exposure, surveys, and sealed-source inventories;
- lack of required training for facility staff that handles or may be exposed to radiation during the course of their duties; and
- improper security of radioactive materials and areas where the materials are used or stored.

For example, in April 2019, the Navy and Marine Corps Public Health Center inspector identified that Naval Medical Center–Portsmouth personnel left a syringe containing a radiopharmaceutical in a room without being properly controlled and maintained under constant surveillance. The CFR requires licensees to control and maintain constant surveillance of licensed material that is in a controlled or unrestricted area and that is not in storage.[30] Naval Medical Center Portsmouth immediately provided training to all Nuclear Medicine personnel on the violation and the requirements for the control and surveillance of all radioactive materials. Navy and Marine Corps Public Health Center officials considered the corrective action satisfactory, and Naval Medical Center Portsmouth maintained the related documentation showing that it had addressed the deficiency.

DoD Management Ensured the Safety and Security of Radioactive Materials

DoD management and medical facility personnel at each of the eight facilities ensured the safety and security of radioactive materials, as well as patient and employee safety. Specifically, medical facility personnel performed the following tasks in accordance with Federal and DoD requirements:

- secured, tested, and maintained allowable inventories of sealed sources;
- received and disposed of radioactive materials, including patient doses;
- performed required quality control on survey instruments;
- limited possession and use to authorized areas, while demonstrating compliance with radiation dose limits;

[30] 10 CFR sec. 20.1802 (1991).

- measured and recorded patient doses and issued written directives for all required procedures; and
- ensured employee radiation exposure was within defined limits.[31]

Medical Facility Personnel Secured, Tested, and Maintained Accurate and Allowable Inventories of Sealed Sources

Medical facility's personnel maintained secure and accurate inventories of sealed sources and performed required leak tests. A sealed source is any byproduct material that is in a capsule designed to prevent leakage or escape of the byproduct material. The facilities used sealed sources for equipment calibration, equipment testing, and cancer radiation therapy.[32]

Sealed-Source Inventory

Medical facility personnel properly maintained a complete sealed source inventory within established permit or license limits. According to the CFR, no person shall manufacture, produce, transfer, receive, acquire, own, possess, or use byproduct material except as authorized in a specific or general license.[33] Additionally, facilities must also conduct a semi-annual physical inventory of all sealed sources in their possession. DoD Instruction 6055.08 requires facilities to develop a complete inventory of radioactive materials. A radioactive material license or permit identifies the chemical/physical form and maximum quantity a facility is allowed to possess of each specific radioactive material. Personnel at each of the facilities conducted semi-annual physical inventory verifications within the scope of our audit. In addition, we conducted an inventory of at least three sealed sources sampled from each facility's sealed source inventory, and confirmed that each source was labeled with the proper serial number and maintained in the proper location.

Personnel at each of the facilities conducted semi-annual physical inventory verifications within the scope of our audit.

[31] 10 CFR sec. 20.1802 (1991), 20.1906 (1998), 20.2001 (2007), 20.1902 (1995), 20.1301 (2002), 20.1302 (1995), 20.1502 (1998), and 20.1201 (2007).

10 CFR sec. 30.3 (2007), 30.41 (1978), and 30.34 (2018).

10 CFR sec. 35.67 (2002), 35.92 (2007), 35.630 (2003), 35.61 (2002), 35.63 (2007), 35.40 (2018), and 35.41 (2018).

DoD Instruction 6055.08, "Occupational Ionizing Radiation Protection Program," August 31, 2018.

[32] Two of the eight medical facilities visited, Naval Medical Center Portsmouth and Walter Reed National Military Medical Center, had Radiation Oncology Departments and performed cancer radiation therapy.

[33] 10 CFR sec. 30.3 (2007).

Security of Sealed-Source Inventory

Medical facility personnel secured sealed sources from unauthorized removal or access. Federal law requires licensees to secure from unauthorized removal or access licensed materials that are stored in controlled or unrestricted areas.[34] Each of the medical facilities maintained security of sealed sources through badge control or cipher lock access to rooms where sealed sources were stored. Additionally, a sealed source at one of the facilities required increased controls.[35] The source was secured with two levels of authentication and a security alarm system.

Leak Tests on Sealed Sources

Personnel at five medical facilities complied with Federal timeliness requirements for sealed-source leak tests and conducted tests every 6 months. However, personnel at Eglin Air Force Base Hospital, William Beaumont Army Medical Center, and Landstuhl Regional Medical Center did not comply and conducted tests up to a few weeks beyond the prescribed interval.[36] Federal law requires licensees to test sealed sources for leakage before first use and at intervals not to exceed 6 months.

The following leak tests were not completed on time.

- Eglin Air Force Base Hospital conducted a leak test on November 2, 2018, that should have been conducted on October 16, 2018, and was 17 days late. According to medical facility personnel, they could not identify why the test was late as staff from October 2018 were no longer present at the facility; however, when results were returned to the facility on November 2, 2018, the tests passed.
- William Beaumont Army Medical Center conducted a leak test on March 27, 2019, that should have been conducted on March 19, 2019, and was 8 days late. According to facility personnel the leak test was late because the RSO had a high workload demand.
- Landstuhl Regional Medical Center conducted a leak test on November 27, 2018, that should have been conducted on October 26, 2018, and was 32 days late. According to medical facility personnel, the leak test was completed late because personnel experienced system access issues.

Not performing leak tests within the 6-month requirement could result in potential contamination and radiation exposure to facility personnel and the public. Although late, in each instance when the facility personnel leak tested the sealed sources the results were within acceptable limits; therefore, we did not

[34] 10 CFR sec. 20.1801 (1991).

[35] Licensees are required to implement enhanced security to control access to radioactive material in quantities of concern as defined by the International Atomic Energy Agency Code of Conduct on the Safety and Security of Radioactive Sources and adopted by the NRC.

