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THE CHALLENGES OF DEVELOPING AND INTEGRATING A QUALITY MANAGEMENT SYSTEM IN A RESEARCH AND DEVELOPMENT ORGANIZATION

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SUMMARY

Tailoring a quality management system to the specific needs of an organization is difficult to say the least. The existence of quality system models and standards help facilitate this process immensely. However, what does an organization do when its work is so unique that quality system models and standards do not exist for it? This and other obstacles are what the Nonproliferation, Arms Control, and International Security (NAI) Directorate at Lawrence Livermore National Laboratory (LLNL) encountered during its strategic initiatives to develop and integrate a new quality management system.

This paper will answer this question to help similar initiatives by:

- Introducing NAI and its unique mission, organization, history, culture and the security environment in which it operates.
- Examining the obstacles to designing and integrating NAI's quality management system.
- Discussing the steps taken to ensure success of the strategic quality initiatives.
- Presenting the quality management system and plan that resulted from these efforts.
- Presenting the improvements in NAI and LLNL that resulted from these strategic initiatives.
- Presenting lessons learned and practical recommendations.

INTRODUCTION

The Nonproliferation, Arms Control, and International Security (NAI) Directorate at Lawrence Livermore National Laboratory (LLNL) is a center of excellence in scientific and technical expertise, analysis, leadership, and technology development for nonproliferation and arms control, proliferation detection and defense systems, counter-terrorism and incident response, and international assessments. The directorate's work ranges from long-term applied research focused on the frontiers of detection science to more near-term treaty verification challenges and requires multi-disciplinary technical skills and effective matrix management of several hundred personnel internal and external to NAI and LLNL. Tens of thousands of customers from around the world regularly use NAI's products and services. The directorate's success also relies significantly on its ability to effectively manage relationships with its diverse customers.

The emerging but not-yet-clear international security environment in which NAI operates also has added to the technological and management challenges. As the Soviet era fades into the past, a major U.S. impetus to help the new Russian republics secure their weapons useable materials and find civilian uses for their weapons-related expertise, technologies, and facilities has unfolded. Instability in Russia also increases the danger of weapons materials and technologies migrating to conflicts in other parts of the world. In addition, chemical and biological warfare agents that are easy and inexpensive to produce are now becoming the poor man's weapon of mass destruction (WMD). The starting materials for these weapons are readily available and are difficult to control, track, and detect. Sub-national groups committed to international terrorism using WMD are also emerging. These times require better tools to deal with terrorism, proliferation, and arms control, monitoring, and WMD crisis response (Ref. 1).

While the NAI Directorate provides unique and essential technological tools, experience, organization, and commitment to meet these security challenges, it also has to manage the resulting changes to its work objectives, verification and work methods, customer base, working relationships, and infrastructure. Some NAI programs are growing exponentially. Others must compete for smaller scope proposals for which economies of scale are more difficult to achieve. Some NAI projects and divisions are converting to a production mode where cost and cycle time reductions and adaptability to market changes are emerging as key elements to success. NAI organizations are being driven to improve, formalize, and streamline work processes. Analytical methods, lessons learned, and a historical knowledge base that are not documented or communicated effectively to affected personnel are often lost or have to be re-invented or re-learned. In addition, some NAI organizations, often for the first time, need to work collaboratively with internal customers from other NAI organizations and other LLNL directorates. The decreasing availability of qualified intelligence, security, and other analysts with appropriate security clearances also adds to the challenges.

The office of the NAI Associate Director, or what is commonly referred to as the NAI AD Office, recognized that effective leadership, planning, process improvement, management, peer review, communications, collaboration, and training are increasingly becoming essential elements for ensuring NAI's success. In response to the new and unique quality management challenges, the NAI AD office, in part, established a strategic quality initiative to develop and integrate a new quality management plan for NAI.

