Balancing Compliance and Cost When Implementing A Quality Assurance Program

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When implementing a Quality Assurance (QA) program, compliance and cost must be balanced. A QA program must be developed that hits the mark in terms of adequate control and documentation, but does not unnecessarily expend resources. As the Waste Isolation Pilot Plant (WIPP) has moved towards certification, Sandia National Laboratories has learned much about balancing compliance and costs. Some of these lessons are summarized, below.

Implementation can be difficult if the QA program was developed with little input from the people performing the work or the QA program requires actions that are not driven by upper-tier requirements. The benefits of a properly developed and implemented QA program include cost reduction and avoidance by doing the right things, correctly, the first time.

Key elements of a QA program to be applied in a regulatory environment include:

1. **Traceability** - understanding the source and justification of data and other inputs that generated the conclusions,

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2. **Transparency** - being able to follow the logic, calculations, and other operations that produced the results,
3. **Reviews** - documented technical, QA, and managerial reviews including comment resolution,
4. **Reproducibility** - being able to reconstruct the results,
5. **Retrievability** - being able to retrieve documentation that demonstrates the above.

Implementing a successful QA program takes commitment from both management and staff. Management supplies the vision and leadership and staff commit to follow the QA program. Management is accountable for communicating expectations and providing feedback on status, successes, and failures at all-hands meetings, during performance reviews, and through memoranda. Staff are accountable for understanding and adhering to the QA program. Change is often associated with implementing a QA program. An attitude of teamwork can be fostered by management interacting with staff to socialize changes, prompting staff for input, and holding staff and managers accountable for noncompliance.

Some fundamental concepts need to be considered when developing or revising a QA program:

1. Implement QA at the earliest stage possible, including training. Costs are reduced by reducing errors, duplication, and rework when the activities incorporate QA requirements from the beginning.

2. Identify the types of information that the system will need to provide and the potential format (e.g., paper records, electronic files).
3. Ensure that decision points are documented with ample justification. Regulators' need for in-depth understanding of the logic followed for various decisions made on WIPP was underestimated. Extensive resources were expended supplementing records to clarify or make the decision process transparent.
4. Use multi-disciplinary teams (e.g., experimentalists, analysts, programmers, QA, records, database administrators) to design or revise processes. Most processes are not stand-alone; they take output from a source upstream and provide input to a user downstream. Integrated processes should be developed with input from a wide range of expertise.
5. Incorporate users' needs into the design of the QA program or QA procedures. The users may include regulators and oversight groups as well as people working under the QA procedures.
6. Only respond to upper-tier QA requirements. Going beyond requirements adds to costs. The efficiency of QA program implementation decreases with increasing procedural complexity.
7. Use standardized tools whenever possible. Keep the expertise to use the tools in house. Bringing in outside expertise for exotic tools is expensive.
8. Use technology to reduce costs (e.g., place controlled documents on the WEB to eliminate hard copy distribution.)

9. Assign a QA and records management point of contact for each work group. Integrate these people into the work groups. On the WIPP, each technical work group has a dedicated QA coordinator.
10. Create one source or reference document for QA requirements. Multiple sources of applicable QA requirements can lead to omissions, errors, and various interpretations.
11. Create stand alone QA procedures, so that different parts of a QA program may be revised without requiring revisions to related documents.
12. Incorporate forms directly into procedures and include procedural steps on the forms. The information that a worker needs is on the form, not buried in a procedure.
13. Read-and-sign training is not a satisfactory way to transfer knowledge. Classroom training with live interaction leads to consistent interpretation and implementation.
14. Records provide the link between regulators and projects. The indexing system must be so "smart" that a third party can ask the "wrong" question (because they have limited experience on the project) and get the "right" answer (one that provides them with the whole story). If the system does not do that, the conclusions drawn will be erroneous and most likely unfavorable to the project. With a properly designed information system, supplemental input from staff is reduced during reviews of the project by a third party.
15. Investigate upper-tier QA requirements to understand how long records must be kept. This will influence how they should be archived. Maintaining more than is necessary will increase costs.

16. In addition to assessing compliance, encourage auditors to evaluate programs for opportunities to streamline QA procedures.
17. Keep improving the QA program. A successful QA program depends on feedback from self-assessments, independent assessments, and a corrective action tracking process.

QA lessons have been learned that apply to data collection and software:

1. Create and adhere to database standards so the exchange of information requires little reprocessing.
2. Use a single source for information whenever possible; e.g., read all physical constants from a single database. Ensure that the data source meets the users needs.
3. Eliminate data that is hard wired into a code. It is very difficult to understand the sources for these types of information (relates to traceability).
4. Ensure data integrity - where did this data come from? Were there any opportunities for corruption or overwriting?
5. Identify a suite of codes that will address most analysis needs. Limit the number of codes that must be qualified and maintained.
6. Use software engineers to develop and maintain software. They can do the testing and documentation much more efficiently than analysts.

The key to successful QA implementation is to balance the need for compliance, which is critical, with the reality of costs. In addition to addressing upper-tier requirements, a

QA program should provide for: traceability, transparency, review, reproducibility, and retrievability. Finally, include the needs of regulators and staff in QA program development or revision. Balance leads to success.

Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy under Contract DE-AC04-94AL85000.

Report Number (14) SAND--97-2832C
CONF-980516--

Publ. Date (11) 199712
Sponsor Code (18) DOE/EM, XF
UC Category (19) UC-2000, DOE/ER

DOE