OFFICE OF
INSPECTOR GENERAL
U.S. DEPARTMENT OF THE INTERIOR

USGS Laboratories Remain Vulnerable to Breaches of Scientific Integrity

This is a revised version of the report prepared for public release.

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Memorandum

To: David Applegate
Director, U.S. Geological Survey

From: Nicki Miller
Acting Assistant Inspector General for Audits, Inspections, and Evaluations

Subject: Final Audit Report – *USGS Laboratories Remain Vulnerable to Breaches of Scientific Integrity*
Report No. 2022-CR-035

This memorandum transmits our audit report on whether there are sufficient internal controls in U.S. Geological Survey (USGS) laboratories to identify vulnerabilities and prevent losses associated with scientific integrity and misconduct.

We will track open recommendations for resolution and implementation. We will notify Congress about our findings, and we will report semiannually, as required by law, on actions you have taken to implement the recommendations and on recommendations that have not been implemented. We will also post a public version of this report on our website.

If you have any questions about this report, please contact me at aie_reports@doioig.gov.

Contents

Results in Brief

What We Audited

The U.S. Geological Survey (USGS) is a Federal earth science agency with the mission of delivering actionable science relevant to U.S. decision makers. USGS is responsible for monitoring, analyzing, and predicting earth-system interactions[1] and providing science about natural hazards, energy and mineral resources, environmental health, and water resources. USGS' reputation for scientific excellence, integrity, and objectivity is crucial to its ability to perform its mission effectively. With nearly 500 laboratories spanning 7 geographic regions and 5 mission areas, the quality of results generated is a critical component of both USGS' reputation and the integrity of its science.

USGS states that these reputational considerations depend on consistent adherence to policies related to fundamental science practices and scientific integrity. Scientific integrity, in turn, is the condition resulting from adherence to professional values and practices when conducting, reporting, and applying the results of scientific activities that ensures objectivity, clarity, and reproducibility and that provides insulation from bias, fabrication, falsification, plagiarism, inappropriate influence, political interference, censorship, and inadequate procedural and information security.[2]

We performed this audit to determine whether there are sufficient internal controls in USGS laboratories to identify vulnerabilities and prevent losses associated with breaches of scientific integrity and misconduct. Specifically, we audited the overarching quality management system (QMS) that has been developed for USGS laboratories to ensure that their laboratory science meets consistent quality assurance standards.

What We Found

We found that USGS lacks sufficient internal controls in laboratories to identify vulnerabilities and prevent losses associated with breaches of scientific integrity and misconduct. After three incidents of misconduct were identified in USGS laboratories, the bureau began developing and implementing an overarching Bureau QMS in 2018 to address potential risks to data and breaches of scientific integrity. However, we identified several continuing deficiencies in the development of the Bureau QMS and its implementation in laboratories.

The Bureau QMS has been in development since 2018 and originally had a 2023 target for full implementation. That implementation date was subsequently modified to the end of 2025 due to the COVID-19 pandemic. As of July 2023, however, less than 20 percent of USGS laboratories had fully implemented the Bureau QMS. Further, USGS has not clearly established oversight

[1] "Earth-system interactions" are the interactions of the Earth's geosphere and biosphere. The geosphere consists of the atmosphere, lithosphere, cryosphere, and hydrosphere.

[2] USGS does not itself define "scientific integrity." Accordingly, we considered definitions from other analogous entities. See the National Institute of Standards and Technology's (NIST's) webpage, "NIST Scientific Integrity Program."

roles and responsibilities for the Bureau QMS. Policy identifies different entities within USGS that provide oversight of the Bureau QMS: the Office of Science Quality and Integrity, regional directors, and associate directors in the laboratories. However, no centralized oversight function within USGS ensures that all laboratories are appropriately implementing a QMS.

We tested QMS checklists for 32 laboratories. Of the eight laboratories that USGS deemed to have fully implemented the Bureau QMS, we found that none, in fact, had implemented basic internal controls such as supervisory reviews of staff work, and only one laboratory required standard operating procedures. The absence of adequate internal controls occurred because the Bureau QMS lacks established minimum requirements, which are necessary for an effective internal control system. The Bureau QMS was designed to be flexible and accommodate the diverse needs and activities of USGS' nearly 500 laboratories. However, the flexibility and discretion provided to laboratories on whether and how to implement certain internal control elements of the Bureau QMS could compromise the very purpose of a QMS.

We found that the USGS *Quality Management System Manual* (the "QMS Manual") does not establish all requirements needed to comply with Federal standards. Specifically, the manual lacks risk assessment internal controls and information technology controls. More specifically, USGS does not require holistic risk assessments at the laboratory level, and the manual does not require assessments of the risk factors that have led to past misconduct, which include factors such as workload capacity and unmet staffing needs. Additionally, there are insufficient internal controls in USGS laboratories to ensure that data and laboratory results are high quality and not susceptible to manipulation or error. One result is, with many laboratories programming or altering software to meet their unique needs, there is insufficient review of software designs, which increases risks of compromising USGS networks, exposing data, and creating inefficiencies due to incompatibility with current systems. Further, the lack of controls has caused USGS to be unaware of what information systems are being used and that these risks even exist.

Why This Matters

USGS has reported three serious incidents of scientific misconduct in USGS laboratories since 1996, two of which involved inappropriate conduct that lasted for several years. According to USGS, these breaches of scientific integrity have had significant consequences, including compromise to data integrity, the reputation of USGS, and the work of scientists who used the erroneous data. Because scientific results, studies, and products from USGS are used by different parties in the U.S. Government and the public, breaches of scientific integrity have significant impacts throughout the scientific community. Indeed, even a single breach can jeopardize others' ability to rely on years of scientific research produced by the laboratory in question. If USGS does not take efforts to strengthen its Bureau QMS, which is intended to address these concerns, its data—either produced from laboratories or affected by them—will remain vulnerable to breaches of scientific integrity.

What We Recommend

We make nine recommendations that, if implemented, will help ensure USGS laboratories have sufficient internal controls to identify vulnerabilities and deter losses associated with breaches of scientific integrity and misconduct.

Introduction

Objective

The objective of our audit was to determine whether there are sufficient internal controls in U.S. Geological Survey (USGS) laboratories to identify vulnerabilities and prevent losses associated with breaches of scientific integrity and misconduct.

See Appendix 1 for our audit scope and methodology.

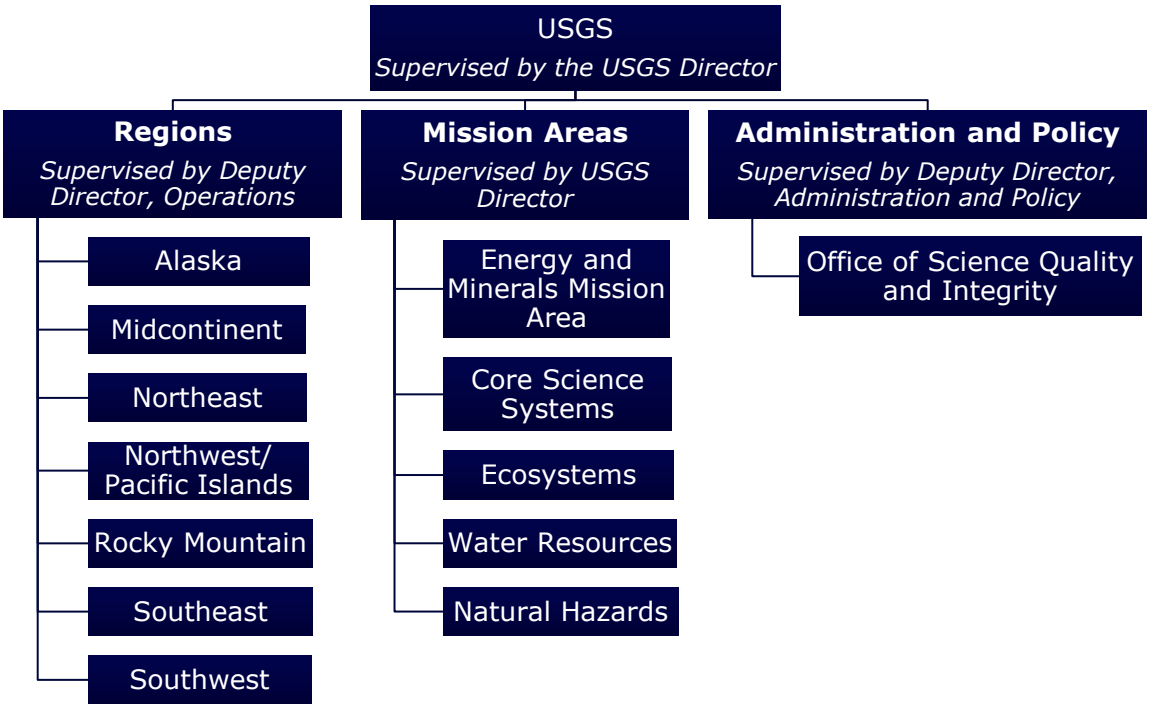
Background

Organization of USGS

USGS is a Federal earth science agency with the mission of delivering actionable science relevant to U.S. decision makers. USGS is responsible for monitoring, analyzing, and predicting current and evolving earth-system interactions and providing science about natural hazards, energy and mineral resources, environmental health, and water resources. According to the USGS website, with partnerships across the United States and the world, USGS scientific activities include (1) mapping the United States' topography and geology, (2) assessing mineral resources across the country and the world that are critical for the U.S. economy, (3) measuring and forecasting water quantities and qualities, and (4) assessing and warning of geological hazards to protect lives and property.

USGS uses what it describes as a matrix organizational structure, in which senior management shares responsibility for leading and managing specific mission areas or functions, with some staff members responsible for more than one functional area. USGS is divided into three main functional areas: seven geographic regions, which are responsible for operations within those regions; five mission areas, which are responsible for strategic science planning; and an office for administration and policy. See Figure 1 for a chart of the functional areas, mission areas, and regions, and the reporting structure.

Figure 1: Three Functional Areas within USGS



The Office of Science Quality and Integrity (OSQI) is one of seven subject areas located under the Office of Administration.[3]

Most laboratories report to science centers, which are under the authority of regional directors. USGS science centers conduct interdisciplinary research and monitoring related to natural resources, ecology, climate, and natural hazards.

