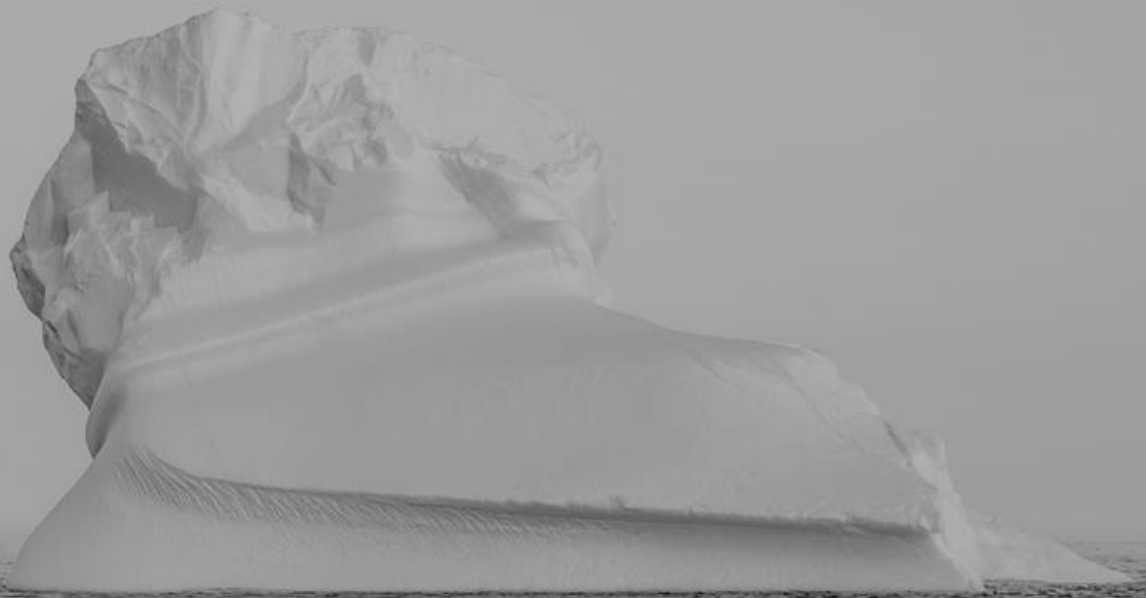# Quality Audits:

Adding Value to Your Organization

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The Problem

Quality audits are typically performed to assure compliance to quality systems, programs, standards, or regulations such as ISO9001, ASME NQA-1, or 10CFR50 App B. Audits are performed by qualified members of your own organization (first-party audits), external parties such as consultants or customers (second-party audits), or by an independent organization such as a registrar or licensing agency (third-party audits). These different types of audits serve an intended purpose, are important, and have merit. However, quality audits are too often performed as a "box-checking" activity and do not provide real value to the organization; this is especially true for internal audits and supplier audits. Furthermore, quality systems tend to evolve to meet auditors' criteria and drift from being an effective and efficient means to run the business, train new employees, and establish standard processes and work instructions. The result is a quality management system that is restrictive and bureaucratic, is not universally understood, and subsequently is not followed because it no longer serves the needs of the business. Instead, the quality management system ends up being a cumbersome set of administratively burdensome documents, must be maintained, and is not routinely used as part of the core business system. Poor quality system audits are the primary cause of these cascading events. They can reduce or, at best, do not improve the quality of products and services while creating costs that have no matching benefits. While its critical for quality assurance functions to maintain sufficient independence from cost and schedule, there is a better way.
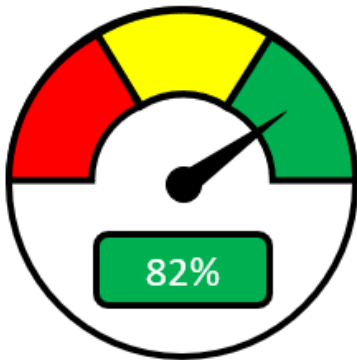
The Solution

Although assuring compliance of a business's quality management system to the appropriate quality standards and regulations is critical, quality audits can also be used to improve business processes and increase the overall performance of the organization. Achieving a balance is possible and the first step is for the organization to view the key elements as a system that work in harmony with one another and not in opposition of one another. This is where quality audits are key. They can be the link to assure compliance as well as drive improvements in both the quality management system and business processes.

Quality Management System. Whether a business is certified or complies with a commercial quality management system standard (IS9001, ASME, 10CFR50 App B, GMP, IATF 16949, etc.) or not, it is important to have documented processes. Doing so enables better training,

ensures consistency of process outputs (products and services), and reduces the reliance on "tribal knowledge". These documented processes should be based on business processes, reflect policies and procedures, and comply with the applicable quality standard. In addition to assuring compliance to the applicable quality management system standard, quality audits can serve the purpose of identifying gaps and subsequently aligning business processes and quality system standards.