[36] 10 CFR sec. 35.67 (2002).

identify any adverse impacts from the late leak tests. Personnel at Eglin Air Force Base Hospital, William Beaumont Army Medical Center, and Landstuhl Regional Medical Center completed all other leak tests within our audit scope in accordance with Federal law.

Medical Facility Personnel Properly Received and Disposed of Radioactive Materials

Medical facility personnel at all eight facilities ensured radioactive materials were received and disposed of in accordance with Federal regulations.[37] The eight medical facilities each had defined procedures for receiving radioactive materials, and most of the facilities used decay-in-storage to dispose of short-lived radiopharmaceuticals used in patient doses. According to the CFR, facilities may store material with a half-life of less than or equal to 120 days to allow the material to "decay-in-storage." Facilities then may dispose of the waste as ordinary trash or medical waste when tests show that the radiation levels are indistinguishable from normal background levels.[38]

Receipt of Radioactive Materials

Medical facility personnel complied with Federal regulations for receiving packages containing radioactive materials.[39] The CFR requires licensees to monitor external surfaces of packages for radiation levels of specific quantities and of all packages with evidence of degradation of package integrity, such as packages that are crushed, wet, or damaged. Each facility exceeded Federal requirements by monitoring the radiation level of external surfaces for all packages containing radioactive materials, not just packages required for monitoring by the CFR.

Disposal of Radioactive Materials

Medical facility personnel complied with Federal regulations for the disposal of radioactive materials.[40] The CFR allows facilities to dispose of licensed radioactive materials by using decay-in-storage procedures and transferring to an authorized recipient.

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37 10 CFR sec. 20.1906 (1998), 20.2001 (2007), and 35.92 (2007).

38 10 CFR sec. 35.92 (2007).

10 CFR Sec. 20.1003 (2009) defines distinguishable from background radiation as the detectable concentration of a radionuclide is statistically different from the background concentration of that radionuclide in the vicinity of the site, or, in the case of structures, in similar materials using adequate measurement technology, survey, and statistical techniques.

39 10 CFR sec. 20.1906 (1998).

40 10 CFR sec. 20.2001 (2007).

According to the CFR, a licensee may hold byproduct material with a physical half-life of less than or equal to 120 days for decay-in-storage before disposal without regard to its radioactivity if the licensee determines that its radioactivity cannot be distinguished from the background radiation level before disposal.[41] None of the eight facilities used radiopharmaceuticals with a half-life greater than or equal to 120 days. While all eight facilities used decay-in-storage procedures for waste contaminated through the administration of doses to patients, six of the medical facilities also used decay-in-storage procedures before disposing of patient dose syringes as regular trash.[42] Each of the facilities monitored all radioactive trash before disposal by performing surveys to obtain readings to ensure the radiation activity could not be distinguished from the background radiation level, and recorded those readings in a handwritten or electronic log. Three facilities (William Beaumont Army Medical Center, Naval Medical Center Portsmouth, and Walter Reed National Military Medical Center) also installed area radiation detectors near hospital exits or waste storage room doors to identify outgoing trash that had not yet been decayed to background levels.

Each of the facilities monitored all radioactive trash before disposal by performing surveys to obtain readings to ensure the radiation activity could not be distinguished from the background.

According to the CFR, a licensee may transfer radioactive waste to a recipient that is properly licensed to receive such waste.[43] Five of the facilities transferred radioactive waste to the original supplier for disposal in accordance with Federal regulations.[44] Of the five, two of the facilities (Eglin Air Force Base Hospital and Naval Hospital Pensacola) returned all patient dose syringes to the supplier for disposal, and the three other of the facilities (Landstuhl Regional Medical Center, Walter Reed National Military Medical Center, and William Beaumont Army Medical Center) transferred Technetium-99m generators to the original supplier after they decayed to background radiation levels. Facilities use Technetium-99m generators to extract the radiopharmaceutical for patient doses or as flood sources for gamma cameras.

41 10 CFR sec. 35.92 (2007).

42 NUREG 1556, Volume 9, Revision 3, and NUREG 1556, Volume 11, Revision 1, state that medical facilities may dispose of radioactive waste as regular trash if radiation levels are indistinguishable from background.

43 10 CFR sec. 20.2001 (2007) and 30.41 (1978).

44 10 CFR sec. 20.2001 and 35.92 (2007).

Medical Facility Personnel Performed Required Quality Control on Survey Instruments

Medical facility personnel at all facilities completed the required calibration on survey meters and quality control tests on dose calibrators and well counters. The medical facilities each maintained a varying number of instruments used to perform various required surveys, such as survey (dosimetry) meters, dose calibrators, and well counters. The frequency of calibration and quality control testing varies by survey instrument.

- **Survey –** an evaluation of the radiological conditions or presence of radioactive material.
- **Dosimetry –** a broad term commonly applied to the use of monitoring devices or other methods to measure and record radiation doses to individuals.
- **Dose Calibrators –** instruments that are used to measure the activity of a patient's dose before it is administered to ensure the dose is within a specific percentage of the prescribed dose.
- **Well Counters –** instruments that are used to perform Federally required leak tests and measure area wipes for radioactive contamination.

Survey Meters

Personnel at each medical facility each maintained calibrated survey instruments as required by the CFR.[45] The CFR requires facilities to calibrate survey instruments before first use, annually, and following a repair. The eight medical facilities used external calibration labs to maintain survey meter calibration. Each of the facilities submitted their survey meters for calibration on at least an annual basis. For example, equipment inventory at Joint Base Elmendorf–Richardson Hospital included a total of five survey meters and facility personnel provided a current calibration certificate for each of the meters.

[45] 10 CFR sec. 35.61 (2002).

