OFFICE OF INSPECTOR GENERAL

U.S. Department of Energy

AUDIT REPORT

DOE-OIG-24-32 September 2024

NNSA'S OFFICE OF SECURE TRANSPORTATION AND THE STRATEGIC SURVIVABILITY RESEARCH GROUP, LLC DID NOT VIOLATE MEDICAL ETHICS OR TRAINING REQUIREMENTS AS ALLEGED

Department of Energy
Washington, DC 20585

September 25, 2024

MEMORANDUM FOR THE ADMINISTRATOR, NATIONAL NUCLEAR SECURITY ADMINISTRATION

SUBJECT: Audit Report: *NNSA's Office of Secure Transportation and the Strategic Survivability Research Group, LLC Did Not Violate Medical Ethics or Training Requirements as Alleged*

The attached report discusses our audit of allegations related to health and safety at the National Nuclear Security Administration's Office of Secure Transportation (OST). We did not substantiate the health and safety practice allegations of medical negligence by OST and Strategic Survivability Research Group, LLC (2SRG) officials. Specifically, we found that the OST and 2SRG's allowance of expired controlled substances in active inventory was not a violation of medical ethics in the circumstances. We also found that 2SRG provided the required number of trainings for OST Federal Agent medics to maintain their *Emergency Medical Technician* certification. This report does not contain recommendations or suggested actions. Therefore, no management response is required.

We conducted this audit from March 2024 through September 2024 in accordance with generally accepted government auditing standards. We appreciated the cooperation and assistance received during this audit.

John E. McCoy II
Deputy Assistant Inspector General
for Audits
Office of Inspector General

cc: Deputy Secretary
Chief of Staff

Department of Energy
Office of Inspector General

NNSA's Office of Secure Transportation and the Strategic Survivability Research Group, LLC Did Not Violate Medical Ethics or Training Requirements as Alleged

(DOE-OIG-24-32)

WHY THE OIG PERFORMED THIS AUDIT

The Office of Inspector General received a hotline complaint that contained multiple allegations regarding the National Nuclear Security Administration's Office of Secure Transportation (OST). Specifically, the complaint alleged that: (1) the OST violated medical ethics by allowing the use of expired controlled substances; (2) the OST contractor, Strategic Survivability Research Group, LLC (2SRG), did not provide *Tactical Combat Casualty Care* certification; and (3) training required by the OST to maintain certification had been canceled.

We initiated this audit to determine the validity of the allegations that the OST violated medical ethics and did not meet training requirements.

What Did the OIG Find?

We did not substantiate the health and safety practice allegations alleging medical negligence by OST and 2SRG officials. Specifically, we found that: (1) the OST and 2SRG allowance of expired controlled substances in active inventory was not a violation of medical ethics in the circumstances; (2) the OST did not require 2SRG to provide Federal Agent medics with *Tactical Combat Casualty Care* certification; and (3) 2SRG provided all the training required by the OST for Federal Agent medics to maintain certification.

What Is the Impact?

Because we did not substantiate any of the allegations, there is no impact related to the reported concerns.

What Is the Path Forward?

We did not identify any issues that need to be addressed. Therefore, we made no recommendations or suggested actions.

BACKGROUND

The Department of Energy's National Nuclear Security Administration (NNSA) is responsible for maintaining and enhancing the safety, security, and effectiveness of the U.S. nuclear weapons stockpile. To help fulfill this responsibility, NNSA established the Office of Secure Transportation (OST), which ensures the safe and secure transportation of nuclear weapons, their components, and special nuclear material by both ground and air. Within the OST, Federal Agents (FAs) are tasked with transporting these materials and are authorized to use deadly force, if necessary, to prevent theft, sabotage, or takeover of protected materials by unauthorized persons or groups.

Given the high-risk nature of its work, the OST requires that FAs are proficient in emergency medical care to respond to attacks or accidents and to maintain their general health on duty and during travel. The OST has contracted with the Strategic Survivability Research Group, LLC (2SRG) to provide training and medical direction for the OST Operational Medical Support Program. The Operational Medical Support Program, through 2SRG, trains up to 50 selected FAs annually to serve as FA medics. These FA medics are authorized to provide medical treatment under the supervision of 2SRG's Medical Director, which includes administering controlled substances[1]. In addition, the 2SRG contract states that the contractor shall track expiration dates of medicines and replace expired items as needed after obtaining Contracting Officer Representative's approval. If the contractor fails to replace controlled medications prior to the expiration date, the contractor must show proof the medication is unavailable. Furthermore, the American Medical Association Principles of Medical Ethics helps ensure that patients have access to necessary medical care, which includes controlled substances. The 2SRG contract also requires the contractor to provide all required FA medic training.