OBSTACLES TO DESIGNING AND INTEGRATING NAI'S QUALITY MANAGEMENT PLAN

The first major obstacle to designing and integrating the quality management plan was the lack of trust in NAI's "quality" efforts. NAI's past quality management plans like other LLNL directorate-level quality plans were written to meet the requirements of the *LLNL Quality Assurance Program* (Ref. 2). The *LLNL Quality Assurance Program* is an institutional quality assurance (QA) plan that is based, contractually, on the criteria of the applicable Department of Energy (DOE) Order on quality assurance (Ref. 3). It is not written to meet the quality management needs of the majority of LLNL's R&D organizations like NAI with unique histories, work, cultures, and best practices. Consequently, the past and current revisions of NAI quality management plans, like many other upper-level quality plans at LLNL, were perceived as providing very little if any value and sat on a shelf and collected dust. This also left a bad taste regarding any quality-related activities in the mouths of NAI personnel. While most NAI folks recognized the need for a quality management system and tools, they did not have much hope of success or trust in similar quality management initiatives at the directorate or institutional level.

The second major obstacle was the limited number of quality management plans, quality system models, and quality standards for R&D that could be used as benchmarks. Four documents that provide some general information on R&D quality plan elements were identified (Refs. 4, 5, 6, and 7), however extensive research via the internet and contacts with several world-class R&D facilities turned up very little detailed guidance. As a result, the efforts to design and tailor a quality plan for NAI would be more tedious and labor intensive than expected.

STEPS TAKEN TO ENSURE SUCCESS OF THE STRATEGIC QUALITY INITIATIVES

Several steps were taken to deal with the obstacles and ensure success of the strategic quality initiatives. First, a Chief Engineer with extensive corporate-level leadership experience external and internal to LLNL was hired to lead the effort. A quality management professional experienced in quality management system design and development was also hired. Throughout the effort, the Chief Engineer and Quality Engineer met with all NAI professional-level employees to introduce themselves and the quality initiatives and to obtain their input on the scope of NAI's work and its culture, customers, good quality processes, fears, and areas needing improvement.

A cross-functional quality committee with representatives from all NAI working and management levels was also established. The committee was chartered with developing clear quality objectives tied to NAI's needs (not to the LLNL QA Plan) and NAI's mission, concurring with the outline of the plan, and

reviewing and concurring with all final drafts of the plan. The final NAI quality management plan was also distributed for comment to numerous senior-level technical, quality, and management professionals, internal and external to NAI and LLNL. Concerted efforts were taken to document, follow-up and address every comment submitted by a reviewer.

Last, a comprehensive directorate-wide assessment was performed to validate the NAI quality management plan and evaluate its adequacy, integration, and level of implementation throughout NAI. The assessment was performed to also identify any vital few issues that could prevent NAI from meeting its quality, management, and performance objectives.

NAI'S QUALITY MANAGEMENT SYSTEM

The NAI *Quality Management Plan for Science and Engineering* (Ref. 8) that resulted from these efforts is based on a quality management system the NAI Directorate Quality Office created and tailored to NAI's unique needs. The system is reflected in the plan's Table of Contents below.

- NAI Mission
- Introduction
 - NAI Organization, Business, and Customers
 - NAI Philosophy of Quality Assurance
 - Quality in the NAI Directorate
- Purpose
- NAI Quality Objectives
- Quality Management Guides
- Responsibilities
- References
- Glossary
- Appendix A - NAI Directorate Quality Management Plan and Quality Management Guides Mapped to the LLNL QA Plan
- Document Revision/Review History

The plan reflects the unique nature and scope of NAI's work, culture, and customers and meets the intent of the *LLNL Quality Assurance Program* (Ref. 2). It was designed using quality standards ANSI/ASQ Z1.13-1999 (Ref. 4) and ANSI/ASQC E-4 (Ref. 5) as baselines. These standards map well into Order DOE O 414.1A (Ref. 3) and the *LLNL Quality Assurance Program*. (Ref. 2).

While the plan naturally includes standard document control and quality plan elements, it also has four distinguishing features that are essential for its acceptance and success in NAI. First is the plan's brevity and tone. Second is the alignment of the NAI mission, quality objectives, organization, and responsibilities. Third is inclusion of a quality system model that captures the essence and uniqueness of R&D work and quality processes. Fourth are the Quality Management Guides that provide practical and flexible requirements for applying work methods that are readily accepted by members of the R&D community.