Dose Calibrators and Well Counters

Medical facility personnel performed required quality control tests on dose calibrators and well counters. NRC guidance outlines a model procedure that provides acceptable methods for dose calibrator testing. The following tests should be performed on dose calibrators at the indicated frequency.[46]

- **Constancy Testing** is performed at least once each day before the instrument is used to measure patient doses. Constancy means reproducibility in measuring a constant source over a long period of time.
- **Linearity Testing** is performed at the installation and at least annually thereafter. Linearity means that the calibrator is able to indicate the correct activity over the range of use of that calibrator.
- **Geometry Testing** is performed at the installation. Geometry means that the indicated activity does not change based on the size and shape of the container being tested.
- **Accuracy Testing** is performed at the installation and at least annually thereafter. Accuracy means that, for a given calibrated reference source, the indicated activity value is equal to a pre-determined activity value.

The guidance also recommends that facilities calculate the efficiency of well counting equipment on an annual basis, before use, and after repair.[47]

All medical facility personnel performed the required quality control tests on dose calibrators at the required frequencies. Additionally, medical facility personnel at all facilities performed annual quality control tests on their well counters; however, Landstuhl Regional Medical Center could not provide evidence of all historical well counter quality control tests during the scope of the audit because the facility's well counter only stores the most recent test performed, which passed.

Additionally, although all facilities conducted quality control tests at least annually, Joint Base Elmendorf–Richardson Hospital, Naval Medical Center Portsmouth, and Elgin Air Force Base Hospital's nuclear medicine departments had instances where a well counter failed a quality control test. For example, while only required to test the well counter annually, personnel at Joint Base Elmendorf–Richardson Hospital tested their well counter more frequently. Specifically, facility personnel tested the well counter five times between February 2018 and February 2019, and of those, the quality control tests conducted in May and August 2018 failed, showing that the results may not be reproducible or accurate.

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[46] NUREG 1556, Volume 9, Revision 3.

The NRC guidance states that facilities may either adopt this model procedure or develop an alternative procedure in accordance with manufacturer's instructions or nationally recognized standard.

[47] NUREG 1556, Volume 9, Revision 3.

While medical personnel at Joint Base Elmendorf–Richardson Hospital did not take action at the time to determine why the tests failed, the instrument passed the required annual tests. Facility personnel later stated that the tests likely failed because an unsealed source was present in the room or personnel were preparing a patient dose at the time the quality control tests were conducted. We did not identify any adverse impacts from the failed quality controls tests.

In a separate instance at Eglin Air Force Base, a backup well counter failed a quality test and personnel immediately replaced the instrument. Existing NRC guidance does not address what actions medical facilities should take when well counter quality control tests fail. Without guidance on what medical facility personnel should do when quality control tests fail, the medical facilities may not have reasonable assurance that personnel are using properly functioning instruments to survey packages, sealed sources, and areas where unsealed byproduct material is prepared for potential contamination. Therefore, the DHA should implement supplemental guidance to instruct the medical facilities on appropriate steps to take after a failed quality control test to ensure instruments are properly calibrated.

William Beaumont Army Medical Center personnel, for example, connected their dose calibrator and well counter to their nuclear medicine information systems and dose calibration and measurement results were auto populated and saved within the systems. Having a process in place to automatically collect calibration results, in addition to any hardcopy records the facility retains, helps the medical facility maintain complete and accurate records for the patient doses measured. If this functionality could be applied at all medical facilities, as well as having the nuclear medicine information systems collect quality control test results, it would help ensure the medical facilities maintained complete and accurate records of the quality control tests conducted on dose calibrators and well counters, and support the instruments are properly calibrated. Therefore, the DHA should conduct a study to determine the benefits and feasibility of directly connecting the nuclear medicine information systems at each medical facility to the facility's dose calibrators and well counters to improve data quality and ensure the facilities maintain calibrated survey instruments and the associated calibration records.

Medical Facility Personnel Demonstrated Compliance With Radiation Dose Limits to Members of the Public

Medical facility personnel confined possession and use of radioactive materials to authorized areas, while also demonstrating compliance with radiation dose limits to members of the general public. The CFR requires facilities to confine possession and use of radioactive materials to the locations and purposes authorized by its

license, and it requires facilities to post signs at each radiation area to identify that radioactive materials may be used or stored.[48] The CFR also establishes dose limits to individual members of the public, and requires facilities to perform surveys of radiation levels in radiation areas to demonstrate compliance with the dose limits.[49] DoD Instruction 6055.08 requires facilities to develop a list of locations where radioactive materials are used, stored, or disposed. Specifically, medical facility personnel:

- developed lists of locations where radioactive materials were used or stored;
- confined possession and use of radioactive materials to the areas identified by the lists and authorized by their licenses and permits; and
- posted appropriate signs at all areas where radioactive materials were used or stored. Specifically, during all facility walk-throughs, we observed that signs bearing the radiation symbol and the appropriate caution wording were posted in all required areas or rooms.[50]

In addition, medical facility personnel demonstrated compliance with established dose limits for members of the public by performing daily surveys and conducting weekly wipe tests in areas where radioactive materials were used or stored to identify potential contamination. Four facilities (Naval Hospital Camp Pendleton, Naval Hospital Pensacola, Naval Medical Center Portsmouth, and Eglin Air Force Base Hospital) also posted dosimeters to monitor areas where members of the public might encounter radiation exposure. All of the radiation exposure results for the posted dosimeters were below the established dose limits.

Medical Facility Personnel Measured and Recorded Patient Doses and Issued Required Written Directives

Medical facility personnel measured and recorded doses before medical use, and they issued written directives for required procedures.[51] The CFR requires the licensees to determine and record the activity of each dose before medical use, and retain a record of the dose determination for 3 years.[52] In addition, the CFR states that an authorized user must date and sign a written directive before the administration of Iodine-131 greater than 30 microcuries and the licensee shall

[48] 10 CFR sec. 30.34 (2018) and 20.1902 (1995).

[49] 10 CFR sec. 20.1301 (2002) and 20.1302 (1995).

