

United States Department of the Interior

U.S. GEOLOGICAL SURVEY

U.S. Nuclear Regulatory Commission ATTN: Document Control Desk, Washington, DC 20555-0001

SUBJECT: REPLY TO INSPECTION REPORT 030-03728/2021-001 AND NOTICE OF VIOLATION DATED April 19, 2022---CONTESTED VIOLATION

Docket No. 030-03728 License No. 05-01399-08

The USGS contests the subject enforcement action with the following justifications:

1. The violation as written identifies a failure to perform an action not required by the cited regulations and/or requirements. Also, the cover letter transmitting the Notice of Violation described a failure to perform physical inventories as specified in Title 10 Code of Federal Regulations (CFR) Part 74.

The Notice of Violation lists the primary requirement as 10 CFR 74.13(a). 10 CFR 74.13(a) requires, in part, that the licensee prepare and submit a report. The cited regulation does not require the licensee to perform physical inventories.

The second requirement listed was NUREG/BR 0007, Instructions for the Preparation and Distribution of Material Status Reports. NUREG/BR007 provides directions for filling out applicable forms. The cited document does not require the licensee to perform physical inventories.

The third requirement listed was 10 CFR 74.4. 10 CFR 74.4 provides the definition of physical inventory. 10 CFR 74.4 does not require the licensee to perform physical inventories.

The requirements for USGS to PERFORM physical inventories are contained in License Condition, not the referenced regulations and documents. The inspection identified no noncompliance with the performance objectives of License Condition requirements. The inspector stated that based upon his review of USGS inventory methods and records, the open SL-IV violation involving inadequate physical inventories performed in 2017 (unrelated to NMMSS reporting) was adequately addressed by the corrective actions taken, and the violation was now considered closed. The cover letter transmitting the subject Notice of Violation documented that action by the NRC.

The fourth paragraph of the citation indicates, in part, contrary to the referenced requirements, the licensee did not validate its initial determination of the amount of unsealed special nuclear material for each dated inventory, to determine that changes had not occurred. 10 CFR 74.13(a), NUREG/BR 0007, and 10 CFR 74.4 do not require that the licensee validate its initial determination of the amount of unsealed special nuclear material, for each dated inventory, to determine that changes that changes had not occurred. USGS recognizes that licensees must ensure that the information provided in each annual report was accurate and that only the authorized licensee personnel had prepared and issued each annual report. The inspection did not identify

any inaccuracies in the reports submitted by the USGS. USGS complied with the instructions in NUREG/BR 0007 as specified in 74.13(a). USGS reported accurate inventories as required by NUREG/BR 0007. USGS did PERFORM physical inventories in accordance with the performance objective of License Condition requirements.

2. The period cited in the violation. The violation indicates that US Geological Survey (USGS) was out of compliance from 2009 to 2021. Many times, during the course of the extended inspection, USGS personnel informed the NRC inspector that no one associated with the USGS Nuclear Materials Management and Safeguards System (NMMSS) forms submitted prior to 2018 was still associated with USGS and therefore a definitive description of the inventory confirmation and validation process used prior to 2018 could not be presented. On multiple occasions during the inspection the inspector was informed that records submitted prior to 2018 had been archived and would take some effort to retrieve. Both the inspector and the inspector's branch chief stated during subsequent discussions that retrieving those records was not necessary and instructed USGS to make no effort to do so. Also, during a phone call conducted on March 2, 2022, the inspector limited his request for additional records to only go back to 2018. Within the scope of the inspection, neither USGS nor NRC reviewed or discussed any information regarding the cited requirements and validation methods from 2009 to 2017. By including that period, it appears the inspector has taken the presumptive position that it was done incorrectly and therefore not in compliance. Lacking evidence to demonstrate a violation did occur, the inspector has taken the position to require the licensee to prove a violation did not occur in this response to the cited violation. This does not appear to be an appropriate application of inspection nor enforcement standards.