PLAN'S BREVITY AND STYLE

The new NAI *Quality Management Plan for Science and Engineering* is prescriptive and addresses all the required elements of the *LLNL Quality Assurance Program*. However, unlike past plans, it is brief (13 pages) and written in a user-friendly style and casual tone. Many formats and styles of the plan were submitted before getting it "just right."

ALIGNMENT OF NAI'S MISSION, ORGANIZATION, AND QUALITY OBJECTIVES

The new NAI quality management plan aligns NAI's mission with its quality objectives, organizational structure, and work responsibilities. The plan first presents NAI's mission to provide technology, analysis, and expertise to help NAI's customers address the key stages of the WMD problem. The plan then

highlights the unique aspects of NAI's work, customers, workers, and management abilities that distinguish its quality management needs from other organizations.

The plan also describes NAI organizational structure. The Directorate's work functions are broken down into the following four programs and center that respectively address the key stages of the WMD problem and help NAI achieve its mission.

Proliferation Prevention and Arms Control (PPAC) serves as the point of contact for NAI's international collaborations. PPAC's activities include management of LLNL nonproliferation efforts, nuclear materials control and disposition research and development, treaty monitoring and analysis methods development, instrument development, and policy analysis. PPAC's major customer is the DOE Office of Nonproliferation and National Security.

The Proliferation Detection and Defense Systems Program (Q Division) focuses on detecting and reversing the proliferation of weapons of mass destruction (WMD). Q Division's activities include research and development of remote sensing and unattended sensor technologies, development of data integration methods, systems analysis, calculations based on physical principles, and experimentation. Its principal customers are the DOE, the U.S. military services and unified military commands, and the U.S. intelligence community.

The International Assessments Program (Z Division) provides detailed country-specific analyses of foreign activities related to the development, production, testing, and deployment of nuclear weapons and other WMD. Z Division reviews export license applications of controlled technologies and conducts cutting-edge R&D related to information operations and information security. Its principal customers include the DOE Office of Nonproliferation and

The Counter-terrorism and Incident Response Program (R Division) develops technologies and operational capabilities to respond to WMD emergencies and terrorist incidents. R Division's activities include threat assessment, emergency response, device disablement, research and development, development of analytical methods and instrumentation, and analysis of unusual material samples. R Division's principal customers are the DOE Office of Nonproliferation and National Security, the DOE Office of Defense Programs, the Federal Bureau of Investigation, and state and local government agencies.

Center for Global Security Research (CGSR) brings scientists, technologists, and the global security policy community together to study ways in which science and technology can enhance national and international security. It also sponsors research exploring substantive new terrain to enhance global security. CGSR's major sponsor is LLNL.

The NAI quality management plan then documents the quality objectives needed to execute the NAI mission. Last, the plan lists NAI, subcontract, and vendor personnel responsibilities that clearly align with every quality objective. Care was taken to specify responsibilities for implementing the quality management plan and quality management guides and aligning work quality objectives with the Directorate's quality objectives specified in the plan.

A MODEL FOR NAI'S QUALITY SYSTEM

The introduction to the NAI plan also provides a model for NAI's quality system (e.g. the fire department model) that captures the uniqueness of its R&D work and distinguishes its quality processes from those in more compliance-oriented and hardware-oriented type organizations. This model was reviewed and concurred with by the NAI Quality Committee members and dozens of other reviewers from NAI and LLNL before it was incorporated into the plan. The model was very helpful in obtaining user buy-in for implementing of the plan and increasing trust in the NAI AD Office's quality initiatives.

The model explains that in R&D organizations, like in a fire department, the work teams have a general idea of the necessary tasks and how to accomplish them, however, the exact outcome and pathway to that outcome are not known at the start. As the work progresses, scientists and engineers like firefighters can

encounter a myriad of unpredictable situations. As they probe new ground, the likelihood increases that they will encounter unexpected problems, with the attendant possibility of failure. Quantitative methods of analysis or measures of success are typically unavailable or undefined. Researchers and firefighters can tip the scales in favor of success predominantly through proper planning and preparation of work teams and with peer input and peer reviews.