[50] 10 CFR sec. 20.1902 (1995).

[51] 10 CFR sec. 35.2 (2018) defines a written directive as an authorized user's written order for the administration of byproduct material or radiation from byproduct material to a specific patient or human research subject.

Only five of the eight facilities performed procedures that required them to issues written directives, while the other three did not perform procedures requiring written directives.

[52] 10 CFR sec. 35.63 (2007).

retain a copy of the written directive.[53] Lastly, for any administration requiring a written directive, the licensee shall develop, implement, and maintain written procedures to provide high confidence that the identity of the patient or human research subject is verified before each administration, and each administration follows with the written directive.[54]

Personnel at each facility used a dose calibrator to obtain a reading of the dose activity before administering patient doses and recorded the readings in their nuclear medicine information system.

Personnel at each facility used a dose calibrator to obtain a reading of the dose activity before administering patient doses and recorded the readings in their nuclear medicine information system. Additionally, all facilities issued written directives as required before administering Iodine-131 doses. For example, Landstuhl Regional Medical Center performed 13 Iodine-131 procedures during the scope of the audit and prepared and maintained a written directive for each dose.

Medical Facility Personnel Limited Occupational Exposure

Medical facility personnel limited occupational radiation exposure for all nuclear medicine department personnel to the radiation exposure limits. The CFR requires licensees to monitor exposure to radiation for all occupational employees likely to receive, in 1 year, a dose in excess of 10 percent of the annual exposure limits.[55] In addition, DoD Instruction 6055.08 and the CFR require facilities to maintain records of occupational radiation exposure results.[56]

Medical facility personnel monitored radiation exposure for all nuclear medicine department personnel. Furthermore, the facilities maintained and updated radiation exposure records at least annually. According to the exposure records, no nuclear medicine department employees at the eight medical facilities were exposed to ionizing radiation that exceeded the defined exposure limits.

While medical facility personnel maintained radiation exposure records, several facilities experienced delays in receiving processed radiation exposure data. Each Military Service has a dosimetry center that processes periodic radiation exposure results for the medical facilities based on submitted dosimetry badges. The Air Force dosimetry center returns radiation exposure results within weeks

[53] 10 CFR sec. 35.40 (2018).

The NRC defines microcurie as an amount of radioactive material which disintegrates at a rate of 37 thousand atoms per second.

[54] 10 CFR sec. 35.41 (2018).

[55] 10 CFR sec. 20.1502 (1998) and 20.1201 (2007).

[56] 10 CFR sec. 20.2106 (1998).

of receiving the dosimeters from the facilities. However, the Army has an estimated processing time of 3 to 6 months, while the Navy has an estimated 5-month processing time before the dosimetry centers return radiation exposure results to the medical facilities. For example, William Beaumont Army Medical Center did not receive radiation exposure results until May 2019 for a monitoring period ending in January 2019. The significant delays in obtaining exposure results may increase the risk of employees exceeding federally defined exposure limits. Therefore, the DHA should review and revise the dosimetry processing procedures that record and measure radiation exposure to occupational employees to ensure timely feedback is provided to all medical facilities so adjustments can be made to reduce the risk of personnel exceeding radiation exposure limits.

Additionally, dosimetry records showed that multiple employees received occupational doses below the 10-percent threshold of the CFR defined exposure limits.[57] For example, William Beaumont Army Medical Center monitored seven technicians from the nuclear medicine department for occupational exposure and none of the technicians received exposures exceeding 10 percent of the defined limits. Monitoring these employees may be unnecessary and could contribute to the increased delays in providing exposure results to the medical facilities and employees. Therefore, the DHA should review the occupational dosimetry program to identify potential workload efficiencies and consider limiting monitoring to only those individuals likely to be exposed to radiation within the Federally defined standards to reduce unnecessary dosimetry center workload.

Conclusion

In conclusion, DoD medical facility management properly trained personnel, conducted inspections and program reviews, and accounted for inventory levels for the safety and security of radioactive materials at the eight facilities. However, DHA management requested that we identify best practices for their consideration as they assume administration and management responsibility of all medical facilities. We identified three areas that DHA management could implement organizational improvements to further strengthen controls over the safety and security of radioactive materials and gain potential cost savings and resource efficiencies. Specifically, we identified potential process changes and improvements related to external audits and sharing best practices across the medical facilities, improving data quality related to calibration records, and promoting efficiency in dosimetry processing procedures.

[57] 10 CFR sec. 20.1502 (1998) and 20.1201 (2007).

Recommendations, Management Comments, and Our Response

Recommendation 1

We recommend that the Defense Health Agency Director:

a. Coordinate and conduct external audits among medical facility Radiation Safety Officers to expedite the sharing of best practices across the Services and individual medical facilities. Additionally, the Defense Health Agency should consider developing a database or repository for inspecting Radiation Safety Officers to input information on best practices and lessons learned through external audits for medical facility personnel to review for potential best practices or process improvements that may be implemented.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that DHA Administrative Instruction 087, "Radiation Safety Program (RSP) and Radiation Safety Committee (RSC)," August 1, 2019, requires medical facilities to receive both internal and external audits. The Director also stated that Headquarters DHA Health Physics Staff conduct the external audits, have experience with multiple programs of various scopes, and are more likely to identify best practices and deficiencies. The Director stated that RSOs at each facility are members of the DHA Radiation Safety Committee and discuss the results of external audits, including best practices, at committee meetings.

Our Response

Comments from the DHA Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides documentation related to current procedures for conducting external audits and sharing best practices among medical facility RSOs.

b. Implement supplemental guidance to instruct the medical facilities on appropriate steps to take after a failed quality control test to ensure survey instruments are properly calibrated.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA will provide specific guidance in the next edition of DHA Administrative Instruction 087. Specifically, the Director stated that if a dose calibrator fails a quality control test, medical facility personnel should investigate the cause and repeat the test. Repeated failure may indicate a needed repair.