Additionally, the USGS has undergone multiple routine inspections since 2009 with the last ending in January 2020 with no violations regarding NMMSS reporting identified. The USGS understands that every routine inspection is a snapshot of the program and not all aspects of a program may be reviewed at each inspection. However, neither the NRC nor the USGS can definitively identify whether the NMMSS reporting was reviewed by the NRC during the inspections conducted between 2009 and 2017. It appears inappropriate to assume that it was both not reviewed and not in compliance at the time of the previous inspections. This is also inconsistent with NRC practice of, absent compelling and indisputable evidence, limiting the scope of a routine inspection to the date of the conclusion of the previous routine inspection to prevent the additional regulatory burden of unlimited reinspection of previously reviewed information and programs. A preponderance of evidence does not exist to indicate that any NMMSS reports submitted prior to January 2020 were non-compliant.

3. The first paragraph of the Violation description states that 10 CFR 74.13(a) requires, in part, that the licensee prepare and submit an annual Physical Inventory Listing Report as specified in the instructions in NUREG/BR 0007.

The instructions in NUREG/BR 0007 applicable to USGS are contained in Sections 2 and 3.1 of the document. Additionally, the Glossary contains the definition of Physical Inventory.

Between March 2018 and March 2021, USGS did prepare and submit an annual Physical Inventory Listing Report as specified in the instructions in NUREG/BR 0007. Neither the NRC nor USGS identified any instructions listed in the NUREG that USGS failed to complete. As stated above, regarding the NMMSS reports submitted prior to March 2018, with the lack of information and availability of knowledgeable personnel, neither the NRC nor the USGS identified a failure to follow any instruction in the NUREG. On multiple occasions during the inspection the inspector was informed that records submitted prior to 2018 had been archived and would take some effort to retrieve. Both the inspector and the inspector's branch chief stated during subsequent discussions that retrieving those records was not necessary and instructed USGS to make no effort to do so.

During multiple discussions of the issue, the USGS asked the inspector to identify which instruction was not completed and the inspector would only respond with no more specificity than the issue was a failure to comply with 10 CFR 74.13(a). The violation as written does not indicate by step number or by parallel language which instruction the USGS failed compliance. Within 10 CFR 74.13(a) there is no requirement to "validate an initial determination of the amount." USGS recognizes, accepts and has complied with the expectation and responsibility to provide true, complete and correct information to the NRC. What appears to USGS to be the most relevant steps and information contained in NUREG/BR 0007 are addressed below:

NUREG/BR 0007 Instruction 2.3 Section C, "Certification" SIGNATURE, TITLE, AND DATE specifies that an authorized representative of the licensee shall sign the report, if submitted as a hard copy. If submitted electronically, each licensee must establish internal procedures to ensure that the information provided in the report is accurate and that only the authorized licensee personnel have prepared and issued the report.

Between March 2018 and March 2021, an authorized representative of the USGS did sign the report. The reports were submitted electronically with an appropriate electronic signature. Also, USGS did establish internal procedures to ensure that the information provided in the reports was accurate and that only the authorized USGS personnel had prepared and issued the report.

Neither the NRC nor the USGS identified any instance in which other than an authorized USGS representative had signed the report. Additionally, neither the NRC nor the USGS identified any instances that the information provided in the report was not accurate and no instances where other than authorized USGS personnel had prepared and issued the report. The lack of findings of this nature demonstrated that the USGS established internal procedures were adequate to validate the information submitted in the subject reports.

NUREG/BR 0007 Instruction 3.1.7 SIGNATURE specifies that an authorized representative of the licensee shall sign the report, if submitted as hard copy. Otherwise, each licensee must establish internal procedures to ensure that the information provided in the report is accurate and that only authorized licensee personnel have prepared and issued the report.

Between March 2018 and March 2021, an authorized representative of the USGS did sign the report. The reports were submitted electronically with an appropriate electronic signature. Also, USGS did establish internal procedures to ensure that the information provided in the reports was accurate and that only the authorized USGS personnel had prepared and issued the report.

Neither the NRC nor the USGS identified any instance in which other than an authorized USGS representative had signed the report. Additionally, neither the NRC nor the USGS identified any instances that the information provided in the report was not accurate and no instances where

other than authorized USGS personnel had prepared and issued the report. The lack of findings of this nature demonstrated that the USGS established internal procedures were adequate to validate the information submitted in the subject reports.

4. The second paragraph of the Violation description states that the instructions in NUREG/BR 0007 require, in part, that the licensee use DOE/NRC Form 742C to report a facility's physical inventory listing, as of a specified date.

