From Peer-Review to Accreditation: Quality Management in USGS laboratories

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Issue:
The U.S. Geological Survey is currently preparing implementation plans for a Quality Management System (QMS) for all USGS laboratories. The system must uphold basic quality tenets while providing support and flexibility for the breadth of laboratory science and range of production (routine processes that aim to answer a repetitive question) to research (novel, unique ever-changing processes that aim to answer varying questions) laboratories. The USGS QMS Working Group has written an Instructional Memorandum (see "USGS Resources" below) that outlines these quality tenets as 11 Core Elements that make up the backbone of the policy, which applies to all USGS laboratories' processes and recorded data. Continuous improvement is the central QMS concept.

USGS laboratory data must be of known and documented quality, and putting a QMS in place makes that achievable. "Known and documented" can be described in the following principles:

- Transparent: easy to perceive; obvious; unambiguous; clear; straightforward
- Traceable: able to be found or discovered. (Example: When a number is reported in Science Base, we must be able to trace the origin of that number back to the lab, analyst, instrument, method used, standards used, calculations used, and even the lot number of the chemicals used in that method.)
- Reproducible: able to be reproduced or copied by a reasonably qualified person and achieve equivalent results.
- Impartial: unbiased; objective.
- Reliable: consistently good in quality or performance; able to be trusted.

Many laboratories (mainly those focused on repetitive processes) seek accreditation from an outside body (e.g. ISO and NELAC) as to their competence at meeting that outside body's standards for an effective QMS. The quality community has a very specific vernacular that may or may not translate well into the culture of the USGS. Currently, several of our laboratories hold outside accreditations, including the National Water Quality Laboratory (NWQL) in Lakewood, CO, and the laboratories at the National Wildlife Health Center in Madison, WI.

Much of what we do in the USGS lies in the "research" realm. Data produced in a research setting must also be of "known and documented quality". However, applying QMS to research is more complicated because of its language, structure, and processes. (See "Other Resources" below.) There is a deep concern among many scientists in the USGS that the imposition of a QMS on their laboratory practices will be overly burdensome and potentially inhibit the productivity of their research, making the USGS less competitive than our academic neighbors. Many research scientists assert that publishing their work in peer-reviewed journal articles is enough to fulfill the quality tenets. While peer-review of information products is an essential component of USGS Fundamental Science Practices, its scope is more limited than a QMS.

Another issue that has been raised is the many policies, processes and procedures that overlap with QMS, including, but not limited to: records management, data management/data release, information product publication, safety, environmental, facilities, accountable property, and IT security. Stacking another policy on top of existing policies where there is overlap is not efficient. This is a unique opportunity to plan strategically and realize efficiencies and synergies across the Bureau.

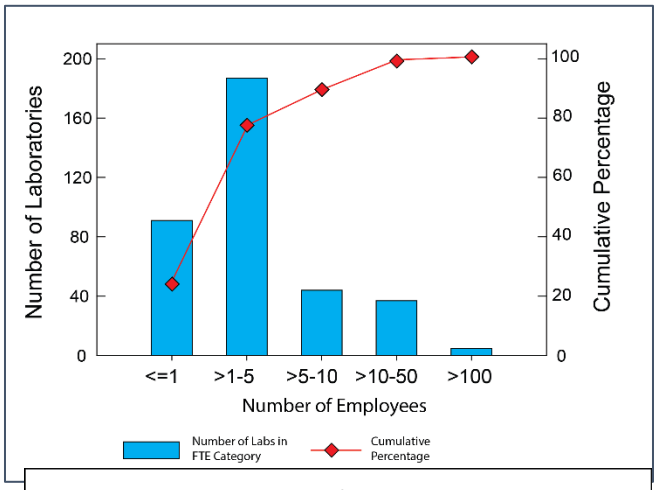
USGS laboratories must implement a system to manage their quality in order to help prevent future incidents and to safeguard our credibility. So, the USGS is faced with this dilemma: How do we implement a QMS in a reasonable manner that takes advantage of existing systems, and does not overburden our scientists unnecessarily? How can the implementation of a QMS be crafted to be easier to understand, while realizing the benefits of the system?

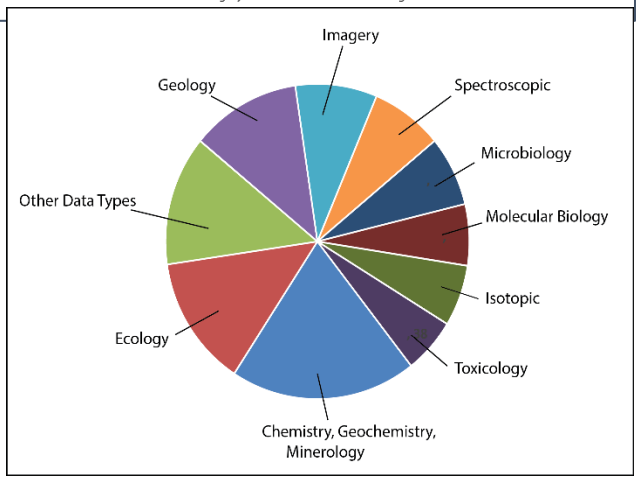
Background:
The USGS has a long-standing reputation for producing high-quality, unbiased, innovative science. Any deviation from our scientific integrity principles could damage the reputation of the Bureau. The USGS has evolved over the decades. More and more, we are taking on controversial scientific issues, and threading the needle between different sides of an issue. There are many people who want to challenge the quality of our information, and we are seeing a dramatic increase in information quality act and freedom of information act challenges. The USGS has had some specific issues on the past. Most notably, in 2014, the Energy Resources Program self-reported an incident of data manipulation (scientific misconduct) in a laboratory in Denver. The incident was the second of its kind in the laboratory, and caused an investigation by both the USGS Office of Scientific Quality and Integrity (OSQI) and the Department of the Interior's Office of the Inspector General (OIG), and subsequent congressional testimony by Bill Werkheiser in 2016 (see "Congressional Testimony" section in Resources below). Although we believe the incident in Denver was an isolated one, it underscored the need to continually and consistently document the quality of our information. Otherwise, those who are trying to find fault with our science or who do not want to use our science at all have a perfect reason not to do so. In more simple terms: If I can't trust these USGS data, then how can I trust any USGS data and why do I have to use it?