Our Response

Comments from the DHA Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides an updated copy of DHA Administrative Instruction 087 that includes guidance addressing failed quality control tests.

c. Conduct a study to determine the benefits and feasibility of directly connecting the nuclear medicine information system at the medical facilities to their dose calibrators and well counters to improve data quality and ensure the facilities maintain calibrated survey instruments and the associated calibration records.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, but stated that implementing the recommendation may be problematic because of information technology concerns on the DoD network.

Our Response

Comments from the DHA Director did not address the specifics of the recommendation; therefore, the recommendation is unresolved. Although the Director agreed with the recommendation, he did not provide a plan of action for conducting a study to determine the benefits and feasibility of directly connecting the nuclear medicine information system at the medical facilities to their dose calibrators and well counters. The Director mentioned potential information technology concerns related to implementing the recommendation but did not provide any details on those concerns. We request that the DHA Director provide additional comments in response to the final report that resolve the recommendation. The Director should provide an estimated completion date for the action.

d. Review and revise, as necessary, the dosimetry processing procedures that record and measure radiation exposure to occupational employees to ensure timely feedback is provided to all medical facilities so adjustments can be made to reduce the risk of personnel exceeding radiation exposure limits.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating that the DHA is evaluating DoD dosimetry programs in order to select the most efficient system. The DHA Director also stated that the Naval Dosimetry Center and the Army Dosimetry Center are improving their processing times. Specifically, the Army Dosimetry System reduced their processing time from 6 months to 28 days.

Our Response

Comments from the DHA Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once we verify that the DHA has implemented a dosimetry system that provides timely feedback to all medical facilities. The Director should provide an estimated completion date for the action.

e. Review the occupational dosimetry program to identify potential workload efficiencies and consider limiting monitoring to only those individuals likely to be exposed to radiation with the Federally defined standards in order to reduce unnecessary dosimetry center workload.

Defense Health Agency Comments

The DHA Director agreed with the recommendation, stating the DoD provides dosimetry at approximately the same level as civilian hospitals. The Director also stated that the NRC, the Joint Commission, and other organizations use the results of personal dosimetry to evaluate facility efforts to maintain radiation doses as low as reasonably achievable. The Director stated that the DHA agrees that some individuals are unlikely to receive a measureable dose and could be removed from the dosimetry program, but a significant departure from current standards may contradict established radiation safety regulations and portray that the agency is not concerned with radiation safety.

Our Response

Comments from the DHA Director addressed all specifics of the recommendation; therefore, the recommendation is resolved but will remain open. We will close the recommendation once the DHA provides documentation showing actions taken to identify workload efficiencies within the dosimetry program.

Appendix A

Scope and Methodology

We conducted this performance audit from July 2019 through March 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

There are 32 medical facilities and 1 training facility within the DoD that possess and use radioactive materials for medical purposes. We nonstatistically selected seven medical facilities based on location, size and DHA transition phase to conduct site visits, obtain documentation and interview personnel. In addition, we visited Naval Medical Center Portsmouth because the DHA requested we review the facility because it possessed Category 2 radioactive material. Specifically, we visited the following eight facilities.

Continental United States

- William Beaumont Army Medical Center, Texas
- Naval Hospital Pensacola, Florida
- Naval Hospital Camp Pendleton, California
- Naval Medical Center Portsmouth, Virginia
- Eglin Air Force Base Hospital, Florida
- Walter Reed National Military Medical Center, Maryland

Outside the Continental United States

- Joint Base Elmendorf–Richardson Hospital, Alaska
- Landstuhl Regional Medical Center, Germany

Review of Documentation and Interviews

To observe daily procedures and obtain information and documentation related to the safety and security of radioactive materials at the medical facilities, we conducted site walk-throughs and interviewed personnel from the DHA, Army, Navy, Air Force and the NCR-MD. Through our reviews of the medical facilities, we reviewed and assessed areas in training, inspections and program reviews, inventory, and safety.

Training

We reviewed documents related to RSO and authorized user training, including the facilities' permits or licenses and NRC Forms 313A. We also reviewed documents on radiation safety training of occupational employees, including training certifications, radiation safety training material, and local training records. We reviewed documentation supporting training from January 2018 through June 2019.

Inspections and Program Reviews

We reviewed documents related to inspections and program reviews, including facility specific standard operating procedures and instructions, the facility permits or licenses, internal and external audits, and Radiation Safety Committee documents. Additionally, we examined corrective actions for any deficiencies identified by inspections and program reviews. We reviewed documentation supporting inspections and program reviews from January 2016 through June 2019.

Inventory

We observed sealed-source inventories and observed access controls to areas where radioactive materials were stored or used. We also selected a sample of at least three sealed sources from each facility's sealed-source inventory, and confirmed that each source was labeled with the proper serial number and maintained in the proper location. We examined the following documents related to radioactive material inventory at each facility, including:

- Facility specific standard operating procedures and instructions
- Facility permits or licenses
- Radioactive material receiving and disposal reports
- Patient dose reports
- Leak test results

Additionally, we examined test history for each facility's dose calibrators, well counters, and other dosimetry equipment. We reviewed documentation supporting radioactive material inventory from January 2018 through June 2019.

Safety

We observed posted radiation signs around locations where radioactive materials were used or stored. We examined documents demonstrating occupational and public safety from radiation exposure at each facility, including facility specific standard operating procedures, facility permits or licenses, area surveys, area wipe tests, public dose surveys, and occupational exposure reports. Additionally,

we examined documents related to patient safety, including patient dose reports, written directives, and reported medical events. We reviewed documentation supporting radiation safety from January 2018 through June 2019.

Criteria

We evaluated the documentation provided by each medical facility according to the following Federal and DoD criteria.