Role of Laboratories

USGS defines a laboratory as "[t]he physical and (or) life science experiments, analyses, or other activities that ultimately produce recorded results and are directly overseen or performed by USGS personnel in stationary or mobile facilities."[4] A single facility could house multiple laboratories or types of activities. USGS has over 490 individual laboratories, all of which fall into one of three categories:

- **Production laboratories** conduct routine or repeated analyses that produce results for USGS or external customers and can be used in support of research projects. Production laboratories can be supported by user fees and are generally led by laboratory managers.

[3] Other areas or roles under the Office of Administration that do not pertain to this audit include: Administration; Budget, Planning, & Integration; Communications & Publishing; International Programs; the Freedom of Information Act (FOIA) Officer; and the Chief Information Officer. These have been omitted from the chart.

[4] USGS Instructional Memorandum (IM) OSQI 2022-01, *Quality Management System for U.S. Geological Survey Laboratories*, issued September 2022.

- **Research laboratories** support innovation or scientific discovery and are typically led by a principal investigator (senior scientist). Some research laboratories develop methods that are needed to answer a scientific question or that other laboratories use for routine analyses; others perform routine activities in support of research.

- **Field laboratories** perform a range of activities primarily or exclusively in support of field activities, including field measurements and observations. They do not generally perform traditional laboratory analyses and rarely produce laboratory data and results.

History of Reported Misconduct

The U.S. Department of the Interior (DOI) implemented its policy, *Integrity of Scientific and Scholarly Activities*, in January 2011. The policy created a mechanism to assess allegations of loss of scientific and scholarly integrity.[5] It also established scientific integrity officer positions, which are responsible for examining, tracking, and resolving allegations of scientific misconduct. Since that time, scientific integrity officers[6] have completed 24 investigations into alleged breaches of scientific integrity concerning USGS. Seven of these investigations involved USGS laboratory activities, and three of those seven investigations concluded that there was a loss of scientific integrity.

Of those three incidents of misconduct in USGS laboratories, two occurred in a laboratory serving the Energy and Minerals Mission Area (EMMA) and were addressed in a single investigation report. The first of these two incidents occurred from 1996 to 2008, and the second occurred from 2008 to 2014. Our office addressed these incidents in a May 2015 evaluation report and recommended that the Energy Resources Program, a program within EMMA, improve internal controls in all its laboratories.[7] As to the third incident, in 2021, USGS issued a press release citing a loss of scientific integrity that occurred from 2019 through 2020 in the National Water Quality Laboratory, one of its largest laboratories. See Figure 2 for the timeline and synopsis of these three incidents of laboratory misconduct.

[5] DOI defines scholarly activities as "the intellectual endeavors involving inventorying, monitoring, experimentation, study, research, modeling, and assessment conducted in a manner specified by standard protocols and procedures in culturally focused disciplines such as history, archeology, ethnography, architecture, and landscape architecture."

[6] Scientific integrity officers serve as ombudsmen within DOI for individuals with scientific integrity concerns. These officers also process scientific integrity complaints and oversee the Scientific Integrity Review Panel.

[7] *Energy Resources Program*, *U.S. Geological Survey* (Report No. CR-EV-GSV-0003-2014), issued May 2015.

Figure 2: Three Known Misconduct Incidents in USGS Laboratories (Described in USGS Incident Investigation Reports)

1996-2008

Energy Geochemistry Laboratory, Inorganic Section

Lakewood, Colorado

- Incident: A laboratory worker adjusted raw data to unacceptable standards and failed to retest samples properly.*
- Cause of incident: Incomplete and ineffective USGS oversight.

2008-2014

Energy Geochemistry Laboratory, Inorganic Section

Lakewood, Colorado

- Incident: A laboratory analyst violated established laboratory practices by intentionally changing results produced by a mass spectrometer, failing to preserve data, and failing to operate the mass spectrometer according to established practices.
- Cause of incident:
  - Insufficient, insignificant, and negligent oversight.
  - Conflict of interest in oversight roles.
  - Improper instrument storage.
  - Standard and sample preparation areas did not meet industry quality standards.
  - Quality assurance and quality control procedures were not timely developed and were not enforced.

2019-2020

National Water Quality Laboratory

Lakewood, Colorado

- Incident: A member of the laboratory staff falsified quality control values generated from a laboratory instrument so that they appeared to fall within specification limits. This represented a significant departure from accepted practices or standards of the relevant scientific community.
- Cause of incident:
  - Pressure on analysts to produce coupled with heavy workloads.
  - Insufficient oversight and support of analysts.
  - Increased problems with method performance.
  - Implementation of a new and problematic information system.

* In its final report of inquiry, a scientific integrity review panel considered a greater than 20 percent deviation from true values to be an unacceptable upper limit. Based on this standard, nearly all jobs in the Energy Geochemistry Laboratory showed evidence of unacceptable data manipulation.

Standards for Quality Management Systems

The Government Accountability Office's (GAO's) *Standards for Internal Control in the Federal Government* (the "Green Book") sets the standards for an effective internal control system for Federal agencies. Internal control is a process used by management to help its organization achieve its objectives. The Green Book is used to design, implement, and operate internal controls that help the organization run its operations efficiently and effectively, report reliable information about its operations, and comply with applicable laws and regulations.

The Green Book provides managers with criteria for designing, implementing, and operating an effective internal control system. Although there are many different topic-specific frameworks that apply to particular scientific endeavors and specific laboratories, our concerns relate to overall internal controls of the system, which are *not* specific to any particular laboratory or scientific discipline. A quality management system (QMS) should implement the standards laid out in the Green Book and provide a structure to ensure that entities (in this case, USGS laboratories) adhere to standards or technical specifications.

Origin of EMMA QMS and Bureau QMS

As a result of a recommendation in our 2015 evaluation report, EMMA developed a QMS, which it fully implemented in the 11 Energy Resources Program-funded laboratories[8] in 2017. As defined by the National Institute of Standards and Technology (NIST), a QMS "provide[s] a basic structure to ensure that [entities, e.g., USGS laboratories] adhere to standards or technical specifications."[9] The International Organization for Standardization (ISO) established the widely followed standard (ISO 9001) that specifies requirements for a QMS.

In December 2016, while EMMA was in the process of implementing its QMS, the House Natural Resources Committee, Oversight and Investigations Subcommittee held a hearing to address concerns expressed by a scientific integrity review panel[10] regarding the integrity of USGS data.[11] In testimony before the subcommittee, USGS committed to provide greater assurance of data integrity emanating from its laboratories by implementing a QMS to encompass all laboratories across USGS, not just those in EMMA. It also committed to having the [redacted] examine a representative sample of USGS laboratories, USGS' quality management systems, and other approaches for assuring the quality of laboratory results. See Figure 3 for a timeline for EMMA QMS and Bureau QMS development.

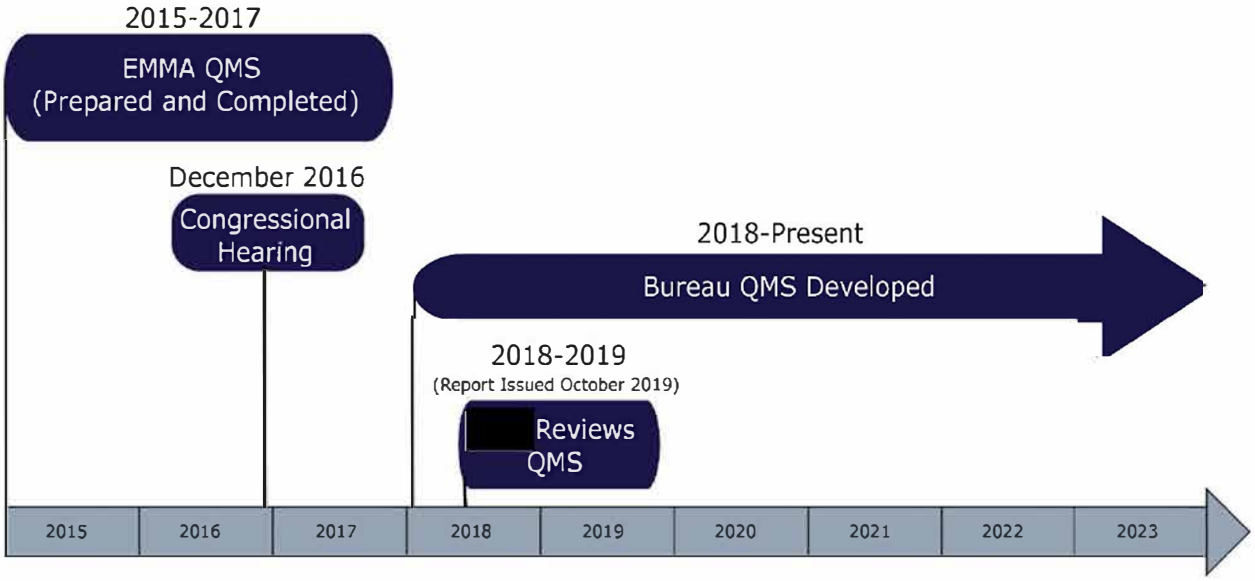
[8] EMMA conducts research and assessments that focus on the location, quantity, and quality of mineral and energy resources. There are total of 56 EMMA laboratories, which are separated into two programs: the Energy Resources Program and the Mineral Resources Program. Only 11 Energy Resources Program-funded laboratories fully implemented the EMMA QMS in 2017.

[9] According to NIST, "Quality management systems provide a basic structure to ensure your systems adhere to standards or technical specifications." The full definition is available at https://www.nist.gov/mep/iso-and-quality-management.

[10] Scientific integrity review panels consist of subject matter experts appointed by DOI scientific integrity officers to review and respond to specific issues that scientific integrity officers have identified.

[11] Examining Decades of Data Manipulation at the United States Geological Survey: Oversight Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Nat. Res., 114th Cong. (2016).