Between March 2018 and March 2021, USGS did use DOE/NRC Form 742C to report the USGS facility's physical inventory listing, as of December 31 of each subject calendar year. Neither the NRC nor USGS identified any failure of the USGS to use DOE/NRC Form 742C to report the USGS facility's physical inventory listing. As stated above, regarding the NMMSS reports submitted prior to March 2018, with the lack of information and availability of knowledgeable personnel, neither the NRC nor the USGS identified a failure to use DOE/NRC Form 742C to report the USGS facility's physical inventory listing inventory listing.

5. The third paragraph of the Violation description states that 10 CFR 74.4 defines a physical inventory as a determination on a measured basis of the quantity of special nuclear material on hand at a given time.

Between March 2018 and March 2021, USGS did conduct semi-annual physical inventories to determine on a measured basis the quantity of special nuclear material on hand at a given time.

10 CFR 74.4 also states Measurement includes sampling and means the determination of mass, volume, quantity, composition or other property of a material where such determinations are used for special nuclear material control and accounting purposes.

Between March 2018 and March 2021, USGS did utilize a combination of physical security, administrative controls, user training, access authorization, visual inspection, volume, mass, activity, concentration and composition of special nuclear material where such determinations were used for special nuclear material control and accounting purposes. Additional sampling, conducted in January 2022, at the inspector's specific suggestion, verified the accuracy of previous measurements used to conduct and report subsequent measurements.

NUREG/BR 0007 Glossary states Physical inventory—A physical determination of the quantity of nuclear material on hand at a given time. The **methods of physical inventory and the associated measurements vary**, depending on the material to be inventoried and the process involved. A book inventory between physical inventory takings can be determined based on the physical inventory quantity from the prior period together with all subsequent inventory changes associated with the determination of that book inventory. The primary purpose of a physical inventory is to confirm the absence of (or to detect) a loss, theft, or diversion of special nuclear material.

Between March 2018 and March 2021, USGS did conduct semi-annual physical inventories of special nuclear material for determination of the quantity of nuclear material on hand at a given time. The methods of physical inventory and the associated measurements were dependent on the USGS material to be inventoried and the process involved. USGS proceduralized, utilized

and maintained a usage logbook to serve as a book inventory between physical inventory takings which were determined based on the physical inventory quantity from the prior period together with all subsequent inventory changes associated with the determination of that book inventory. The USGS semi-annual physical inventories confirmed the absence of (or had been able to detect) a loss, theft, or diversion of special nuclear material. Neither the NRC nor the USGS identified any instances that the information recorded in the special nuclear material semi-annual inventory was not accurate. Neither the NRC nor the USGS identified any instances of (or a failure to detect) a loss, theft, or diversion of special nuclear material semi-annual inventory was not accurate. Neither the NRC nor the USGS identified any instances of (or a failure to detect) a loss, theft, or diversion of special nuclear material. The lack of findings of this nature demonstrated that the USGS established internal procedures were adequate to validate the information submitted in the subject reports.

6. Paragraph 4 of the Violation description states, in part, the licensee did not validate its initial determination of the amount of unsealed special nuclear material in a Permit 35 uranium calibration set, for each dated inventory, to determine that changes had not occurred.

The language used to write the contrary to the above portion of this violation does not appear to reiterate or parallel any language in 10 CFR Part 74.13(a), NUREG/BR 0007 or 10 CFR 74.4. USGS recognizes and accepts the responsibility to provide true, complete and correct information to the NRC. The certification and signature sections of the NMMSS forms clearly state that. USGS representatives have willing signed the required documents understanding the responsibility. Neither the NRC nor USGS has identified any instances that the USGS failed to provide true, complete and correct information to the NRC. The fact that neither the NRC nor USGS has identified any instance of information submitted in the NMMSS reports as being inaccurate, untrue, incomplete, or incorrect has demonstrated that the methods used to validate each physical inventory and each report was adequate.