- 10 CFR sec. 19.12 (1995)
- 10 CFR sec. 20.1003 (2009), 20.1101 (1998), 20.1201 (2007), 20.1301 (2002), 20.1302 (1995), 20.1502 (1998), 20.1801 (1991), 20.1802 (1991), 20.1902 (1995), 20.1906 (1998), 20.2001 (2007), 20.2102 (1991), and 20.2106 (1998)
- 10 CFR sec. 30.3 (2007), 30.34 (2018), and 30.41 (1978)
- 10 CFR sec. 35.2 (2018), 35.24 (2018), 35.40 (2018), 35.41 (2018), 35.50 (2018), 35.51 (2018), 35.55 (2018), 35.59 (2006), 35.61 (2002), 35.63 (2007), 35.67 (2002), 35.92 (2007), 35.630 (2003), and 35.633 (2002)
- 10 CFR sec. 71.5 (2004)
- 49 CFR sec. 172.702 (1996) and 172.704 (2015)
- NUREG 1556, Volume 9, Revision 3, "Program-Specific Guidance about Medical Use Licenses" November 2016
- NUREG 1556, Volume 11, Revision 1, "Program-Specific Guidance About Licenses of Broad Scope" February 2017
- DoD Instruction 6055.08, "Occupational Ionizing Radiation Protection Program," August 31, 2018

Use of Computer-Processed Data

We used computer-processed data from the information systems at the medical facilities to perform this audit, including survey results and reports for patient doses, radioactive material inventories, and radioactive material receipt and disposal. To test the reliability of the data, we interviewed medical facility personnel responsible for the data and when possible, compared the data to what we observed at the medical facilities. Additionally, routine inspections and program audits at the medical facilities add assurance that the computer-processed data were sufficiently reliable for our purposes.

Prior Coverage

No prior coverage has been conducted on safety and security of radioactive materials at medical facilities during the last 5 years.

Appendix B

The table shows the 33 DoD medical facilities that have radioactive materials.

Military Service	Medical Facility	State or Country
Army	Womack Army Medical Center	North Carolina
	Eisenhower Army Medical Center	Georgia
	Moncrief Army Health Clinic	South Carolina
	Martin Army Community Hospital	Georgia
	Blanchfield Army Community Hospital	Kentucky
	Ireland Army Health Clinic	Kentucky
	Darnall Army Medical Center	Texas
	Reynolds Army Health Clinic	Oklahoma
	Brooke Army Medical Center	Texas
	William Beaumont Army Medical Center	Texas
	Evans Army Community Hospital	Colorado
	General Leonard Wood Army Community Hospital	Missouri
	Madigan Army Medical Center	Washington
	Tripler Army Medical Center	Hawaii
	Landstuhl Regional Medical Center	Germany
Navy	Naval Hospital Jacksonville	Florida
	Naval Medical Center Portsmouth	Virginia
	Naval Medical Center Camp Lejeune	North Carolina
	Naval Hospital Pensacola	Florida
	Naval Medical Center San Diego	California
	Naval Hospital Bremerton	Washington
	Naval Hospital Camp Pendleton	California
	Naval Hospital Guam	Guam
	Naval Hospital Okinawa	Japan
Air Force	Keesler Medical Center	Mississippi
	Wright-Patterson Air Force Base Medical Center	Ohio
	Eglin Air Force Base Hospital	Florida
	Mike O'Callaghan Federal Medical Center	Nevada
	Joint Base Elmendorf-Richardson Hospital	Alaska
	David Grant USAF Medical Center	California

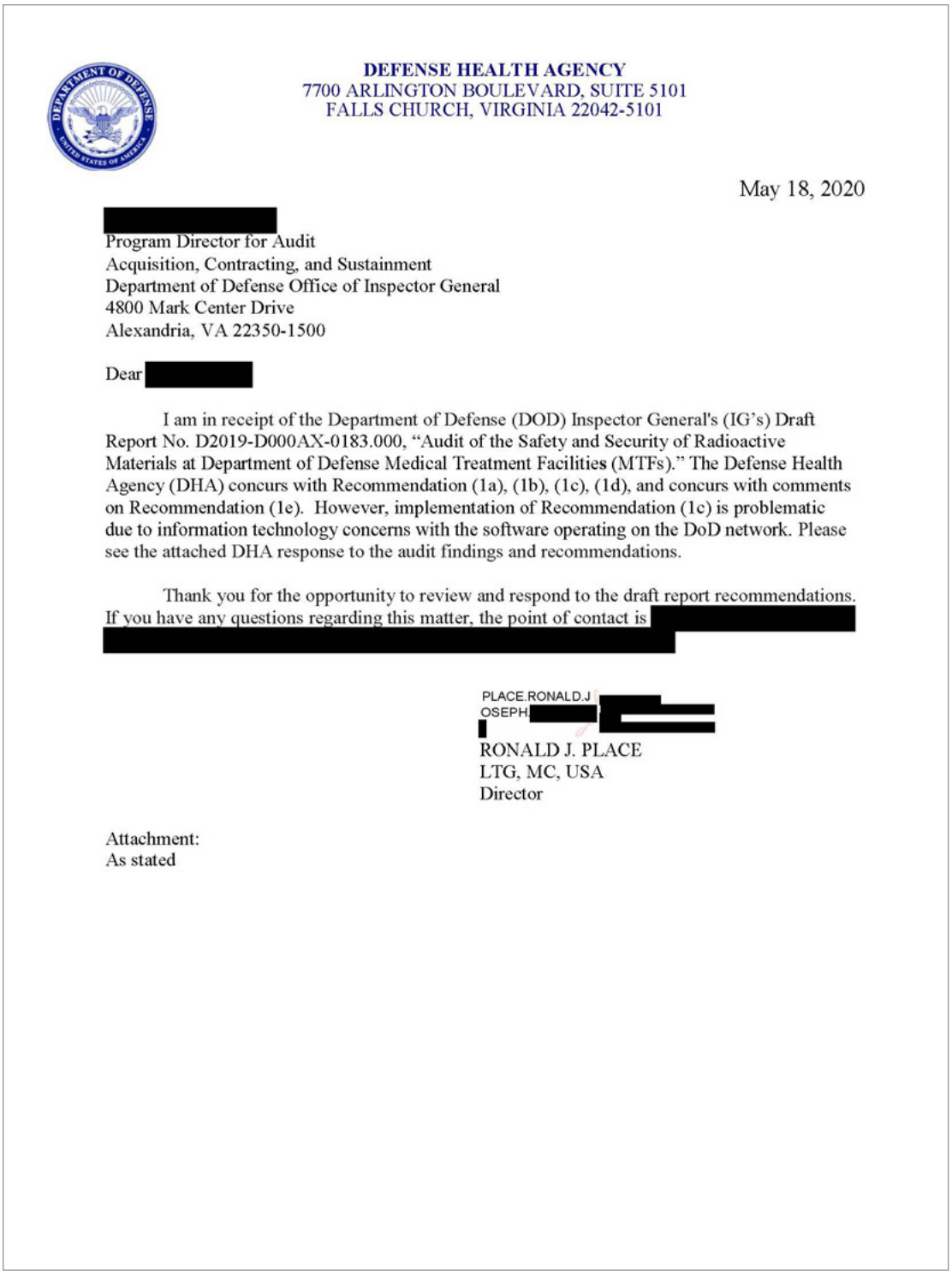
DoD medical facilities with radioactive materials (cont'd)