Figure 3: Timeline of EMMA QMS and Bureau QMS Development



In 2019, the [redacted] issued its report, which provided the results of its review and recommendations to USGS.[12] One of the [redacted] recommendations was a "slow implementation of QMS to allow ample time to develop institution-defined best practices, take advantage of lessons learned, provide training, and obtain input and buy-in from USGS laboratory staff."[13] The [redacted] did not define what it meant by "slow" implementation or provide additional suggestions on how this might be accomplished. Based on this recommendation, USGS decided that, rather than adjusting the existing EMMA QMS, it would develop a separate QMS to be used throughout USGS that would allow laboratories discretion and flexibility in implementation. As a result, there are now two main QMS programs in operation: a QMS for EMMA (EMMA QMS) and a more general QMS to encompass *all* USGS laboratories (Bureau QMS).[14] Because the EMMA QMS has more rigorous requirements than the Bureau QMS, OSQI has determined that it meets Bureau QMS standards. As a result, USGS considers any laboratory implementing the EMMA QMS to also be in compliance with the overarching Bureau QMS.

Implementation of Bureau QMS

OSQI, the office primarily responsible for the Bureau QMS, maintains the USGS QMS policy and provides oversight and assurance over the QMS policy, implementation, and corrective actions from quality-related problems and concerns. OSQI is also responsible for developing the USGS *Quality Management System Manual* (the "QMS Manual")[15] and training laboratory staff

[12] The National Academies Press, *Assuring Data Quality at U.S. Geological Survey Laboratories*, issued October 2019.

[13] *Id.* at p. 65.

[14] Prior to the Bureau QMS, there were four quality management systems implemented in different parts of USGS: EMMA QMS and three others that were adopted to meet specific laboratory accreditation standards. Our audit focused on the implementation of a standard Bureau QMS, the standards of which all USGS laboratories are required to either meet or exceed.

[15] USGS, *Quality Management System Manual*, version 3.01, effective December 20, 2023.

on implementing the Bureau QMS. However, regions and mission areas share responsibility for oversight of QMS implementation and operation. As a result, QMS staff are dispersed throughout the organization, with staff reporting to various management in the regional structure, the mission area structure, and the Administration and Policy functional area (see Figure 1).

As part of its design and implementation process, an OSQI official stated that OSQI obtained input from laboratory staff while USGS prepared the QMS Manual, which was finalized in April 2023. The manual has 10 chapters:

- Chapter 1, "Roles, Responsibilities, and Management Support."
- Chapter 2, "Documentation and Document Management."
- Chapter 3, "Laboratory Methods."
- Chapter 4, "Quality Controls."
- Chapter 5, "Laboratory Environment."
- Chapter 6, "Laboratory Personnel Training."
- Chapter 7, "Sample Management."
- Chapter 8, "Review and Delivery of Results."
- Chapter 9, "Quality Assessments."
- Chapter 10, "Corrective Action."

Each chapter identifies internal controls that laboratories may implement, such as developing standard operating procedures (SOPs), implementing secondary review of laboratory work products, and implementing corrective actions as a result of internal or external audits or assessments. The manual explicitly states that science centers and laboratories "may tailor how the [QMS] requirements are implemented," allowing management to opt out of specific parts of the QMS. OSQI and QMS staff are in the process of training laboratories on a chapter-by-chapter basis.

USGS' Instructional Memorandum (IM) OSQI 2022-01, *Quality Management System for U.S. Geological Survey Laboratories*, the precursor and basis for the Bureau QMS program (including the QMS Manual), was developed to hold laboratories to consistent quality standards while allowing laboratories the flexibility to tailor implementation to (1) address the specific scientific and operational needs of each laboratory and (2) use resources in the areas that are critical to ensuring the reliability of laboratory results. That is, the flexibility built into this QMS is intended to allow each laboratory to decide which control elements apply. Organizational units below the bureau level (e.g., mission area, region, science center, division, laboratory) moreover have the flexibility to set additional QMS requirements beyond those included in the QMS

Manual itself by writing policies or procedures that supplement the QMS Manual. After completing training, laboratories documented the level of completion with each QMS requirement in the QMS checklist and which control elements are or are not applicable.

Other Accredited Quality Management Systems

While the Bureau QMS is not fully based upon a specific accreditation standard, USGS allows laboratories to use other quality management systems if they meet minimum Bureau QMS standards. In this way, the Bureau QMS is a floor, not a ceiling.

Sixty-one laboratories use standards other than the Bureau QMS. In particular, 56 laboratories that service EMMA use the more rigorous EMMA QMS, and 2 accredited USGS laboratories use the QMS of an accrediting agency. EMMA QMS has requirements that exceed Bureau QMS standards, such as a review and approval processes for SOPs, clear identification of requirements that must be implemented, and compliance monitoring.

Numerous U.S. institutions accredit laboratories based on their adherence to ISO and other industry-specific standards. These accrediting agencies ensure that laboratories conform to specific requirements and that the requirements are effectively implemented and produce valid results. For example, NIST administers the [redacted] which provides third-party accreditation to testing and calibration laboratories. These laboratories are assessed against the management and technical requirements published in ISO 17025. Another example is the [redacted]), which is a laboratory certification program that fosters the generation of data of known and documented quality. [redacted], organized by the [redacted] relies on standards representing the best professional practices in the environmental laboratory industry to establish the requirements for this program, which are modeled after ISO 17025.

[16] Established by EPA in 1995 to bring consistency in environmental laboratory accreditation programs, the [redacted] strives for consistent standards for environmental laboratories through developing consensus standards based on ISO requirements, such as ISO 17025.

Results of Audit

We found that USGS lacks sufficient internal controls to ensure scientific integrity in its laboratories. Specifically, we found that USGS has not:

- Implemented the Bureau QMS in a timely manner or with an effective oversight structure.

- Incorporated the Green Book in the Bureau QMS. Specifically, USGS failed to implement basic internal controls in individual laboratories such as supervisory review, SOPs, risk assessments, and information system controls.

The Bureau QMS was developed to address the specific scientific and operational needs of each laboratory and use resources in the areas that are most critical to ensuring the reliability of laboratory results. However, without clear internal controls and oversight responsibilities and requirements, the Bureau QMS cannot accomplish this goal. Correcting the identified deficiencies would improve internal controls at USGS laboratories and help identify vulnerabilities and deter losses associated with breaches of scientific integrity and misconduct.

USGS Has Not Implemented the Bureau QMS in a Timely Manner or Provided an Effective Oversight Structure

We found that, while OSQI began the process through which USGS laboratories would implement the Bureau QMS in 2018, the majority of USGS laboratories had not fully done so as of July 2023. Further, OSQI has not clearly identified which organization within USGS will provide oversight of the implementation to ensure that minimum requirements are met.

The Bureau QMS Has Not Been Implemented in a Timely Manner

The Green Book provides managers with criteria for designing, implementing, and operating an effective internal control system, which is integral to the overall QMS process. Many of the standards set forth in the Green Book emphasize timeliness. Principle 2 states that "the oversight body should oversee the entity's internal control system." Principle 9 provides that "management should identify, analyze, and respond to significant changes that could impact the internal control system" and emphasizes that issues should be remediated in a timely manner. Specifically, the Green Book states that management should identify and respond in a timely manner to conditions that either have occurred or are expected to occur.

As an initial matter, the overall Bureau QMS implementation process has been delayed by the slow development of the QMS Manual, which is used for training and is the basis for determining a laboratory's progress in implementing the Bureau QMS. As noted previously, the QMS Manual itself was not completed until April 2023. The implementation process for the QMS Manual requires incorporating the manual's requirements into the laboratories on a chapter-by-chapter basis, with each chapter taking varying amounts of time to implement. The first group of laboratories selected by OSQI began implementing the QMS in September 2020.

As of July 2023, 82 percent of USGS laboratories had not fully implemented the Bureau QMS, even though OSQI began developing the Bureau QMS in 2018. According to OSQI, a laboratory has fully implemented the Bureau QMS if it has been trained on all chapters of the QMS Manual and is complying with the quality standards as established in those chapters.[17] We note that the QMS Manual provides that a laboratory can determine which quality standards do not apply. Laboratories can still be considered to have fully implemented the Bureau QMS even if they have decided not to apply significant portions of the manual.

More specifically, of the 495 laboratories in USGS, OSQI determined that:

- 90 laboratories (18 percent) have fully implemented a QMS—either the Bureau QMS or the EMMA QMS. Of these, 56[18] laboratories used the EMMA QMS, which meets and exceeds all Bureau QMS standards. OSQI identified that the other 34 non-EMMA laboratories fully implemented the Bureau QMS.

- 185 laboratories (37 percent) were in the process of implementing the Bureau QMS. A laboratory is identified as being in the process of implementing the Bureau QMS if it has been trained on some, but not all, of the chapters in the QMS Manual and is complying with the quality standards established in those chapters that it has determined apply.

In November 2023, 220 laboratories (44 percent) began to implement the Bureau QMS. USGS originally set a target date for all laboratories to fully implement the Bureau QMS by the end of 2023; however, this date was set before the COVID-19 pandemic. USGS has since revised its target date for full implementation to December 31, 2025. To meet this deadline, OSQI took a phased approach, implementing chapter trainings in four groups of laboratories based on a risk assessment, with the work of Group 1 deemed at highest risk of breaches of scientific integrity (see Figure 4). Although there is no congressionally prescribed timeline, USGS expected to implement Groups 1 and 2 by the end of September 2023, while the remainder of the labs are proposed to be fully implemented by the end of 2025—9 years after USGS committed to improving scientific integrity in its laboratories at the 2016 congressional hearing. By way of comparison, EMMA began developing the EMMA QMS in 2015, completed development in 2017, externally audited the system and the energy laboratories in 2018, and fully implemented the EMMA QMS in mineral laboratories in 2019—4 years later. As of April 2023, all 56 EMMA laboratories had fully implemented the EMMA QMS.

[17] Although USGS had identified some laboratories as having fully implemented the Bureau QMS, by the end of our fieldwork in March 2023, OSQI was still revising the last two chapters of the QMS Manual—one of which covers monitoring laboratories' compliance with the QMS—and editing the previous eight chapters. It is unclear how OSQI could have determined these laboratories to have fully implemented the Bureau QMS while OSQI was still revising the manual.

