Consensus Study Report

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HIGHLIGHTS

Assuring Data Quality at U.S. Geological Survey Laboratories

The mission of the U.S. Geological Survey (USGS) is to provide reliable and impartial scientific information to understand the Earth, minimize loss of life and property from natural disasters, and manage water, biological, energy, and mineral resources. Data collection, analysis, interpretation, and dissemination are central to everything the USGS does. To ensure that its data are of the highest quality, the USGS is developing and implementing a quality management system (QMS) for all its laboratories. This report reviews a sample of USGS laboratories, examines the QMS and other approaches for assuring data quality, and recommends best practices for assuring the integrity of USGS laboratory results.

The USGS operates some 250 laboratories across the country to analyze physical and biological samples, including water, sediment, rock, plants, invertebrates, fish, and wildlife. The data generated in the laboratories help answer pressing scientific and societal questions or support regulation, resource management, or commercial applications. Consequently, it is important to maintain public trust in USGS data.

In 2016, an Inspector General report found scientific misconduct and data manipulation at a USGS laboratory in Colorado. Two laboratory analysts had adjusted values outside of protocols over two extended periods. To restore confidence in USGS data, the USGS began developing a quality management system (QMS) in 2016 and set an aggressive schedule for its implementation. A QMS is a structured system that establishes and documents the requirements for how work is to be managed, conducted, and monitored to assure data quality. This system is a paradigm shift for the USGS because all laboratories will be required to implement a centrally defined quality standard in a similar and consistent way.

OVERVIEW OF USGS LABORATORIES

Before 2016, the USGS did not have a complete inventory of its laboratories, their capabilities, and their quality assurance practices. To fill that knowledge gap, the USGS issued two data calls to its employees: one on basic laboratory information and one on data quality procedures. In responding to the questionnaires, laboratory managers and principal investigators defined their own laboratory boundaries, with some grouping similar activities into a single laboratory, and others splitting similar activities into more than one laboratory.

Analysis of the responses to the data calls revealed substantial diversity in USGS laboratories in terms of such factors as scientific objectives, analysis techniques, funding sources, sample throughput rate, budget, staff numbers, and user profiles. For example, some laboratories focus on a specific mission area (e.g., water), a region (e.g., Grand Canyon), or a measurement technique (e.g., stable isotopes or molecular genetics). Funding for laboratory operations may come from a combination of sources, including the USGS, grants from other federal agencies, and user fees. Sample throughput, which depends on the type of sample being analyzed and the analytical procedures being performed, ranges from tens of samples per year to tens of thousands of samples per year. Users may include any combination of federal and academic scientists, federal and state resource managers and regulators, or private companies.

The USGS distinguishes research laboratories (those supporting innovation and scientific discovery) from production laboratories (those carrying out routine analyses for USGS or external users). The laboratories focused primarily on supporting research are generally small (2–3 full-time equivalents [FTEs] on average), have low annual budgets (typically $0.2 million or less), and serve USGS scientists as well as scientists in other federal agencies and academic institutions. In contrast, laboratories that also serve regulators, resource managers, and commercial

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users generally have more staff (7 FTEs on average) and larger annual budgets (typically 2–4 times higher) than laboratories primarily supporting research. The largest USGS laboratory—the National Water Quality Laboratory, which primarily provides sample analyses and specialized services to customers, has 134 FTEs and an annual budget of $6 million or more. All of the USGS laboratories have quality assurance and quality control procedures in place, but those procedures are generally more comprehensive and better documented in laboratories supporting production activities than in laboratories primarily supporting research.

The report also assessed the extent to which operational and personnel resources are sufficient to meet the scientific and applications objectives of USGS laboratories. Interviews conducted at the 17 laboratories visited indicated that staff are skilled in what they do and take pride in their work, but staffing shortfalls and turnover are a common resource problem. Funding appeared adequate to meet science and applications objectives, but adding responsibility for QMS implementation without adding sufficient resources may hinder a laboratory's ability to meet its science goals in the future.

EXPERIENCES WITH QMS

To provide a benchmark for the USGS QMS effort, eight organizations that are using a QMS for at least some of their laboratories were invited to share their approach and experiences. The organizations chosen were the USGS, Navy, Centers for Disease Control and Prevention, Environmental Protection Agency, the French and Norwegian geological surveys, Texas A&M University, and Duke University Medical Center. Each of these organizations had different motivations for developing a QMS, different QMS challenges, and different QMS implementation strategies.