Compliance. Traditionally, quality audits are focused on three elements of compliance: 1) inclusion of the quality management standard in the company's quality management system, 2) implementation procedures that reflect the quality management system, and 3) objective evidence that the applicable standards are being implemented. Many times, there are several ways to comply with quality management system standards. Therefore, it is possible to ensure that the quality management system standard is implemented in a way that complies with the standard, effectively enables the business processes, and maintains the requisite independence that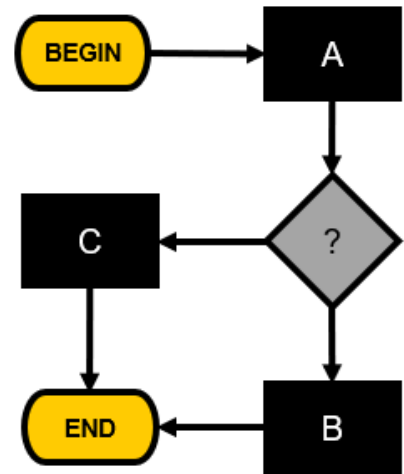 is necessary. All too often, companies implement quality management system standards in a manner that increases the administrative burden. Auditing your quality management system in a way that keeps these key points in mind can improve your quality management system and the overall effectiveness of business processes simultaneously.

Performance. Well planned, organized, and objective audits can provide a valuable insight into the performance of a quality management system as well as business processes in general. Further, by utilizing a standard audit process, standardizing checklists, communicating effectively, training employees, establishing audit metrics, implementing a system to monitor audit results over time, and ensuring that meaningful changes occur from audit results will create value for any organization. These tenets can be applied to both internal audits as well as supplier audits and pertain to complia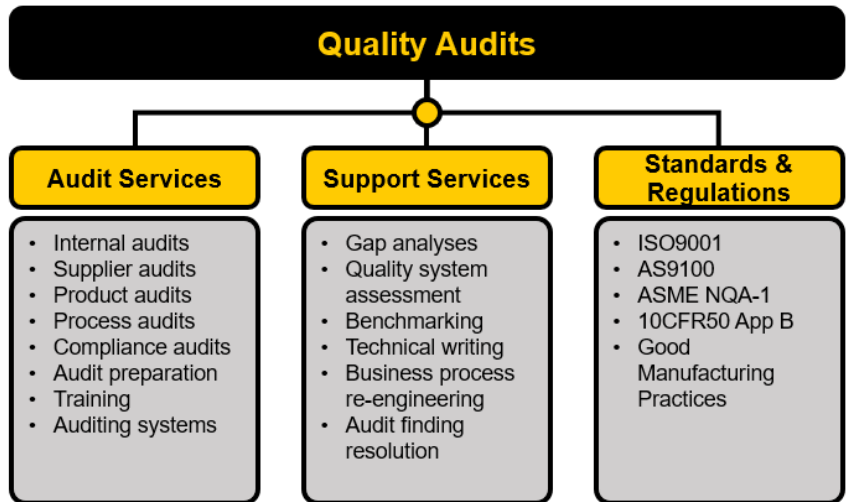nce audits, process audits, and product audits. Integrating audit results into the overall assessment of the business is a powerful way to take an organization to the next level of performance and create lasting value.

Business Processes. As the quality guru W. Edwards Deming once said, "If you can't describe what you are doing as a process, you don't know what you're doing." Identifying and documenting the key business processes is the first step in being able to effectively audit your quality management system as well as establish a baseline upon which to improve. Business processes, policies, and procedures should be synchronized with the quality management system overall and drive organizational performance. Once processes are documented effectively, these documents can serve as the basis for training new employees, knowledge transfer, and establishing consistent processes as well as expectations. Business process documentation should reflect actual practice and serve as a flexible and living system whereby documents are reviewed and updated on a regular basis. Effective document control and maintenance policies and systems need established to minimize administration and provide employees ease of access at the point of use.

The Toolkit

Next Ridge Technologies has experience working for a variety of businesses in operations, engineering, project management, quality, and supply chain functions. Examples of industries served include nuclear, aerospace, defense, oil and gas, power generation, medical device, and many others. We also have experience working with regulating bodies such as the U.S Nuclear Regulatory Commission (USNRC), American Society of Mechanical Engineers (ASME), and others. Our industry experience enables us to both directly and indirectly support your auditing needs with respect to a variety of quality management system standards and regulations. If you are exploring an area that you do not see listed, please contact us to see if we are still able to support your specific needs. No matter the service, we will maintain the requisite independence and ensure that value is added each step of the way.

Quality Audits

Audit Services
- Internal audits
- Supplier audits
- Product audits
- Process audits
- Compliance audits
- Audit preparation
- Training
- Auditing systems

Support Services
- Gap analyses
- Quality system assessment
- Benchmarking
- Technical writing
- Business process re-engineering
- Audit finding resolution

Standards & Regulations
- ISO9001
- AS9100
- ASME NQA-1
- 10CFR50 App B
- Good Manufacturing Practices