[18] There were 57 labs that fully implemented the EMMA QMS, however, one lab closed.

Figure 4: QMS Manual Drafting and Implementation by Chapter and Laboratory Group*

Chapter	Version Dates†	Implementation Date		
		Group 1	Group 2	Groups 3 and 4
1. Roles, Responsibilities, and Management Support	09/28/2020 06/16/2021	01/15/2021	08/6/2021	02/29/2024
2. Documentation and Document Management	09/28/2020 06/16/2021	03/05/2021	09/24/2021	06/30/2024
3. Laboratory Methods	09/28/2020 03/01/2022	03/26/2021 08/31/2022‡	08/31/2022	12/31/2024
4. Quality Controls	03/01/2022	08/31/2022	08/31/2022	12/31/2024
5. Laboratory Environment	06/16/2021	04/28/2022	04/28/2022	08/31/2024
6. Laboratory Personnel Training	08/12/2022	12/31/2022	12/31/2022	03/31/2025
7. Sample Management	08/15/2022	12/31/2022	12/31/2022	03/31/2025
8. Review and Delivery of Results	01/09/2023	03/31/2023	03/31/2023	06/30/2025
9. Quality Assessments	03/30/2023	09/30/2023	09/30/2023	12/31/2025
10. Corrective Action	04/26/2023	09/30/2023	09/30/2023	12/31/2025

* Based on data received on July 28, 2023, out of the total 492 laboratories, Group 1 consisted of 142 laboratories, Group 2 consisted of 192 laboratories, and Groups 3 and 4 consisted of 158 laboratories.

† Version dates are the dates the chapters were finalized to be implemented. Multiple version dates indicate that different iterations of the chapters were implemented. Group 1 adjusted its practices to incorporate significant changes in Chapter 3.

‡ Group 1 also implemented a revised Chapter 3 of the QMS Manual.

Source: USGS data.

Without implementing the Bureau QMS, USGS laboratories are without required internal controls that can help ensure data integrity. In contrast, one of EMMA QMS's internal control requirements is to conduct periodic internal audits and retain periodic external audits. As a result of these audits, EMMA QMS staff have been actively tracking 200 corrective actions, which gives staff insight into potential vulnerabilities and risk areas and concrete steps to address them. EMMA QMS staff oversee only 57 laboratories—or 12 percent—of all USGS laboratories.

Recommendation
We recommend that USGS: 1. Reassess the Bureau Quality Management System implementation approach and prepare a framework to fully implement the Bureau Quality Management System at all laboratories on a more rapid timeline than December 2025.

USGS Has Not Clearly Assigned Oversight Responsibilities

Principle 3 in the GAO Green Book states that management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objectives. Further, the Green Book provides that management should monitor the internal control system, as it is essential to respond to changing objectives, requirements, resources, and risks. Specifically, Principle 16 states that management should establish and operate monitoring activities to monitor the internal control system and evaluate the results.

USGS policy provides that OSQI is responsible for developing and overseeing the Bureau QMS.[19] However, USGS policy does not clearly define the responsibilities for developing, overseeing, and implementing the Bureau QMS. Instead, the policy uses imprecise language and seemingly assigns overlapping roles to OSQI and three other USGS branches, including science centers, the regions, and laboratory personnel. In particular, in its instructional memorandum issued on September 28, 2022, OSQI states that it "provides oversight and assurance over the QMS policy, implementation, and corrective actions from quality related problems and concerns."[20] However, the same memorandum states that associate directors and regional directors, who are external to OSQI, also are to "provide guidance and oversight for the processes and requirements that govern the laboratory QMS."

USGS policy should clarify each branch's roles and responsibilities to ensure the QMS is properly implemented and to avoid a lack of accountability. The Green Book states, "Members of an oversight body scrutinize and question management's activities, present alternative views, and act when faced with obvious or suspected wrongdoing. Independent members with relevant expertise provide value through their impartial evaluation of the entity and its operations in achieving objectives." It is therefore important to have a clearly identified, single oversight body that is independent of laboratory operations. The Green Book further states, "The oversight body and management set the tone at the top and throughout the organization by their example, which is fundamental to an effective internal control system."[21]

[19] IM OSQI 2022-01.

[20] *Id.* at 7 § 6(B).

[21] Green Book, Principle 1.03.

Perhaps because of the lack of clarity in the policy, OSQI leadership does not agree that it has oversight responsibility for QMS implementation and operation. For example, the OSQI manager responsible for the development and roll-out of the Bureau QMS stated that OSQI collaborates with regional directors and associate directors but considers regions—not OSQI—responsible for oversight of the QMS and ensuring it is operating as intended. While collaboration is vital to ensuring internal controls are designed well and implemented appropriately, clearly assigning oversight responsibility for the overarching QMS can help ensure a consistent, rather than a siloed, approach across laboratories, which can create duplication of efforts, inefficiencies, and potentially inconsistencies.

We also noted that the completed QMS Manual does not clearly delineate oversight responsibilities to OSQI (or elsewhere). The manual states that QMS management will define the scope of internal assessments, which will be completed by laboratory management and personnel, but has no other responsibilities required under the quality assessment. However, the QMS Manual defines QMS management as "any of the following: Bureau QMS Coordinator, Mission Area QMS Managers, and Regional QMS Managers." When asked what the role of OSQI QMS staff will be when the Bureau QMS is fully implemented, an OSQI manager responded that the future expectations of QMS staff members were uncertain.

Additionally, we found that, of the 19 total QMS staff members located in all three functional areas, at least 6 staff responsible for QMS implementation report to regions. This creates the possibility that QMS staff members may detect and report noncompliances in laboratory operations in the regions they answer to. Further, because those in charge of the laboratories' operations may be under pressure to achieve results, they may not always appropriately prioritize QMS matters when faced with potentially competing obligations. A lack of prioritization, in turn, creates the risk that staff may not focus on identifying QMS matters. Without addressing this issue and clearly delineating roles and responsibilities, there is the potential that QMS requirements, once established, could be ignored or that noncompliances at laboratories may go either undetected or unreported.

Similar challenges as well as potential paths to resolution occurred when the EMMA QMS was implemented. In a 2018 report,[22] the external auditor reviewing the EMMA QMS (the only USGS developed QMS at the time)[23] stated that QMS staff reported to science centers located under the regions' chain of command. Because regions are responsible for laboratories' operations, the external auditor concluded that this posed a potential threat to data quality due to potential conflict of interest and lack of independence. In response, EMMA moved all its QMS staff outside of the laboratory management structure to report to leadership in the mission area, the branch of USGS responsible for strategic science planning.

Moreover, specific applications of the EMMA QMS demonstrate the value of a framework that clearly identifies oversight roles and responsibilities. For example, laboratories using the EMMA QMS are required to undergo periodic internal and external audits. In an internal audit conducted in early 2023, EMMA QMS staff visited a laboratory and found that it was not

[22] *United States Geological Survey Energy Resources Program External Audit Report*, issued May 24, 2018.

[23] Prior to the EMMA QMS, there were laboratories in different parts of the USGS that adopted and followed accreditation standards developed through the accrediting agencies. Those quality management standards were not developed by the USGS.

compliant with the EMMA QMS. They identified that laboratory results were not traceable, chemicals were neglected, and there was no demonstration of laboratory staff capabilities. Staff also stated that it was unclear whether the laboratory was even being used. They reported their findings to the science center responsible for the laboratory's operations, and a stop-work order was put in place. This incident highlights that an independent entity outside of the laboratory management structure but with responsibility for USGS' strategic science planning can help identify and report these incidents.

Our concern with QMS staff reporting to leadership responsible for the management and operations of laboratories is further demonstrated in the case of a USGS laboratory that handles radioactive materials and serves EMMA. The laboratory was shut down in 2018 as a result of quality control violations found during a Nuclear Regulatory Commission inspection. Although the laboratory has resumed operation, we received information from EMMA QMS staff that leadership in the region may not require the laboratory to implement the more rigorous internal controls of the EMMA QMS. Instead, the laboratory may be allowed to comply with only the Bureau QMS, which, as previously discussed, currently only provides general guidance and does not require specific internal controls. This is an example of the concern that management could override controls due to competing priorities.

Recommendation

We recommend that USGS:

2. Develop an oversight function with clearly delineated roles and responsibilities to ensure that all laboratories are implementing the Bureau Quality Management System appropriately.

OSQI Did Not Require Key Internal Control Principles in the Bureau QMS Implementation

The Green Book and other Federal standards, such as the Federal Information Security Modernization Act of 2014, provide agencies with minimum criteria for internal controls. We found, however, that OSQI did not provide key requirements for laboratories implementing the Bureau QMS. In particular, OSQI did not require risk assessments and information system controls.

OSQI Did Not Provide Minimum Requirements for QMS Implementation

We found that the implementation of the Bureau QMS does not ensure an effective internal control system with clear requirements and standards for monitoring and enforcing the QMS. Even though the QMS Manual references internal control elements that are described as "requirements," it allows laboratories to opt out of implementing them. Specifically, the QMS Implementation Checklist states, "If a requirement does not apply, select 'Requirement is not applicable'." This ability to opt out applies to all internal control elements.