In addition to the contract with 2SRG, the OST has established controls to help ensure both proper FA medic training and the handling of controlled substances. Specifically, the *National Nuclear Security Administration Office of Secure Transportation Medical Standard Operating Procedures* limit access of controlled substances to Lead Medics and requires controlled substances to be stored in designated safe drawers with separate dedicated space for expired medication until it can be disposed of in accordance with Drug Enforcement Administration requirements. The *National Nuclear Security Administration Office of Secure Transportation Medical Standard Operating Procedures* also contain the training requirements to be an FA medic.

In May 2023, the Office of Inspector General received an anonymous health and safety complaint alleging medical negligence by OST and 2SRG officials. Specifically, the complainant alleged that the OST and 2SRG engaged in medical negligence by allowing the use of controlled substances that were expired for more than 4 years despite concerns expressed by FA medics. In addition, the complainant stated that there was no OST FA medic who had been certified through the National Association of Emergency Medical Technicians *Tactical Combat*

[1]21 United States Code §802, Chapter 13, states that a controlled substance is a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of Part B of the cited subchapter. OST controlled substances include Schedules 2, 3, and 4, which consist of Fentanyl (Schedule 2), Hydrocodone (Schedule 2), Ketamine (Schedule 3), and Midazolam (Schedule 4).

Casualty Care, and that required training was cancelled. As a result, the complainant alleged that 2SRG did not provide adequate opportunity for FA medics to maintain their *Emergency Medical Technician* certification. Due to these allegations, we conducted this audit to determine the validity of the allegations that the OST violated medical ethics and did not meet training requirements.

VIOLATION OF MEDICAL ETHICS ALLEGATION

The OST did not violate medical ethics by allowing FA medics to use controlled substances beyond the expiration date because the 2SRG Medical Director authorized the use of expired controlled substances in instances when the medication was unavailable. The U.S. Food and Drug Administration, when appropriate (such as a national emergency), can allow certain medical products (including controlled substances) to be used beyond their manufacturer-labeled expiration dates. Additionally, the contract between the OST and 2SRG authorizes the 2SRG Medical Director emergency use authorization of expired medication when the medication is unavailable. In addition, the 2SRG Medical Director adhered to the American Medical Association Principles of Medical Ethics by ensuring that patients had access to necessary controlled substances.

We reviewed all OST's records of controlled substances between 2019 and 2023 and found that most of the inventory had been expired by at least 1 year. Each of the three OST commands had controlled substances in inventory that were expired for over 4 years including 240 lozenges and 99 vials of Fentanyl, among other substances. However, we confirmed that there was a nationwide shortage of controlled substances, including those identified in OST inventory. The nationwide shortage began well before 2019 but was exacerbated by COVID-19. As a result, the 2SRG Medical Director met his ethical responsibilities by ensuring that proper medical care, including controlled substances, was available to patients despite the nationwide shortage.

We also determined that the OST active inventory[2] did not contain any expired controlled substances. Although the allegation did not include OST active inventory of controlled substances, we included it in our audit to ensure appropriate practices were followed related to expired controlled substances. Specifically, the OST's Western Command active inventory of controlled substances included 60 vials of Ketamine, and none were expired. Similarly, none of the Ketamine vials included in active inventory from the Eastern and Central Commands were expired.[3]

Although we found expired controlled substances in OST's records during our audit, by September 2023, the OST was able to replace all expired controlled substances with the exception of 100 vials of Fentanyl at the Central Command. The Fentanyl was expired and no longer included in the active inventory; has been appropriately separated; and awaits disposition.

[2] Active inventory refers to the current inventory available for use.
[3] Ketamine was the only controlled substance included in the active inventories.

IMPROPER CERTIFICATION AND INADEQUATE TRAINING ALLEGATIONS

The OST's *National Nuclear Security Administration Office of Secure Transportation Medical Standard Operating Procedures* does not require its FA medics to be certified for *Tactical Combat Casualty Care*. Therefore, we did not substantiate the allegation that the OST contractor, 2SRG, did not provide *Tactical Combat Casualty Care* certification. We verified these requirements with OST and 2SRG officials and confirmed that the OST does not require this certification.

We verified that 2SRG provided the contractually required continuing education opportunities for FA medics to maintain the National Registry of Emergency Medical Technicians requirements and certification. Therefore, we did not substantiate the allegation that the OST did not provide all the required training for FA medics. According to the allegation, in 2020 and 2021, the OST had numerous classes cancelled due to COVID-19. However, our audit of all medical training scheduled and conducted from 2019 through 2022 found that 2SRG had provided the OST with 3 major FA medic training events per year for a total of 12 major FA medic training events. 2SRG ensured FA medics had the opportunity to reach 40 hours of biannual continuing education in courses such as *Care Under Fire*, *Tourniquet Use*, and *Hemostatic Agent Use*.

MANAGEMENT RESPONSE

With no recommendations or suggested actions, NNSA was not required to respond to this report. NNSA informed us that it is choosing not to formally respond to this report.