Validate is not defined in 10 CFR Part 74 or NUREG/BR 0007. A standard definition is to check or prove the validity or accuracy of (something). A standard definition of Accuracy is the degree to which the result of a measurement, calculation, or specification conforms to the correct value or a standard. USGS has in place practices and procedures to validate each physical inventory and the special nuclear material quantities reported in the Physical Inventory Listing Report. Semi-annual physical inventories are conducted by authorized personnel using established procedures to review administrative controls and physical security practices to determine if material had been loss, stolen, or mishandled. An inventory report is submitted to the Radiation Safety Officer and Radiation Safety Committee quantifying on a measured basis the amount of material on hand during the reporting period. The inventory reports are reviewed by authorized user prior to submission to confirm that the accounting is true and accurate. The submitted inventories undergo a secondary review by gualified and authorized licensee personnel to verify the adherence to USGS physical inventory practices and to check the accuracy of the reported quantities, therefore by standard definition the physical inventories are validated. Prior to the completion of the Physical Inventory Listing Report required by 10 CFR 74.13(a), a tertiary review of special nuclear material quantities reported in the most recent semi-annual physical inventories is conducted to further confirm and validate that the information reported on the NMMSS forms is true, complete and correct. Prior to submission of the NMMSS forms, USGS physical inventories of special nuclear material, including unsealed special nuclear material in the Permit 35 uranium calibration set, have been reviewed three times and validated twice.

The inspector was clear that he did not question the accuracy of any of the information submitted by USGS in the subject reports and USGS was therefore not being cited for a failure to conduct adequate physical inventories. In fact, during the exit meeting the inspector stated that based upon his review of USGS inventory methods and records, the open SL-IV violation involving inadequate physical inventories performed in 2017 (unrelated to NMMSS reporting) was adequately addressed by the corrective actions taken, and the violation was now considered closed. The cover letter transmitting this Notice of Violation documented that action by the NRC. The inspector's position appears to be the conflicting conclusion that USGS special nuclear material physical inventories were properly conducted, accurate and met License Condition performance objectives, but when the data was transferred to the NMMS report, it was not valid.

USGS did utilize a combination of physical security, administrative controls, user training, access authorization, visual inspection, volume, mass, activity, concentration and composition of special nuclear material where such determinations were used for unsealed special nuclear material control and accounting purposes and to determine changes did not occur. Neither the NRC nor USGS has identified any instances that the USGS failed to identify planned or unplanned special nuclear material inventory changes. Sampling conducted in January 2022, at the inspector's specific suggestion, confirmed the accuracy of the current inventory and therefore the accuracy of all previous inventories that had been measured utilizing previous physical and book inventories (logbook) maintained since the original receipt of the special nuclear material.

On multiple occasions, USGS personnel explained that the initial receipt of the special nuclear material had occurred in the 1970s or 1980s. USGS indicated to the inspector that the original receipt records were most likely archived as hard copies at a USGS document warehouse. USGS indicated to the inspector that historical logbooks and physical inventories maintained since the receipt of the material should further validate the accuracy of the initial and subsequent amount inventories of unsealed special nuclear material. Both the inspector and the inspector's branch chief stated during subsequent discussions that retrieving those records was not necessary and instructed USGS to make no effort to do so. Neither the NRC nor USGS has identified any instances that the USGS special nuclear material inventory documentation was inaccurate.

Additionally, the USGS primary user of Permit 35 explained to the inspector that by nature of the science for which the uranium calibration set had been used, the accuracy of the concentration, activity and mass of the uranium were of critical importance. All scientific procedures, including mass spectroscopy, using the uranium in the course of scientific investigations have further confirmed the accuracy of the USGS Permit 35 special nuclear material physical property and physical inventory records. Neither the NRC nor USGS has identified any instances that USGS science was compromised due to the use inaccurate special nuclear material concentrations, activities or mass.

During multiple discussions of the issue, the inspector stated that had USGS used tamper proof tape or even just a line indicating content height on the vials containing special nuclear material, the USGS inventories would be validated because USGS could then ensure that material inventories had not changed. USGS acknowledged that tamper proof tape or a line on the vial may be a best practice but does not appear to be a requirement. The USGS also indicated that neither tape nor a line would prevent a person with malicious intent from removing material.