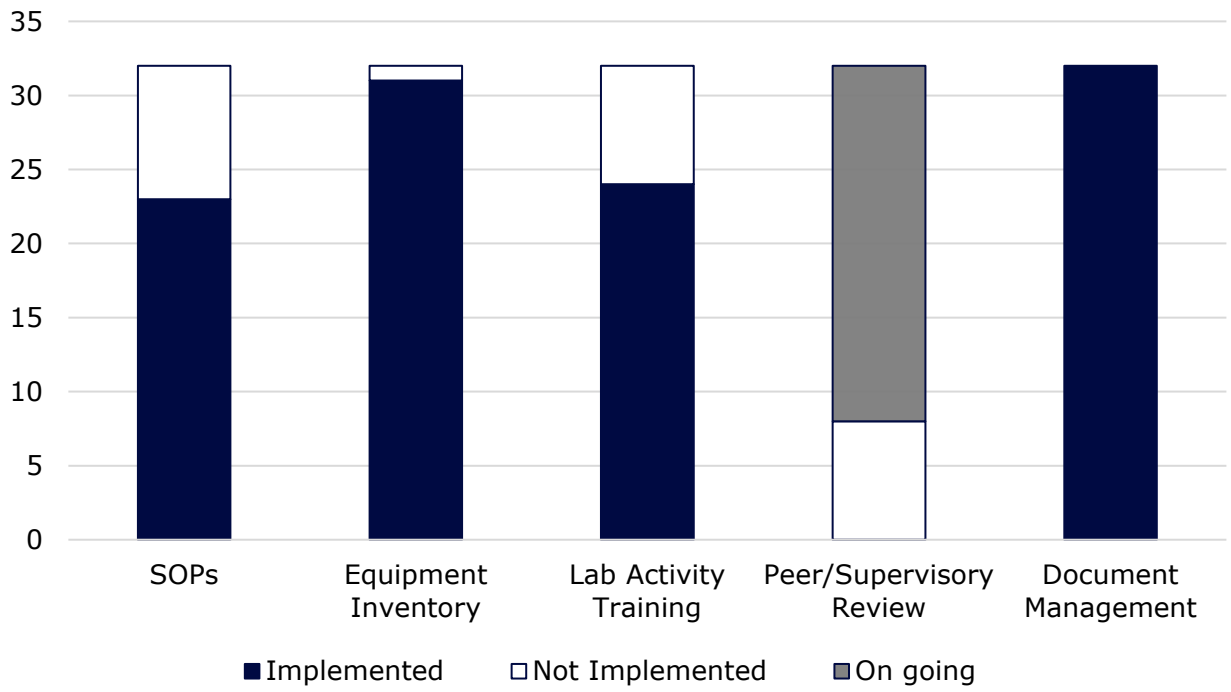
According to OSQI, the Bureau QMS is designed to be flexible and to allow laboratories to decide which QMS quality control elements are applicable to their activities and products. We recognize that USGS operates a wide variety of laboratories with distinct functions but note that all share some common features. Most notably, all have basic elements such as equipment, personnel, processes, inputs, and outputs and operate within a particular physical and cultural environment that can affect everything from supervision to the layout of the laboratory. Some of the issues cited as causes of previous incidents of misconduct were related to these elements: improper instrument storage (equipment), heavy workload (input), and poor supervision (culture). Similar to the Green Book's applicability to Government organizations with varying missions, a QMS for laboratories can be designed to apply to all laboratories.

The Bureau QMS allows laboratories that are already implementing a QMS, such as those that are accredited through other agencies or utilizing the EMMA QMS, to continue to do so if they meet minimum standards. This is not a concern if senior leadership ensures that laboratories following a more rigorous QMS continue to comply with that QMS and do not opt to follow the more lenient Bureau QMS. Conversely, if laboratory management decides not to continue adhering to the more rigorous internal controls, the laboratory may be at risk of breaching scientific integrity.

As part of the QMS Manual, laboratories complete QMS checklists that identify which internal control elements are applicable to that laboratory and the status of their implementation of the QMS. Internal control elements include SOPs, inventory of equipment, laboratory training, secondary review of laboratory staff's work, and data and document control. We reviewed the QMS checklists for 32 laboratories that were reported as either partially or fully implementing the Bureau QMS.[24] Of the 32 selected laboratories, 8 were reported to have fully implemented the Bureau QMS. All eight of those laboratories determined that a secondary review of laboratory staff work was not an applicable internal control, and seven stated that having SOPs was not applicable. Reviewing staff work is a primary way to determine that the laboratory results are reliable and to detect errors. If errors go undetected, it could affect future research that relies on the laboratory results. SOPs are necessary to train employees and ensure consistent application and continuity of operations. We question whether allowing certain internal controls to be optional is appropriate because it undermines the purpose of the Bureau QMS. In contrast, the EMMA QMS does require the secondary review process and SOPs. Figure 5 identifies the results of our review of the 32 selected laboratories' QMS checklists.

[24] OSQI designated laboratories as fully implementing the Bureau QMS if they were fully trained on implementing the Bureau QMS and were determined to not require training on the last two chapters of the QMS Manual. OSQI designated laboratories as partially implementing the Bureau QMS if they were not fully trained on implementing the QMS Manual and were determined to require training on all chapters of the QMS Manual.

Figure 5: Thirty-Two Selected Laboratories Implementing or Declining To Implement Select Internal Controls*



* See Appendix 2 for additional information.

We note that OSQI is not playing an active role in this process. In particular, although OSQI is overseeing the design of the QMS, including the QMS Manual, it did not include mandatory minimum requirements. Instead, OSQI has taken an educational and advisory role, providing laboratory management and staff with information about the quality control elements of the QMS and what should be implemented but not what *must* be implemented.

While we understand the need for flexibility for USGS laboratories as they operate a large variety of laboratories with unique needs, research activities, and results, we note that all laboratories have some commonalities and therefore can benefit from a baseline of internal control elements that are universally applicable. For example, standard minimum requirements could address issues that all laboratories face, such as having equipment in need of maintenance, personnel who must be trained and supervised, processes that must be established for consistency, samples or inputs that require proper handling and conditions, and laboratory results that must be accurate, all to ensure and bolster scientific integrity. Given GAO's Green Book standards and past findings of misconduct relating to improper instrument storage, heavy workloads, and poor supervision, the Bureau QMS—which was established to deter misconduct and reduce errors—must have sufficient internal controls to address this threat.

Without clearly established minimum requirements, USGS cannot ensure that laboratories' implementation of the Bureau QMS will meet the overall purpose of the QMS: to ensure that USGS laboratory science meets consistent quality assurance standards. We are concerned that the lack of clear QMS minimum requirements will negatively affect not only laboratories' compliance with necessary internal controls but also QMS personnel's ability to monitor and audit laboratories once they fully implement the Bureau QMS.

As a result of unclear requirements, laboratory staff seemed uncertain of the function and importance of the Bureau QMS. We visited 10 laboratories that had either fully or partially implemented the QMS: 5 used only the Bureau QMS, 2 met Bureau QMS requirements by using the stricter quality management systems of their accrediting agency, and 3 met the Bureau QMS requirements by following the added controls of EMMA QMS guidelines. Staff at the five laboratories using only the Bureau QMS, however, informed us that they were unsure of what control elements need to be implemented or how to do so. Given the lack of clarity, they also questioned what the role of QMS staff will be once the QMS is fully rolled out. Without minimum requirements, they questioned the need to monitor for compliance.

We acknowledge the goal of the Bureau QMS was to develop a flexible QMS responsive to the needs and feedback of individual laboratories. We therefore encourage OSQI to address and respond to laboratory management and staff's input and feedback as it develops and implements the QMS while also ensuring it meets the established intent of the QMS: to ensure data integrity in the face of potential misconduct and mishaps.

Recommendations

We recommend that USGS:

3. Ensure that all required Federal internal control standards are incorporated into individual laboratory quality management systems.

4. Require the Office of Science Quality and Integrity to clarify Bureau Quality Management System minimum requirements needed to ensure that the Bureau Quality Management System is designed, implemented, and operating effectively, including monitoring the system for necessary changes.

USGS Did Not Provide Sufficient Guidance or Require Laboratories To Conduct Thorough Risk Assessments

Principle 7 of the Green Book provides that "management should identify, analyze, and respond to risks related to achieving the defined objectives." This includes assessing the potential for fraud within the organization and laboratories.

To identify risks, management should consider risk factors that could affect the organization, such as the complex nature of the work being performed, internal and external pressures, the use of new technologies, as well as risks the organizational structure poses.

Once management identifies risks, it should analyze them to determine the significance of their potential impacts. The Green Book notes that the analysis should be performed at various levels, from the organization to the group (such as mission area) to the individual unit (laboratory). Identification and analysis provide a basis for how to respond to the risks, including what measures to implement to reduce them. The analysis includes management's determination of how much risk it is willing to assume, which then determines the degree to which it needs to implement control or quality measures.

We found that USGS laboratories do not always conduct risk assessments and that, when they do, they do not always consider key risk factors, including ones that have led to past instances of misconduct. This absence of effective risk assessments occurred because the QMS Manual does not provide guidance on how to identify and address risk factors. Instead, it only recommends—but does not require—risk assessments and does not require that risks be reassessed on a periodic basis.

The QMS Manual does not provide overarching guidance on how to address known risk factors for misconduct. Although the draft QMS Manual provides guidance on how to perform a risk assessment, the guidance focuses on activities within a laboratory, such as addressing the vulnerability of sample contamination by wiping down machines. The guidance does not, however, address broader risk factors that have been found to contribute to misconduct and errors, such as:[25]

- Workload pressures,
- Insufficient staffing,
- Inattentive supervision,
- Conflict of interest in oversight roles, and
- Falsifying data.

Each of these risk factors could jeopardize data integrity and were contributing factors to the last three misconduct incidents (see Figure 2). For example, not sufficiently considering staffing levels and workloads can open the door to data integrity issues. Specifically, if laboratories fail to identify the point at which personnel cannot accommodate the workload, they are at risk of producing erroneous results and damaging scientific integrity.

During our interviews and USGS laboratory visits, we identified similar vulnerabilities across all types of USGS laboratories. For example, several science and production laboratory managers stated that they must manually transfer data from an instrument to another data storage system. In some cases, laboratory scientists may first download the data to their workstations for their analysis. In one instance, we learned that a scientist had been saving the data to an external hard

[25] This list is derived from previous USGS incident investigation reports as identified in Figure 2.

drive.[26] Manual transfer could leave data vulnerable to corruption or disappearance or simply introduce errors. As another example of a vulnerability, a preparation laboratory manager stated that a risk in his laboratory was that a rock crushing instrument could contaminate subsequent rock samples if not properly cleaned. Several other laboratories stated that they had staffing shortages.

Without a formal risk assessment and consideration of all significant risks, laboratories cannot identify and address areas of vulnerability to laboratory results or areas in need of improvement. Additionally, without such an assessment, QMS management cannot monitor the key internal controls that would mitigate those vulnerabilities. This, in turn, increases the risk of potential breaches of scientific integrity.

Given that control activities address risks and achieve the organization's objectives, risk assessments provide a basis for determining the extent to which the controls in the QMS should be implemented. OSQI has provided laboratories latitude in which QMS measures to implement; as such, a thorough risk assessment should be used as a basis for these determinations.