AUDITOR COMMENTS

The Office of Inspector General appreciated NNSA's cooperation during this audit.

OBJECTIVE

We initiated this audit to determine the validity of the allegations that the Office of Secure Transportation (OST) violated medical ethics and did not meet training requirements.

SCOPE

The audit was performed from March 2024 through September 2024 at the OST's Agent Operations Western Command in Albuquerque, NM; Agent Operations Central Command in Amarillo, TX; and Agent Operations Eastern Command in Oak Ridge, TN. Information at Agent Operation Central Command and Agent Operation Eastern Command was obtained via remote access techniques. The audit was conducted under Office of Inspector General project number A24AL004.

METHODOLOGY

To accomplish our audit objective, we:

- Performed a no-notice site visit at Agent Operations Western Command;
- Identified criteria (i.e., laws, regulations, OST policies, contracts) related to the allegations;
- Interviewed OST Headquarters personnel and subject matter experts;
- Reviewed supporting documents;
- Performed a physical inventory review of all controlled substances at Agent Operations Western Command;
- Reviewed inventory records of all reported controlled substances at all OST Commands from January 2021 through October 2023; and
- Reviewed all OST Federal Agent Emergency Medical Technician training documentation from calendar year 2019 through calendar year 2022.

We conducted this performance audit 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 objective. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective. We assessed internal controls and compliance with laws and regulations necessary to satisfy the audit objective. We assessed the following internal control components and underlying principles significant to the audit objective: control activities and the related underlying principle to design control activities; monitoring component and the related underlying principle to monitoring activities.

However, because our review was limited to these internal control components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

We assessed the reliability of data to satisfy our audit objective. To assess the reliability of the data elements to answer the audit objective, we verified all documents were original. We determined that the data was sufficiently reliable for the purposes of this report.

Management officials waived an exit conference on September 25, 2024.

Office of Inspector General (OIG)

- Inspection Report on *Pacific Northwest National Laboratory Management of Controlled Substances* (DOE/IG-23-02, October 2022). The objective was to determine the extent that Pacific Northwest National Laboratory (PNNL) effectively manages controlled substances. The OIG found PNNL did not incorporate all applicable Federal property regulations into its management of controlled substances. Specifically, PNNL did not: classify them as personal property; categorize them as sensitive personal property, and follow prescribed inventory standards. This occurred because PNNL and the Pacific Northwest Site Office (PNSO) misclassified controlled substances as chemical assets. This prior audit cites 40 Code of Federal Regulations 102, which lists all controlled substances in its definitions section and prescribes special handling requirements for their disposition. Additionally, 40 Code of Federal Regulations 109 requires sensitive personal property to be inventoried annually with 100 percent accuracy. PNNL's inventory procedures and practices did not meet regulations for sensitive personal property standards due to its procedures and practices only adhering to Drug Enforcement Administration standards. The cause noted in this report was that PNNL and the PNSO misclassified controlled substances as chemical assets rather than recognizing them as sensitive personal property. The misclassification led to the absence of required inventory and disposition reports, and that limited the PNSO's oversight of controlled substances. The misclassification also limited the PNSO's ability to identify lost, misplaced, or stolen controlled substances, which could pose a danger to public health and safety.

- Inspection Report on *Management of Controlled Substances at Los Alamos National Laboratory* (DOE/IG-19-54, September 2019). The report states that 21 Code of Federal Regulations 1300-1317 categorizes controlled substances and specifies the requirements for registration and usage. Federal Acquisition Regulation 52.245-1 lists controlled substances as sensitive property; therefore, they are subject to exceptional physical security, protection, control, and accountability. The Federal Acquisition Regulation further states that the Contractor shall initiate and maintain the processes, systems, procedures, records, and methodologies necessary for effective and efficient control of Government property. The OIG's review of the eight controlled substances within two institutional databases and researcher records identified mislabeled procurement records, incomplete and inaccurate inventory records, and controlled substances held in inventory longer than necessary. The OIG found this occurred because Los Alamos did not apply consistent procedures across the lab to appropriately classify or account for controlled substances from acquisition to final disposition. This reduced the Department of Energy's assurance that Los Alamos National Laboratory is protecting controlled substances from misuse or loss.

FEEDBACK

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Office of Inspector General (IG-12)
Department of Energy
Washington, DC 20585

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Report Addendum for Contractor Comments

The U.S. Department of Energy Office of Inspector General (OIG) released a public report that refers to work performed by external parties. Pursuant to Public Law 117-263, Section 5274, non-governmental organizations and business entities specifically identified in an audit report issued by the OIG have an opportunity to submit a written response for the purpose of clarifying or providing additional context to any specific reference. The OIG notified each external party related to this report on October 9, 2024, giving them 30 days to provide a response. None of the external parties submitted a response to the OIG.