Peer input and peer reviews are two of the primary methods for ensuring the quality of planning and work outcomes in scientific organizations like NAI. Peer input is information on one or more aspects of the development of work plan, process, procedures, or methods that is actively acquired from subject matter experts. A peer review is a process of intellectual inquiry conducted by qualified individuals (or organizations) who are independent of those who performed the work, but who are collectively equivalent in technical expertise (i.e. peers) to those who performed the original work. By ensuring a sound basis for decisions in R&D environments, greater cost savings are realized since decisions will not be challenged as often and extra effort will not be required to go back and redo the work (Ref. 9). Peer review enhances the credibility and acceptance of the decision based on the work outcome. Peer input and peer reviews may be used at all points of along the R&D work continuum from reviewing the planned activities, observing the work in progress, suggesting mid-course corrections or new approaches to problem solving, and reviewing the final results.

However, other more quantitative verification methods are used in R&D and fire-fighting as well. Statistical analysis and selective testing can be used to assure the proper performance of equipment or procedures that are well understood and characterized and that must operate predictably and reliably to ensure quality of the work outcomes and safety of workers.

NAI'S QUALITY MANAGEMENT GUIDES

Fourteen Quality Management Guides that represent NAI's core processes for successful work were developed to supplement the NAI *Quality Management Plan for Science and Engineering*.

1. Scientific Proposals (NAI-QMG-001).
2. Project Management* (NAI-QMG-002).
3. Peer Reviews* (NAI-QMG-003).
4. Request for Proposals (NAI-QMG-004).
5. Scientific Notebooks (NAI-QMG-005).
6. Project Files* (NAI-QMG-006).
7. Sample Management (NAI-QMG-007).
8. Data Management (NAI-QMG-008).
9. Experiments, Tests, and Inspections (NAI-QMG-009).
10. Monitoring and Improving NAI Work* (NAI-QMG-010).
11. Calibration of Measuring and Test Equipment (NAI-QMG-011).
12. Integrated Safety Management for NAI Work* (NAI-QMG-012).
13. Software Management (NAI-QMG-013).
14. Configuration Management (NAI-QMG-014).

The guides are based upon the scientific method and established research and engineering practices that are readily accepted by the scientific community. They also enable workers and managers to successfully develop proposals, manage work and all associated risks, and document the work so that future teams can build upon the work of those who came before them. The guides are prescriptive but brief with a casual tone and provide flexibility in their application. Like the NAI quality management plan, many formats and styles for the quality management guides were submitted before getting it "just right."

The five guides marked by an asterisk (*) were identified as basic to all NAI work and, therefore, applicable to all NAI work. These required guides emphasize the importance of careful work and safety planning, peer input, peer review, records, and assessments in an R&D-based environment.

The NAI *Quality Management Plan for Science and Engineering* also requires that managers, on a case-by-case basis, evaluate the applicability of the remaining nine guides and the extent of their application to the work. Each guide further provides information to allow managers to apply it based on risk, cost, complexity, scale, and other factors applicable to the work. In addition, managers must also evaluate the need for additional or modified quality management controls in a working-level quality assurance plan for projects with unique features, high complexity, long duration, higher than normal levels of risk, or special customer requirements.

IMPROVEMENTS IN NAI AND LLNL THAT RESULTED FROM THESE INITIATIVES

NAI's quality efforts resulted in many planned and unplanned benefits. Some of the major ones are:

- Employees regained faith and trust in NAI's quality efforts.
- Regularly scheduled assessments became a channel for employees to communicate quality-related concerns, share effective work practices, and keep senior and mid-level managers apprised of the "current state of quality affairs."
- The NAI quality management system is being used as a model for LLNL and other organizational and laboratory quality plans. An implementation guide for developing quality management plans in R&D organizations is also being developed.
- Established best practices are highlighted, documented, and shared. The documented practices provide baselines for improvement.
- Major gaps in the quality management system and its implementation are identified and corrected.
- Tools for training in quality processes are provided.