Military Service	Medical Facility	State or Country
NCR-MD	Walter Reed National Military Medical Center	Maryland
	Fort Belvoir Community Hospital	Virginia
Training	Medical Education and Training Campus	Texas

Source: The Defense Health Agency.

Management Comments

Defense Health Agency



DEFENSE HEALTH AGENCY
7700 ARLINGTON BOULEVARD, SUITE 5101
FALLS CHURCH, VIRGINIA 22042-5101

May 18, 2020

[redacted]
Program Director for Audit
Acquisition, Contracting, and Sustainment
Department of Defense Office of Inspector General
4800 Mark Center Drive
Alexandria, VA 22350-1500

Dear [redacted]

I am in receipt of the Department of Defense (DOD) Inspector General's (IG's) Draft Report No. D2019-D000AX-0183.000, "Audit of the Safety and Security of Radioactive Materials at Department of Defense Medical Treatment Facilities (MTFs)." The Defense Health Agency (DHA) concurs with Recommendation (1a), (1b), (1c), (1d), and concurs with comments on Recommendation (1e). However, implementation of Recommendation (1c) is problematic due to information technology concerns with the software operating on the DoD network. Please see the attached DHA response to the audit findings and recommendations.

Thank you for the opportunity to review and respond to the draft report recommendations. If you have any questions regarding this matter, the point of contact is [redacted]

PLACE.RONALD.J
OSEPH[redacted]

RONALD J. PLACE
LTG, MC, USA
Director

Attachment:
As stated

Defense Health Agency (cont'd)

DEPARTMENT OF DEFENSE INSPECTOR GENERAL DISCUSSION DRAFT REPORT UNDATED
PROJECT NUMBER D2019-D000AX-0183.000

"AUDIT OF THE SAFETY AND SECURITY OF RADIOACTIVE MATERIALS AT DEPARTMENT OF DEFENSE MEDICAL TREAMENT FACILITIES"

Defense Health Agency Comments to the Inspector General Recommendations

RECOMMENDATION 1a: Coordinate and conduct external audits among medical facility Radiation Safety Officers to expedite the sharing of best practices across the Services and individual medical facilities. Additionally, the Defense Health Agency (DHA) should consider developing a database or repository for inspecting Radiation Safety Officers to input information on best practices and lessons learned through external audits for medical facility personnel to review for potential best practices or process improvements that may be implemented.

RESPONSE: DHA concurs with this recommendation. DHA Administrative Instruction (AI) 087, Radiation Safety Program and Radiation Safety Committee (RSC), requires internal and external audits. The external audits are conducted by members of the Headquarters DHA Health Physics Staff who have the advantage of experience and exposure to multiple programs of various scopes of practice. These inspectors are much more likely to identify best practices and deficiencies. Results of external audits, to include best practices, are discussed at the DHA RSC Meetings, the radiation safety officers at each of the sites are members of this committee.

RECOMMENDATION 1b: Implement supplemental guidance to instruct the medical facilities on appropriate steps to take after a failed quality control test to ensure survey instruments are properly calibrated.

RESPONSE: DHA concurs with this recommendation and will provide specific guidance in the next edition of DHA AI 087. Facilities have multiple hand held instruments for conducting surveys and any of these instruments that fail quality control test should be immediately taken out of service and sent for repair. However, most facilities have only one or two dose calibrators. If a dose calibrator fails any of the quality control tests, the cause is investigated and the test repeated. Repeated failure may indicate a need for repair. Title 10 Code of Federal Regulations 35.63 allows the facility utilize radiopharmaceuticals based on the manufacturers stated activity (corrected for decay).

RECOMMENDATION 1c: Conduct a study to determine the benefits and feasibility of directly connecting the nuclear medicine information system at the medical facilities to their dose calibrators and well counters to improve data quality and ensure the facilities maintain calibrated survey instruments and the associated calibration records.

RESPONSE: DHA concurs with this recommendation; however, implementing this action is problematic due to information technology concerns with the software operating on the Department of Defense (DoD) network.

Defense Health Agency (cont'd)

RECOMMENDATION 1d: Review and revise, as necessary, the dosimetry processing procedures that record and measure radiation exposure to occupational employees to ensure timely feedback is provided to all medical facilities so adjustments can be made to reduce the risk of personnel exceeding radiation exposure limits.