Despite differences, some common themes emerged. All said that implementing a QMS provides benefits, such as improving documentation, reliability, or reproducibility of laboratory data; finding and correcting data quality problems; and enhancing the organization's reputation for quality data. However, these benefits come with substantial monetary and personnel costs. The high costs and paperwork burden associated with implementing a QMS, as well as the need to learn a new way of doing things can create resistance among laboratory scientists and staff. Institutional commitment and strong leadership are required to gain buy-in and to change the organization's culture. Consistent messaging is important for explaining why a QMS is needed, and good two-way communication between managers and laboratory staff is essential for developing a QMS that meets the needs of the laboratories. Finally, implementing the QMS slowly allows the system to evolve in response to lessons learned and thus ensure that the system fulfills its intended purpose.

QUALITY ASSURANCE PROGRAMS AND BEST PRACTICES

Quality assurance programs are designed to establish the criteria for assessing and improving laboratory performance, and to ensure that best practices are routinely identified and adopted across laboratory activities. A variety of approaches can be taken to assure data quality in laboratories. Approaches range from highly autonomous scientific oversight programs designed to meet individualized requirements to centrally controlled quality management systems designed to meet the requirements of an organization. Table 1 lists some of the benefits and drawbacks of four approaches to an organization.

BEST PRACTICES

The report identifies best practices and procedures for achieving scientific and applications objectives and assuring the integrity and reliability of results for USGS laboratories. The report recommends best practices for production laboratories and comments on best practices for research laboratories.

Institution-defined expectations of data quality are important for generating data of known and consistent quality across large organizations such as the USGS, which has to manage some 250 diverse laboratories around the country. The USGS is already implementing one type of institution-defined approach (QMS; step 3 in Figure 1) for its laboratories. This is a good fit for laboratories that carry out well-characterized and routine analyses for internal or external users (production activities). A few of these laboratories may also need to meet additional externally-defined QMS requirements (Step 4 in Figure 1) for some procedures, based on client requirements.

Approximately half of USGS laboratories are used primarily by researchers. In these laboratories, analyses are frequently adjusted as research hypotheses unfold or as the process of method optimization and validation proceeds. Creative experimentation is necessary before processes can be standardized. For these laboratories, institution-defined best practices (Step 2 in Figure 1) are appropriate because the laboratory does not have to comply with the requirements of a centrally-controlled quality standard. Instead, the laboratory lead scientist develops a custom program to meet the generalized best practices chosen by the USGS. Moving from scientist-defined procedures to institution-defined best practices would retain the ability of research-oriented laboratories to experiment and innovate, while fully participating in a centralized USGS laboratory culture committed to accountability and data quality and integrity. Adding periodic independent data quality checks (e.g., peer review, internal audits, and interlaboratory sample exchange) would confirm that institution-defined best practices have become routine in research and method development laboratories at the USGS.

Few USGS laboratories support only research activities or only production activities. Consequently, the USGS, in consultation with its laboratories and their users, will have to decide which laboratories need a QMS and which need institution-defined best practices.

Recommendation 1. The USGS should implement institution-defined best practices (Step 2) or institution-defined QMS (Step 3), as appropriate, for its laboratories.

Table 1. Approaches for Quality Assurance Programs

Scientist-defined procedures and protocols that are implemented at the individual laboratory level.	
Benefit	Disadvantage (or drawback)
Scientists have the autonomy and flexibility to be creative and innovative in developing their laboratory methods.	Practices may be ad hoc, highly variable across laboratories, or may not cover quality planning, quality control, and quality improvements for all processes that contribute to data quality.

** This approach is common in academic laboratories and was used by most USGS laboratories prior to 2016.*

Institution-defined best practices that are implemented at the individual laboratory level.	
Benefit	Challenge
Having standardized expectations for data quality should improve the consistency, reliability, and efficiency of processes across the laboratory system.	Implementation requires more time, effort, training, and oversight than the previous approach.

Institution-defined QMS requirements that are implemented throughout the institution.	
Benefit	Challenge
Centralization achieves consistency, efficiency, and a shared quality culture across the laboratory network.	Increases cost because quality assurance professionals are needed to coordinate and monitor activities (e.g., document and change control, methods and error management, and audits) across the organization, and staff require training and support to take on additional quality assurance activities.

** The USGS is implementing this approach.*

Externally-defined QMS requirements that are implemented at the institution or individual laboratory level to demonstrate compliance with an external quality standard.	
Benefit	Challenge
Demonstrates a high level of research accountability to clients, collaborators, or regulatory agencies with established quality standards.	Expensive, periodic external reviews (audits) are required for laboratories to maintain accreditation.