Recommendations

We recommend that USGS:

5. Require laboratories to perform an initial risk assessment to identify risks and, if necessary, implement internal controls that address risks identified in the risk assessment.

6. Require laboratories to perform risk assessments on an ongoing basis, such as annually, and address any new risks identified in the risk assessments.

7. Update risk assessment guidance to laboratories to incorporate a more comprehensive risk assessment to include other potential risks, such as staffing needs or information systems.

The Bureau QMS Does Not Have Sufficient Information System Controls

Principle 11 of the Green Book provides that management should design the entity's information system and related control activities to achieve objectives and respond to risks. Additionally, USGS *Survey Manual 502.6*, Section 4(H), states "[d]ata management activities . . . must be done in a consistent, objective, documented, and replicable manner to help ensure that high-quality and verifiable results are achieved. Quality assurance checks must be made throughout the science data lifecycle." Additionally, relevant Federal information security

[26] NIST Special Publication (SP) 800-53, Revision 5, *Security and Privacy Controls for Federal Information Systems and Organizations*, CP-6, provides that alternative storage sites of duplicate backup information are needed. In addition, USGS *Survey Manual* 502.6, Section 4(H), states "[d]ata management activities . . . must be done in a consistent, objective, documented, and replicable manner to help ensure that high-quality and verifiable results are achieved."

requirements state that agencies must develop and maintain inventories of information systems being used.[27]

In addition to the Bureau QMS and the EMMA QMS, the quality and reliability of the data that USGS produces and handles also depends on the integrity of the information systems that process and house that data. We found that USGS does not have sufficient internal controls and oversight over the information systems in use in its laboratories. First, USGS is not fully aware of what information systems are being used in its laboratories because there is no comprehensive inventory of all laboratory information systems, even though Federal law requires such an inventory. We also learned that many laboratories developed their own data processing systems or enhanced off-the-shelf programs to suit their specific needs. While there are not specific DOI policies precluding laboratories from developing their own systems or using off-the-shelf software, the USGS information system inventory should include all such off-the-shelf and internally developed software to be complete and meet Federal requirements. Because of this, USGS must ensure that these systems and modifications are meeting appropriate standards, operating appropriately, and storing data securely. Without a complete inventory of these systems, USGS cannot effectively monitor and ensure compliance.

Second, USGS has insufficient information system controls in its laboratories to ensure that data and laboratory results are of the highest quality. Specifically, there is no requirement that the laboratories provide evidence that information technology personnel review of these systems has taken place. Specifically, the Green Book provides that management should design controls to prevent unauthorized access and properly safeguard the information within the system.[28]

We found other issues surrounding information system controls in the laboratories including the ability of laboratory staff to access and edit information from other laboratories, information systems developed that are not under USGS control, inappropriate backup techniques, and inconsistent data entry. For example, during a site visit to USGS laboratories, we identified an information system that one laboratory used with few controls in place to protect it. Specifically:

- All laboratory personnel had full administrative rights to the system, which does not comply with NIST's *Security and Privacy Controls for Federal Information Systems and Organizations*.[29]

- Backups of the data on the system were maintained at the principal investigator's residence on an unencrypted external hard drive. The principal investigator stated that this backup contained decades of scientific testing data not only for USGS but also for other agencies such as the U.S. Department of Defense. This practice again contradicts NIST's Federal information system controls practices.[30]

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[27] 44 U.S.C. § 3505(c)1.

[28] Green Book, Attribute 11.11.

[29] NIST SP 800-53 (Revision 5), SC-2, provides that information systems should separate user functionality from information system management functionality.

[30] NIST SP 800-53 (Revision 5), CP-9(d), provides that organizations (such as USGS) should protect the confidentiality, integrity, and availability of backup information at storage locations.

In another example, we noted that a laboratory technician was able to access another laboratory's data and make edits to its system. As provided in NIST's *Security and Privacy Controls for Information Systems and Organizations*, agencies should limit access to information and system resources and constrain what actions individuals can take.

It is particularly crucial for USGS laboratory information systems to have strong internal controls since the three past instances of identified misconduct involved data manipulation. Without these controls, the data produced within USGS laboratories are at risk of failures in scientific integrity, erroneous editing, or data loss.

Recommendations

We recommend that USGS:

8. Develop and maintain an inventory of all information systems in U.S. Geological Survey laboratories.

9. Assess controls over all identified information systems and implement controls necessary to protect system data and comply with Federal regulations.

Conclusion and Recommendations

Conclusion

USGS has made minimal progress toward developing and implementing internal controls that provide greater assurances that its laboratories are operating and producing results with scientific integrity. Only one mission area has shown significant progress, EMMA, whose laboratories have fully implemented the EMMA QMS, which exceeds the Bureau QMS standards.

Over 80 percent of USGS laboratories have not fully implemented the Bureau QMS, the system of internal controls developed specifically for all USGS laboratories. While USGS has designed the QMS to offer laboratories flexibility on whether to implement certain internal control elements, it lacks clear requirements and so creates uncertainty for laboratory staff and QMS staff as to how QMS compliance will be monitored and enforced.

Similarly, because USGS did not clearly establish oversight responsibilities for each of the three functional areas administering the Bureau QMS, there is a lack of clarity regarding relevant roles for QMS staff and an increased risk of potential conflicts of interest.

The QMS Manual does not require USGS laboratories to conduct holistic risk assessments that include factors that have led to past instances of misconduct, such as vulnerabilities related to data systems, insufficient resources, and workload capacity.

Finally, we found that data generated by, transferred from, and stored in USGS laboratories remain vulnerable to loss, manipulation, or errors due to insufficient controls and oversight of the information systems used in USGS laboratories.

Ultimately, due to ongoing design of the Bureau QMS, partial implementation, and unclear requirements and oversight responsibilities, USGS has not fully established oversight of laboratories to ensure that scientific activities and laboratory results are reliable. Without proper oversight in all phases of QMS implementation and without important internal controls for risk assessment and information systems management, scientific integrity at USGS laboratories remains vulnerable. USGS considers the reputation for scientific excellence, integrity, and objectivity to be one of its most important assets. The quality of results generated from USGS laboratories is integral to USGS' reputation and the integrity of its science.

We make nine recommendations to help USGS ensure that it has sufficient internal controls in USGS laboratories to identify vulnerabilities and deter losses associated with breaches of scientific integrity and misconduct.

Recommendations Summary

We provided a draft of this report to USGS for review. USGS provided us with technical comments, which we evaluated. Where appropriate, we made changes to the draft report based upon those comments. In its written response to the draft report, USGS concurred with eight recommendations and partially concurred with one recommendation. USGS provided target implementation dates for each recommendation in its email transmitting its response to our draft report.

We consider Recommendations 1 through 4 and 7 through 9 resolved and Recommendations 5 and 6 implemented. We determined that Recommendations 2 through 9 are significant and will be reported as such in our semiannual report to Congress in accordance with the Inspector General Act.[31] Below, we summarize USGS' response to our recommendations, as well as our comments on its response. See Appendix 3 for the full text of USGS' response; Appendix 4 lists the status of each recommendation.

We recommend that USGS:

1. Reassess the Bureau Quality Management System implementation approach and prepare a framework to fully implement the Bureau Quality Management System at all laboratories on a more rapid timeline than December 2025.

   USGS Response: USGS partially concurred with Recommendation 1 and stated it will accelerate QMS implementation by December 31, 2024, for as many laboratories as they can but not for all laboratories. USGS noted that most laboratories have initiated the process as of August 2023 and that 233 labs have since completed implementation. USGS explained that it may not be possible to accelerate implementation in all remaining laboratories due to the availability of laboratory staff and science quality staff.

   OIG Comment: Based on USGS' response, we consider this recommendation resolved. USGS reassessed its approach and determined it was able to accelerate the timeline for 30 percent of the over 250 laboratories still implementing the Bureau QMS. USGS stated that it was unable to accelerate the implementation date at all laboratories, as the OIG recommended, due to staffing and operational limitations. We will consider this recommendation implemented when USGS provides evidence demonstrating the identified laboratories currently implementing the Bureau QMS have accelerated progress toward completing implementation by December 31, 2024.

[31] The Inspector General Act of 1978, 5 U.S.C. § 405(b), requires inspectors general to prepare semiannual reports summarizing OIG activities during the immediately preceding 6-month periods ending March 31 and September 30. It also states that these semiannual reports should include an identification of each "significant recommendation" described in previous semiannual reports on which corrective action has not been completed.

2. Develop an oversight function with clearly delineated roles and responsibilities to ensure that all laboratories are implementing the Bureau Quality Management System appropriately.

   USGS Response: USGS concurred with Recommendation 2 and stated it will develop an oversight function with clear roles and responsibilities and will include this oversight function in the next version of the QMS policy. USGS stated that the recommendation will be implemented by December 31, 2024.

   OIG Comment: Based on USGS' response, we consider this recommendation resolved. We will consider this recommendation implemented when USGS provides evidence demonstrating it has developed and implemented an oversight function with clearly delineated roles and responsibilities to ensure that all laboratories are implementing the Bureau QMS appropriately. Additionally, USGS should include this oversight function in the next version of the QMS policy.

3. Ensure that all required Federal internal control standards are incorporated into individual laboratory quality management systems.

   USGS Response: USGS concurred with Recommendation 3 and stated it will use the QMS annual internal assessment process to ensure compliance with required QMS internal controls. USGS stated that the recommendation will be implemented by December 31, 2024.

   OIG Comment: Based on USGS' response, we consider this recommendation resolved. While USGS concurred with the recommendation, its response stated that the USGS would "use the QMS annual internal assessment process to ensure compliance with required QMS internal controls." Although USGS stated that the QMS annual internal assessment process would ensure compliance with QMS internal controls, it did not provide details on how it would meet Federal internal control standards. USGS subsequently clarified that "the USGS will ensure the GAO Green Book 'Standards for Internal Control in the Federal Government' are applied to the operation of the Quality Management System in USGS laboratories." We will consider this recommendation implemented when USGS provides evidence demonstrating it has incorporated all required Federal internal control standards into individual laboratory quality management systems.