RESPONSE: DHA concurs with this recommendation and is evaluating the different DoD dosimetry programs in order to select the optimal system for all personnel. At this time, DHA is in coordination with the United States Air Force School of Aerospace Medicine radioanalytical and dosimetry laboratory services for possible radiation dosimetry services at all its Medical Treatment Facilities. The Naval Dosimetry Center is improving its processing time and the Army Dosimetry Center has indicated they have reduced the process time from the stated three to six months to 28 days.

RECOMMENDATION 1e: Review the occupational dosimetry program to identify potential workload efficiencies and consider limiting monitoring to only those individuals likely to be exposed to radiation with the federally defined standards in order to reduce unnecessary dosimetry center workload.

RESPONSE: DHA concurs with comments with this recommendation. The Nuclear Regulatory Commission, the Joint Commission, and other organizations use the results of personal dosimetry to evaluate facilities' efforts to maintain radiation doses As Low as Reasonably Achievable. If dosimetry is not provided at a level significantly lower than the Federal (and DHA) "required" limits, then it is much more difficult to demonstrate compliance. In addition, history with atomic veterans suggest that the current cost of dosimetry may be much less than the future cost for claims of individuals who worked around radiation and exposure records don't exit. DHA agrees that some individual are highly unlikely to receive a measureable dose and could be removed from the dosimetry program. The DoD currently provides dosimetry at approximately the same level as civilian hospitals. A significant departure from this standard-of-care may contradict established radiation safety regulations and give the impression that the agency is not concerned with radiation safety.

2

Acronyms and Abbreviations

CFR	Code of Federal Regulation
DHA	Defense Health Agency
NCR-MD	National Capital Region–Medical Directorate
NRC	Nuclear Regulatory Commission
NUREG	Nuclear Regulatory Commission Regulation
RSO	Radiation Safety Officer

Glossary

As low as (is) reasonably achievable (ALARA). ALARA means making every reasonable effort to maintain exposures to ionizing radiation as far below the dose limits as practical, consistent with the purpose for which the licensed activity is undertaken, taking into account the state of technology, the economics of improvements in relation to state of technology, the economics of improvements in relation to benefits to the public health and safety, and other societal and socioeconomic considerations, and in relation to utilization of nuclear energy and licensed materials in the public interest.

Authorized User. A physician, dentist, or podiatrist who is identified as an authorized user on: (1) a Commission license that authorizes the medical use of byproduct material; (2) a permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material; (3) a permit issued by a Commission specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or (4) a permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material. A person named as an authorized user on an NRC license is responsible for ensuring that radioactive materials are handled and used safely and in accordance with NRC regulations.

Brachytherapy. A nuclear medicine procedure during which a sealed radioactive source is implanted directly into a person being treated for cancer (usually of the mouth, breast, lung, prostate, ovaries, or uterus). The radioactive implant may be temporary or permanent, and the radiation attacks the tumor as long as the device remains in place. Brachytherapy uses radioisotopes, such as iridium-192 or iodine-125, which are regulated by the NRC and its Agreement States.

Byproduct material. Any radioactive material (except enriched uranium or plutonium) produced by a nuclear reactor.

Curie. One of three units used to measure the intensity of radioactivity in a sample of material. This value refers to the amount of ionizing radiation released when an element (such as uranium) spontaneously emits energy as a result of the radioactive decay (or disintegration) of an unstable atom.

Decay. The spontaneous transformation of one radioisotope into one or more different isotopes (known as “decay products” or “daughter products”), accompanied by a decrease in radioactivity (compared to the parent material).

Dose Calibrator. An instrument used to measure the activity of an unsealed byproduct material before it is administered to each patient.

Dosimeter. A small portable instrument (such as a film badge, thermoluminescent dosimeter, or pocket dosimeter) used to measure and record the total accumulated personal dose of ionizing radiation.

Dosimetry. The theory and application of the principles and techniques involved in measuring and recording doses of ionizing radiation.

Exposure. Absorption of ionizing radiation or ingestion of a radioisotope.

Half-life. The time in which one half of the atoms of a particular radioactive substance disintegrate into another nuclear form.

Occupational Employee. Individuals within the military treatment facilities who interact with radioactive material on a regular basis and may have their exposure tracked by the Army, Navy, or Air Force dosimetry centers.

Patient Dose. The activity or range of diagnostic activities specified by an authorized user to be administered to a patient in either a written directive or in the directions for diagnostic procedures.

Radiation Safety Officer (RSO). An individual who is identified as a Radiation Safety Officer on a specific medical use license issued by the Commission or a medical use permit issued by a Commission master material license. The RSO must ensure that the licensee's radioactive material is used and stored safely and securely according to approved policies and procedures, and that all regulatory requirements are met.

Radioactivity. The process possessed by some elements (such as uranium) of spontaneously emitting energy in the form of radiation as a result of the decay (or disintegration) of an unstable atom.

REM (Roentgen equivalent man). One of the two standard units used to measure the dose equivalent (or effective dose), which combines the amount of energy (from any type of ionizing radiation that is deposited in human tissue), along with the medical effects of the given type of radiation.

Sealed Source. Any radioactive material or byproduct encased in a capsule designed to prevent leakage or escape of the material.

Survey. An evaluation of the radiological conditions and potential hazards incident to the production, use, transfer, release, disposal, or presence of radioactive material or other sources of radiation. When appropriate, such an evaluation includes a physical survey of the location of radioactive material and measurements or calculations of levels of radiation, or concentrations or quantities of radioactive material present.

Teletherapy. Treatment in which the source of the therapeutic radiation is at a distance from the body. Because teletherapy is often used to treat malignant tumors deep within the body by bombarding them with a high-energy beam of gamma rays (from a radioisotope such as cobalt-60) projected from outside the body, it is often called "external beam radiotherapy."

Well-Counter. An instrument used for performing leak tests and measuring wipe samples from surveys for radioactive contamination.

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