** The USGS National Water Quality Laboratory is using this approach.*

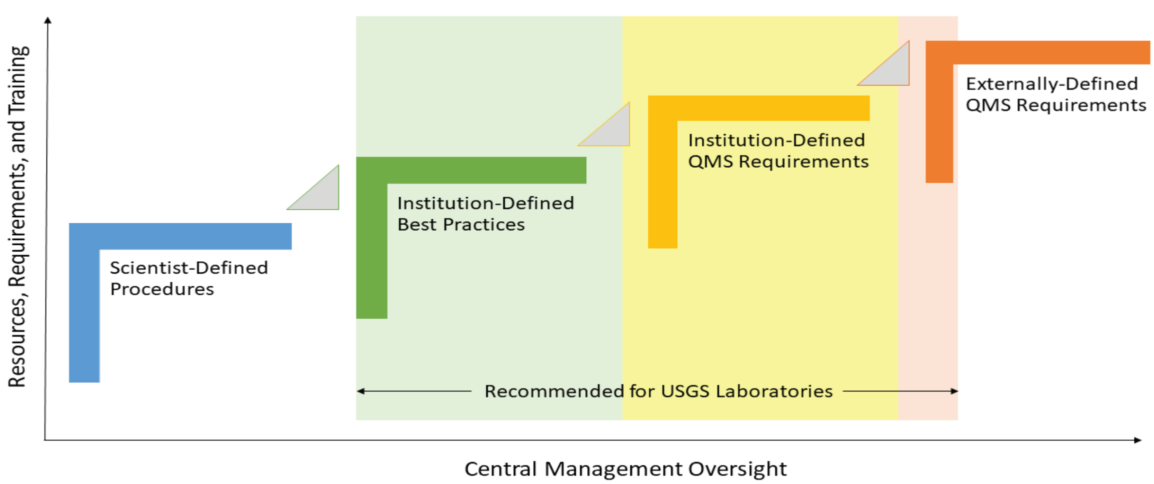

FIGURE 1. Step diagram illustrating the increasing complexity, cost, requirements, and oversight needed for approaches 1 to 4. Prior to 2016, most USGS laboratory practices were consistent with scientist-defined procedures (blue, Step 1). The USGS is now implementing an institution-defined QMS (yellow, Step 3). The committee recommends that USGS laboratories follow institution-defined best practices (green, Step 2) and QMS, as appropriate (primarily Step 3, with a few in Step 4, orange).

RESOURCES

A key responsibility of management is to support implementation and maintenance of the quality assurance program. However, current USGS resource commitments, quality assurance staffing, and training are insufficient to implement the central QMS for all USGS laboratories. The USGS expects its laboratories to devote an estimated 20 percent of their resources for about two years to implement the QMS and about 10 percent annually thereafter to maintain the system. This substantial effort should be recognized, supported, facilitated and rewarded by USGS management.

Institution-defined best practices are less expensive to implement than a comprehensive QMS. Consequently, implementing institution-defined best practices for the laboratories focused primarily on research would free up central USGS resources to support QMS implementation and maintenance for the subset of laboratories engaged in production activities.

Recommendation 2. The USGS should optimize and prioritize centralized resources for the subset of laboratories doing production activities that would most benefit from a QMS.

TIMELINE

The USGS is developing and implementing its QMS too quickly. QMS development began in 2016 and the system was implemented in 11 energy laboratories in mid-2017. Quality assurance programs such as QMS and institution-defined best practices are relatively new concepts in research and method development laboratories. Such systems are complex and take time to develop, implement, and evolve. The USGS will need to take the time to

- Communicate more extensively with staff, including explaining the quality goals of the organization and gaining staff input and feedback on system design and implementation;
- Provide staff training, including meetings with quality assurance experts;
- Establish mechanisms to recognize, support, and reward the substantial time and resources invested by laboratory scientists and quality assurance experts to meet USGS data quality goals;
- Develop QMS champions who would help lead the necessary culture change; and
- Learn from implementation experiences and continually improve the system.

Recommendation 3. The USGS should slow implementation of its QMS and 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.

REVIEW OF THE U.S. GEOLOGICAL SURVEY'S LABORATORIES: PROCESSES, PROCEDURES, AND BEST PRACTICES TO MEET NATIONAL NEEDS

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