LESSONS LEARNED AND PRACTICAL RECOMMENDATIONS

NAI's strategic quality initiatives were a difficult but educational journey. The following lessons learned and practical recommendations should help to facilitate similar efforts:

1. Use personnel with comprehensive leadership, planning, listening, team-building, and quality management skills to lead strategic quality initiatives. Two qualified people can do the job of ten unqualified people in one tenth of the time.
2. Developing a quality management plan or a major revision to one is tedious and labor intensive. As frequently heard in the quality arena, "eat the elephant one bite at a time." Be patient, positive, and plan strategies carefully. Identify all obvious and hidden obstacles to success and methods to address each one. Set reasonable goals and time limits. Periodically assess and fine-tune the strategies as needed.
3. Use a collaborative approach. Gone are the days when the QA Group writes the quality plans. As practicable, use a cross-functional quality committee to develop and concur with strategic decisions and documents from planning through implementation and integration of the quality initiatives. Include credible and willing participants from all working and management levels. This group can provide an excellent source for information as well as a conduit to communicate quality-related messages vertically and horizontally through the organization.
4. Regularly keep all participants including committee members informed of the status of action items and provide feedback on solicited and unsolicited input. Highlight successes.
5. Work continuously to assess the status of and to obtain buy-in on the efforts. Meet personally with as many people as possible throughout the organization to actively communicate the objective of the effort and obtain input on fears, good practices, vital few areas of concern, or major gaps. If needed, develop an accepted quality management system model that captures the essence and uniqueness of the work.

6. Find a quality management system that best fits the organization and highlights its uniqueness. If one does not exist, tailor one. The system should identify the set of quality management elements for planning, implementing, and improving work that apply to all activities in the organization.
7. Carefully align the organization's mission with its quality objectives (and policy), organizational structure, and responsibilities in your plan. Establish clear responsibilities for implementing the quality management plan and developing work objectives that align with the corporate quality objectives.
8. Identify the readily accepted "good" work practices and include them in the quality plan and implementing procedures. Don't assume that processes are of poor quality because they are not delineated in procedures or supporting records are not readily available. Identifying effective work processes may be difficult in organizations that historically have had little need for comprehensive records or procedures. Searching for these quality practices may be tedious but is well worth the effort. Assess carefully to distinguish the "good" established practices from any significant processes that may need improving.
9. Use a tone, style, and format for your quality plan and implementing procedure that fits well with the history and culture of your organization. Remember that less is best in quality plans and procedures but also be sure to meet any applicable document control requirements.
10. A quality management plan with a reasonable and practical approach will be used far more often than one that is not. One size of quality management system does not typically fit every one or every project in an organization. Provide suitable flexibility and guidance in use and application of your quality management system. Identify which elements are required, which can be tailored, and the circumstances that merit additional or modified quality management controls.
11. As practicable, use a matrix or table to demonstrate how the quality plan and implementing procedures align with applicable corporate and regulatory requirements.
12. After all is said and done, perform a comprehensive organization-wide assessment to validate the quality management plan and evaluate its adequacy, integration, and level of implementation. The assessment can also serve to identify any significant areas that could prevent the organization from meeting its quality, management, and performance objectives.

CONCLUSIONS

The challenges of developing a quality management plan are compounded in unique R&D organizations such as NAI for which few quality management system models and standards exist and trust in quality efforts is typically low. However, R&D organizations can take several steps to overcome the obstacles and ensure success of their quality initiatives. Hire qualified leadership and quality management personnel to lead the effort. Use a cross-functional quality committee to develop and concur with strategic decisions and documents. Work continuously to assess and communicate the status of and to obtain buy-in on the efforts from users, customers, and stakeholders. Design and tailor the quality management system that is based on the needs of the organization and highlights the organization's uniqueness. Use a matrix or table to demonstrate how the quality plan elements align with applicable quality requirements. Carefully align the organization's mission with its quality objectives, organizational structure, and responsibilities. Provide suitable flexibility and guidance in use and application of the quality management system. Identify which elements are required, which can be tailored, and the circumstances that merit additional or modified quality management controls. And last, perform a organization-wide assessment to validate the quality management plan and identify the vital few areas that could prevent the organization from meeting its quality and other primary objectives.

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