4. Require the Office of Science Quality and Integrity to clarify Bureau Quality Management System minimum requirements needed to ensure that the Bureau Quality Management System is designed, implemented, and operating effectively, including monitoring the system for necessary changes.

   USGS Response: USGS concurred with Recommendation 4 and stated that, when developing an oversight function to fulfill Recommendation 2, it will develop the metrics by which the design, implementation, operational effectiveness, and change control

monitoring will be developed. USGS stated that the recommendation will be implemented by March 31, 2025.

OIG Comment: Based on USGS' response, we consider this recommendation resolved. We will consider this recommendation implemented when USGS provides evidence demonstrating it has required OSQI to clarify Bureau QMS minimum requirements to ensure that the Bureau QMS is designed, implemented, and operating effectively, including monitoring the system for necessary changes.

5. Require laboratories to perform an initial risk assessment to identify risks and, if necessary, implement internal controls that address risks identified in the risk assessment.

   USGS Response: USGS concurred with Recommendation 5 and stated that it revised the QMS Manual (QMS Manual, version 3, dated October 24, 2023) to include a new chapter on risk that added four requirements. The risk evaluations are now performed during QMS implementation, verified at the end of QMS implementation, and reevaluated annually as part of the internal assessment process.

   OIG Comment: Based on USGS' response and review of the updated QMS Manual's requirement to assess risks, we consider this recommendation implemented.

6. Require laboratories to perform risk assessments on an ongoing basis, such as annually, and address any new risks identified in the risk assessments.

   USGS Response: USGS concurred with Recommendation 6. As stated in response to Recommendation 5, USGS stated that the QMS Manual (dated October 24, 2023) was updated to include a new chapter on risk that added four requirements. The risk evaluations are now performed during QMS implementation, verified at the end of QMS implementation, and reevaluated annually as part of the internal assessment process.

   OIG Comment: Based on USGS' response and review of the updated QMS Manual's requirement to assess risks at least annually, we consider this recommendation implemented.

7. Update risk assessment guidance to laboratories to incorporate a more comprehensive risk assessment to include other potential risks, such as staffing needs or information systems.

   USGS Response: USGS concurred with Recommendation 7 and agreed that multiple risks such as staffing levels, workload pressures, and level of supervision pose potential risks to laboratory performance. USGS stated that it will use various mechanisms to provide more comprehensive risk assessment guidance by March 31, 2025.

   OIG Comment: Based on USGS' response, we consider this recommendation resolved. We will consider this recommendation implemented when USGS provides evidence demonstrating it has updated risk assessment guidance to laboratories to incorporate a

more comprehensive risk assessment to include other potential risks, such as staffing needs or information systems.

8. Develop and maintain an inventory of all information systems in U.S. Geological Survey laboratories.

   USGS Response: USGS concurred with Recommendation 8 and stated that it will conduct a full inventory of all laboratory information systems and ensure they are properly maintained by March 31, 2025.

   OIG Comment: Based on USGS' response, we consider this recommendation resolved. We will consider this recommendation implemented when USGS provides evidence demonstrating it has developed and maintained an inventory of all information systems in USGS laboratories.

9. Assess controls over all identified information systems and implement controls necessary to protect system data and comply with Federal regulations.

   USGS Response: USGS concurred with Recommendation 9 and stated it will assess the compensating controls[32] applied to all laboratory information systems to ensure physical and technical security controls are in accordance with the NIST risk management framework by March 31, 2025.

   OIG Comment: Based on USGS' response, we consider this recommendation resolved. We will consider this recommendation implemented when USGS provides evidence demonstrating it has accessed controls over all identified information systems and implemented controls necessary to protect system data and comply with Federal regulations.

[32] According to NIST, compensating controls are security and privacy controls implemented in lieu of NIST minimum control requirements that provide equivalent or comparable protection for a system or organization. The full definition is available at: https://csrc.nist.gov/glossary/term/compensating_controls.

Appendix 1: Scope and Methodology

Scope

We audited internal controls in U.S. Geological Survey (USGS) laboratories, with a primary emphasis on the Bureau Quality Management System (QMS), the tool developed to improve internal control and ensure data quality in USGS laboratories. The scope of our review was from fiscal year (FY) 2015 to March 2023.

We reviewed USGS' *Quality Management System Manual* and the Energy and Minerals Mission Area (EMMA) *Quality Assurance Manual*; USGS' training records and training attestations; QMS workbooks; and laboratory standard operating procedures, logbooks, and QMS checklists. We visited a total of 10 laboratories: 4 in Lakewood, Colorado; 2 in Reston, Virginia; and 4 in Madison, Wisconsin.

Methodology

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 objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

To audit the internal controls at USGS laboratories, we reviewed documentation related to scientific integrity at USGS laboratories; interviewed USGS management responsible for scientific integrity at the headquarters, regional, and mission area levels; interviewed staff; visited and tested internal controls at 10 USGS laboratories; and analyzed internal control elements for 32 laboratories.

Out of the 245 laboratories that are either fully or partially implementing QMS, we selected 10 laboratories for site visits, which included testing of laboratories' internal controls and interviews of laboratory managers and personnel. The 10 laboratories included 4 in Lakewood, Colorado; 2 in Reston, Virginia; and 4 in Madison, Wisconsin. They are listed as follows:

- Isotope Research Laboratory
- National Water Quality Laboratory
- Petroleum Geochemistry Research Laboratory
- Lakewood Field Office Preparation Laboratory
- Reston Preparation Laboratory

- Reston Stable Isotope Laboratory
- Hall Virology West Nile Virus Laboratory
- Hofmeister Virology Laboratory
- Diagnostic Virology Laboratory—National Animal Health Laboratory Network
- Diagnostic Microbiology Laboratory

At the time of our analysis, the remaining 244 laboratories were not implementing a QMS. We selected laboratories to visit based on data analyzed and professional judgment. We selected laboratories based upon:

- Alleged or confirmed locations of incidents of misconduct.
- Laboratory type (production, research, and field laboratories).
- Number of laboratory staff.
- QMS type in use.

We assessed whether internal control was significant to the audit objective and determined that USGS' control environment, control activities, risk assessment, monitoring, and the following 12 principles were significant to the audit objective:

- The oversight body and management should demonstrate a commitment to integrity and ethical values.
- The oversight body should oversee the entity's internal control system.
- Management should establish an organizational structure, assign responsibility, and delegate authority to achieve the entity's objectives.
- Management should demonstrate a commitment to recruit, develop, and retain competent individuals.
- Management should evaluate performance and hold individuals accountable for their internal control responsibilities.
- Management should identify, analyze, and respond to risks related to achieving the defined objectives.

- Management should identify, analyze, and respond to significant changes that could impact the internal control system.

- Management should design control activities to achieve objectives and respond to risks.

- Management should design the entity's information system and related control activities to achieve objectives and respond to risks.

- Management should implement control activities through policies.

- Management should establish and operate monitoring activities to monitor the internal control system and evaluate the results.

- Management should remediate identified internal control deficiencies on a timely basis.

We relied on QMS management and laboratory personnel to provide evidence of their performance with the objectives we reviewed. To accomplish our objectives, we reviewed:

- U.S. Department of the Interior and USGS policies and memoranda related to the development and implementation of USGS laboratories' QMS, including the *DOI Scientific Integrity Procedures Handbook*; the USGS *Survey Manual* 500.25 on scientific integrity; Office of Science Quality and Integrity instructional memorandum, *Quality Management System for USGS Laboratories*; the *Quality Management System Manual* for the Bureau QMS; and the *Quality Assurance Manual* for EMMA.

- Laws and regulations, including Federal policy on research misconduct and Office of Management and Budget Circular No. A-123.

- Prior audits and evaluations related to scientific integrity at USGS laboratories.

- USGS budget justifications.

- The Government Accountability Office's *Standards for Internal Control in Federal Government*.

- Data provided by USGS, including laboratory statistics, QMS workbooks, and spreadsheets documenting QMS requirements.

- Results from testing the implementation of 6 internal control elements at the 10 laboratories visited.

During our audit, we conducted limited testing of laboratories' implementation of 6 control elements at 10 laboratories. Specifically, we looked at laboratories' standard operating procedures, evidence of staff trainings, equipment inventories, document control, QMS oversight, and monitoring and corrective action activities. We analyzed 32 laboratories'

documentation related to implementation of the Bureau QMS internal control elements—specifically their QMS checklists.

We determined that the data we used as a basis for our findings and conclusion were sufficiently reliable for the purposes of this audit. While we identified significant issues with internal controls for USGS laboratories, the data used to support our findings was corroborated through document reviews, interviews, and direct observations.

Appendix 2: Criteria for Internal Controls Included in Figure 5

Figure 5 of the report identifies the number of laboratories from our sample of 32 that either implemented internal controls or deemed them not applicable. The following contains descriptions of the internal controls as described in the *Quality Management System Manual* (the "QMS Manual") and relevant principles from the U.S. Government Accountability Office's *Standards for Internal Control in the Federal Government* (the "Green Book").

Standard Operating Procedures (SOPs)

The QMS Manual states:

> SOPs provide instructions to carry out routine procedures in a consistent manner to produce repeatable outcomes or results. SOPs contain a detailed description of the steps needed to perform the procedure, written so that similarly trained personnel not familiar with the procedure would be able to successfully perform it. For QMS, high-risk activities are supported by SOPs, but laboratories may choose to use SOPs for other procedures.

The Green Book provides that control activities are "the actions management establishes through policies and procedures to achieve objectives and respond to risks in the internal control system, which includes the entity's information system." Specifically, Principle 12, "Implement Control Activities," states, "Management should implement control activities through policies." This includes defining the policies through procedures.

Equipment Inventory

The QMS Manual provides that laboratory equipment is essential for conducting experiments and performing laboratory methods and activities.

Principle 10 of the Green Book, "Design Control Activities," states, "Management should design control activities to achieve objectives and respond to risks." This includes management establishing physical control to secure and safeguard vulnerable assets and periodically counting and comparing assets to control records. To do this, inventories of the laboratory equipment would need to be maintained.