The inspector agreed that neither that tamper proof tape nor a line on the vial was a requirement but stated that it did not need to have been someone with malicious intent but that an authorized user may have removed material and failed to document the removal in the logbook and because USGS could not definitively prove that an authorized user had not failed to follow procedure, USGS cannot be sure that material had not been removed by an authorized user. USGS responded that given the USGS training program, user authorization process, physical security, physical inventories, logbook maintenance and administrative controls, USGS is highly confident that no material has been lost, stolen, misplaced or diverted. The inspector replied that although he saw no problems or weaknesses with the USGS training program, user authorization process, physical security, physical inventories, logbook use and other administrative controls, USGS cannot guarantee to his satisfaction that special nuclear material was not missing from the Permit 35 uranium calibration set, and USGS inventories were not proven to be accurate and thereby could not be validated. USGS then stated that the sampling, conducted in January 2022, at the inspector's specific suggestion, further verified that material had never been lost, stolen, misplaced or diverted and that Permit 35 inventories were accurate. The inspector stated that although he did not question the method or the results of that sampling, it was his belief that USGS did not definitively know that no material was missing until January 2022 and previous special nuclear material inventories could not be validated. The inspector further hypothesized that an authorized user could have removed special nuclear material from one vial and placed it into a different vial. The inspector directly stated that because authorized users had unsupervised access to unsealed material, USGS could not validate special nuclear material physical inventories. The implication that a trained authorized user failed to follow procedure and never informed the primary user or other USGS official suggests careless disregard or willful violation of the requirements, but the inspector has not indicated a suspicion of wrongdoing since there was no evidence that the inspector's described scenarios had occurred. The inspector repeatedly stated that although no indication that any unauthorized individual or authorized user actions resulting in absent, lost, stolen, misplaced or diverted special nuclear material was identified by the NRC or USGS, the events MAY have happened and therefore USGS did not comply with 10 CFR 74.13(a). Additionally, although no inaccuracies have been identified or reported, the inspector indicated that it was his opinion that USGS did not definitively know that there were no inaccuracies, so the information could not be validated. USGS asked how the inspector's described use of tamper proof tape or any other additional administrative control would have provided definitive knowledge and eliminated the violation. The inspector responded that each license was to determine an adequate manner to ensure special nuclear material inventories were accurate and validated. USGS responded that each inventory conducted to assess the absence, loss, theft, or misplacement of special nuclear material and each NMMSS report submitted, prior to submittal, was reviewed for accuracy by qualified and authorized USGS personnel and found to be accurate.

During a subsequent telephone call with the NRC branch chief the USGS discussed the appropriateness of the applied inspection standard. Additionally, a discussion of what constitutes "validated" was conducted. The branch chief indicated that there are many methods to validate information and licensees should establish methods appropriate for their programs to ensure the accuracy of data used to demonstrate regulatory compliance.

The conduct of this inspection and citation of this violation appears to USGS to be the enforcement of unwritten requirements. As stated in the Notice of Violation, 10 CFR 74.13(a) requires, in part, that the licensee prepare and submit an annual Physical Inventory Listing

Report as specified in the instructions in NUREG/BR 0007. Although neither tamper proof tape nor any other administrative control is specifically indicated in 10 CFR 74.13(a) or NUREG/BR 0007, the inspector repeatedly stated that had USGS only used tamper proof tape or at least a hand drawn line on vials, the issue would not be a violation. This indicates to USGS that specific unwritten administrative controls were required since no such instruction is listed in NUREG/BR 0007.

Additionally, the citation of a failure to validate appears to have no basis in the indicated requirements. The cited regulation only requires that a report be submitted in accordance with specific instructions. USGS understands that all information provided to the NRC must be true, complete and correct. USGS established internal procedures to ensure that the information provided in the reports was accurate, true, complete and correct. The inspection identified no instances within the scope of the inspection in which USGS internal procedures resulted in inaccurate, untrue, incomplete or incorrect information being reported in fulfillment of 10 CFR 74.13(a). The lack of findings of this nature demonstrated that the USGS established internal procedures were adequate to validate the information submitted in the subject reports. Additionally, the lack of findings regarding the physical inventory performance objectives required by License Condition established those internal procedures were also adequate to validate the results.

USGS would also ask that it be noted that following the onsite inspection of Permit 35, the primary user contacted the USGS RSO and Radiation Safety Committee Chair to inform them that it was his understanding that the inspector suggested USGS to sample the unsealed material and he felt compelled to comply with the suggestion. The primary user indicated that no work was planned with the unsealed special nuclear material and conducted the non-ALARA action of opening and emptying a sealed vial of dispersible special nuclear material for the sole purpose of the inspection activity.

Margaret (Marci) Marot Radiation Safety Chair U.S. Geological Survey

cc: Director, Office of Enforcement United States Nuclear Regulatory Commission Washington, DC 20555-0001.