Laboratory science is an integral part of the larger scientific integrity issue, and we all must be more vigilant ensuring we can defend and reproduce our data. On the heels of the identification of misconduct in Denver, Bill Werkheiser charged the USGS Strategic Laboratory Committee with forming a working group to address the implementation of a QMS in our laboratories. That linkage caused a perception in some that QMS implementation is a punitive measure, but QMS is not new to many of our laboratories, and the implementation of a QMS in the USGS can help prevent future catastrophic laboratory issues by putting proper checks and balances in place to ensure quality tenets are upheld. Therefore, this is something we should have implemented long ago, and it will add value to our Bureau and to the defensibility of our laboratory data.

In an effort to assess the status of USGS laboratories, the Strategic Laboratory Committee collected information through a series of two surveys in 2016 and 2017. The following bullets are findings from those surveys:

- 361 laboratories responded to the surveys, though the actual number of laboratories in the USGS may be different depending on how each entity self-identified (did they lump groups of labs together or did they split them up).
- Over three-quarters (77%) of the laboratories have 1 to 5 full-time employees, meaning that most of our laboratories are small. In fact, 25% of the laboratories have 1 or fewer full-time employees.
- Laboratories are geographically dispersed and scientifically diverse.





The implementation of QMS in our laboratories is a significant undertaking. It impacts multiple levels of our scientists, including student employees, laboratory scientists, supervisors, and managers at the center, regional and Mission Area levels… all the way to the Office of the Director. QMS presents a daily process change for scientists. Although most of our scientists are using some components of an established QMS in their daily routines, most are not using the full package of processes. Therefore, implementation will require a lot of training, checks, and balances, and a drive to continuously improve the system.

In response to the Inspector General's report and findings, the Energy and Minerals Mission Area has developed a QMS and has implemented it in many of its laboratories. It has been reviewed by an external body (contractor who regularly reviews quality systems) and is heavily influenced by NELAC accreditation standards. Other Mission Areas that fund and/or manage laboratories (Ecosystems, Natural Hazards, and Water Resources) have a heavy research component and are critically evaluating the varying methods of implementing QMS to fit their needs. As they develop their mission-based approaches to QMS, it will be critical that their plans have a level of consistency. Many of our science centers and laboratory projects are funded by multiple mission areas. So, if a laboratory is working under the Water Resources' QMS, that must be equivalent or acceptable by the Ecosystems' QMS.

Challenge and Expectations:
QMS is not a "standard" in research institutions and academia, but it is recognized more and more as a necessary component of a robust research system. Creating something from scratch that works for the USGS provides a unique opportunity to strategically examine how a QMS can support our research without putting unnecessary burdens on our scientists. Additionally, for a process change of this magnitude that impacts so many employees, it is critical that this policy is not created in a vacuum. It is imperative that it is not another policy that is stacked on top of others and viewed as another hoop to jump through. This affords us the ability to look at the overlapping policies and procedures to determine how these systems can work synergistically.

With that context, we are asking you to develop your vision for how the USGS should implement a process change (QMS) for our laboratories that ensures the data produced in them are of "known and documented quality". The vision should examine where the USGS should be on the continuum that runs from relying solely on peer-reviewed journal articles for defensibility to accrediting all of our laboratories. It should also consider how a QMS can augment or work with current processes, policies, and procedures that may overlap.

Resources
Many resources are included below. The resources with an "**" next to them will be most helpful to get you started.

USGS Resources
USGS Instructional Memorandum (interim policy) on QMS: https://www2.usgs.gov/usgs-manual/im/im-osqi-2018-01.html
** USGS Internal QMS Website (including definitions and FAQs): https://internal.usgs.gov/fsp/slc/qms/index.html
** Handout summarizing the 11 Core Elements that make up the QMS policy: https://internal.usgs.gov/fsp/slc/qms/documents/Handout_QMS_Core_Elements.pdf
Video of the Town Hall Bill Werkheiser hosted: https://internal.usgs.gov/thecore/news/2018/03/12/town-hall-from-denver-quality-management-system-for-usgs-laboratories-thursday-march-22-2018/
Video of the QMS Training Webinar presented in April 2018: https://internal.usgs.gov/fsp/slc/qms/events.html#qmstraining

Congressional Testimony (for background information only)
Video of testimony: https://www.c-span.org/video/?419628-1/william-werkheiser-testifies-falsified-geological-data
** Official statement from Bill Werkheiser: https://www.usgs.gov/congressional-statement/statement-bill-werkheiser-deputy-director-us-geological-survey

Other Resources
** "20181211 – Summary of QMS in Research Journal Articles"
ISO Accreditation Standards – general requirements: https://www.iso.org/files/live/sites/isoorg/files/store/en/PUB100424.pdf