Laboratory Activity and Training

The QMS Manual states:

> Personnel participate in training to develop and maintain the necessary knowledge and skills to successfully perform activities required by their job. For Laboratory Personnel, this includes training on the concepts and requirements of the QMS

and training on specific laboratory activities for which Laboratory Personnel are responsible. Training encompasses the identification of training needs and the training techniques, objectives, trainer, content, frequency, and documentation.

The Green Book provides in Principle 4, "Demonstrate Commitment to Competence," that management establishes expectations of competence for key roles. Competence "requires relevant knowledge, skills, and abilities, which are gained largely from professional experience, training, and certifications." The principle also provides that training tailored to the needs of the role enables "individuals to develop competencies appropriate for key roles [and reinforces] standards of conduct."

Peer/Supervisory Review

The QMS Manual provides that "laboratory results, quality-control results, information about results, and elements from acquiring and processing laboratory results are reviewed to verify accuracy, completeness, and traceability before use."

Principle 10 of the Green Book, "Design Control Activities," provides that management should design appropriate types of control activities for the entity's internal control system. Control activities help management fulfill responsibilities and address identified risk responses in the internal control system. Common categories of control activities include reviews by management at the functional or activity level to ensure proper execution of transactions (activities) and accurate and timely recording of transactions (activities).

Documentation

The QMS Manual provides that document management is "the process of tracking, uniquely identifying, versioning, and controlling laboratory documents." Document management is "informed by the purpose of the document and the criticality of the information" that the document contains.

The Green Book notes that documentation is a necessary part of an effective internal control system and that documentation is required for the effective design, implementation, and operating effectiveness of an entity's internal control system. The Green Book includes minimum documentation requirements as follows:

- "If management determines that a principle is not relevant, management supports that determination with documentation that includes the rationale of how, in the absence of that principle, the associated component could be designed, implemented, and operated effectively." (attribute OV2.06)

- "Management develops and maintains documentation of its internal control system." (attribute3.9)

- "Management documents in policies the internal control responsibilities of the organization." (attribute 12.2)

Appendix 3: Response to Draft Report

The U.S. Geological Survey's response to our draft report follows on page 37.

United States Department of the Interior
U.S. Geological Survey
Office of the Director
Reston, Virginia 20192

Memorandum

To: Mark Lee Greenblatt
Inspector General

From: David Applegate
Director

Digitally signed by JAMES D. APPLEGATE
Date: 2024.05.08 14:38:17 -04'00'

Subject: Response to Draft Report – USGS Laboratories Remain Vulnerable to Breaches of Scientific Integrity (Report No. 2022-CR-035)

Thank you for the opportunity to review and respond to the Office of the Inspector General's draft audit report entitled, *USGS Laboratories Remain Vulnerable to Breaches of Scientific Integrity*.

The audit focused on internal controls to address research misconduct in laboratories, which is one type of a loss of scientific integrity. Research misconduct at the USGS is addressed through multiple internal control strategies that include, but are not limited to, Quality Management Systems (QMS). The QMS is focused on quality and provides a set of internal controls that are part of this multipronged approach. Since the audit was initiated in September 2022, the USGS has substantially strengthened other checks on research misconduct. Such actions include hiring of a full-time Scientific Integrity Officer and staff scientists to support the implementation of Departmental and USGS scientific integrity policies; hiring of a full-time Science Quality Officer to provide structure and accountability in addressing science quality problems; enhanced training in Fundamental Science Practices; and the chartering of a USGS Federal Advisory Committee for Science Quality and Integrity. A Laboratory Advisory Board was established to inform policies, processes, and strategies for laboratory quality, integrity, research protections, and workforce (e.g., competency, shortages, workloads, and management pressures). The Board leadership comprises three senior career positions that are independent of the chain of command of those performing USGS lab activities and will fulfill the role of an oversight body for QMS.

The USGS has benchmarked dozens of organizations and international standards, hired highly qualified staff at multiple organizational levels, established the first-ever QMS for research laboratories of its size and complexity and used risk to inform the level of controls needed for each activity. Additionally, the USGS engaged the [redacted] to provide recommendations on how the QMS should be developed and implemented. The USGS exceeded the scope of the QMS proposed by [redacted] and, in response to their recommendations, the USGS developed a QMS that provides internal controls for all laboratories using a risk-informed implementation. The October 2023 version of the QMS Manual adds a chapter with recommendations for annual risk evaluations and a new requirement to establish standard operating procedures for high-risk routine activities.

Recommendation 1: Reassess the Bureau Quality Management System implementation approach and prepare a framework to fully implement the Bureau Quality Management System at all laboratories on a more rapid timeline than December 2025.

> **USGS Response:** Partially concur. As of April 2024, 233 laboratories have completed implementation. Most of the remaining laboratories began implementation in August 2023. The USGS has reassessed the QMS implementation approach and will accelerate implementation for 30% of the more than 250 laboratories currently implementing the USGS QMS to complete implementation by December 31, 2024. However, the timeline for implementation was informed by the availability of laboratory staff and science quality staff to ensure the USGS can meet its commitments to stakeholders and collaborators. Therefore, it will not be possible to accelerate implementation in all remaining labs.

Recommendation 2: Develop an oversight function with clearly delineated roles and responsibilities to ensure that all laboratories are implementing the Bureau Quality Management System appropriately.

> **USGS Response:** Concur. The USGS will develop an oversight function with clear roles and responsibilities. The USGS will include this oversight function in the next version of the QMS policy.

Recommendation 3: Ensure that all required Federal internal control standards are incorporated into individual laboratory quality management systems.

> **USGS Response:** Concur. The USGS will use the QMS annual internal assessment process to ensure compliance with required QMS internal controls.

Recommendation 4: Require OSQI to clarify Bureau Quality Management System minimum requirements needed to ensure that the Bureau Quality Management System is designed, implemented, and operating effectively, including monitoring the system for necessary changes.

> **USGS Response:** Concur. When developing an oversight function to fulfill recommendation #2, the USGS will develop the metrics by which the design, implementation, operational effectiveness, and change control monitoring will be developed.

Recommendation 5: Require laboratories to perform an initial risk assessment and identify and, if necessary, implement internal controls that address risks identified in the risk assessment.

Recommendation 6: Require laboratories to perform risk assessments on an ongoing basis, such as annually, and address any new risks identified in the risk assessments.

> **USGS Response:** Concur with recommendations 5 and 6. As a result of the OIG Audit Notice of Potential Findings and Recommendations, the QMS Manual was revised (QMS Manual v03, 10/24/2023) to include a new chapter on risk that added four requirements: evaluate activity-level risk; center manager review and approval ofrisk level related to activities and the use of laboratory results at least annually; demonstrate high rigor in meeting QMS requirements for activities that are evaluated as high risk; and evaluate and document points at which something might go wrong that might impact laboratory performance or the quality of

laboratory results. Controls are then applied to mitigate the risks identified throughout implementation. The risk evaluations are now performed during QMS implementation, verified at the end of QMS implementation, and re-evaluated annually as part of the Internal Assessment process. Controls are adjusted or added to address newly identified risks and changing risk levels. (See Attachment: "USGS QMS Manual_v03_20231024_signed.pdf')

Recommendation 7: Update risk assessment guidance to laboratories to incorporate a more comprehensive risk assessment to include other potential risks, such as staffing needs or information systems.

USGS Response: Concur. The USGS agrees that multiple risks, outside of a standard QMS, such as staffing levels, workload pressures, and supervision pose potential risks to laboratory performance. Therefore, the USGS will use various mechanisms to provide more comprehensive risk assessment guidance of these items.

Recommendation 8: Develop and maintain an inventory of all information systems in U.S. Geological Survey laboratories.

USGS Response: Concur. As part of the USGS IT Security Assessment and Authorization (A&A) process, laboratory information systems that are joined to the GS Active Directory domain (usgs.gov) are properly inventoried. The USGS will conduct a full inventory of all laboratory information systems and ensure it is properly maintained.

Recommendation 9: Assess controls over all identified information systems and implement controls necessary to protect system data and comply with Federal regulations.

USGS Response: Concur. USGS laboratory information systems joined to the USGS Active Directory have adequate technical security controls implemented. The USGS will assess the compensating controls applied to all laboratory information systems to ensure physical and technical security controls are in accordance with the National Institute of Standards and Technology Risk Management Framework. Mitigating measures will be determined and implemented until the corresponding recommendations are applied.

Attachment

Appendix 4: Status of Recommendations

Recommendation	Status	Action Required
2022-CR-035-01 We recommend that the U.S. Geological Survey (USGS) reassess the Bureau Quality Management System implementation approach and prepare a framework to fully implement the Bureau Quality Management System at all laboratories on a more rapid timeline than December 2025.		
2022-CR-035-02 We recommend that USGS develop an oversight function with clearly delineated roles and responsibilities to ensure that all laboratories are implementing the Bureau Quality Management System appropriately.		
2022-CR-035-03 We recommend that USGS ensure that all required Federal internal control standards are incorporated into individual laboratory quality management systems.	**Resolved**	We will track implementation.
2022-CR-035-04 We recommend that USGS require the Office of Science Quality and Integrity to clarify Bureau Quality Management System minimum requirements needed to ensure that the Bureau Quality Management System is designed, implemented, and operating effectively, including monitoring the system for necessary changes.		

Recommendation	Status	Action Required
2022-CR-035-05 We recommend that USGS require laboratories to perform an initial risk assessment to identify risks and, if necessary, implement internal controls that address risks identified in the risk assessment.	**Implemented**	No action is required.
2022-CR-035-06 We recommend that USGS require laboratories to perform risk assessments on an ongoing basis, such as annually, and address any new risks identified in the risk assessments.		
2022-CR-035-07 We recommend that USGS update risk assessment guidance to laboratories to incorporate a more comprehensive risk assessment to include other potential risks, such as staffing needs or information systems.	**Resolved**	We will track implementation.
2022-CR-035-08 We recommend that USGS develop and maintain an inventory of all information systems in U.S. Geological Survey laboratories.		
2022-CR-035-09 We recommend that USGS assess controls over all identified information systems and implement controls necessary to protect system data and comply with Federal regulations.		

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U.S. DEPARTMENT OF THE INTERIOR

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