

Verification Audits

Checking products, services and processes

By: J.P. Russell

Introduction:

There are many more product, service and process audits conducted than system audits. System audits verify management system conformance and or compliance. Product, product and service audits focus on verification of specific methods and product/service characteristics. Since a process audit may include a product or service audit, I have called the combination, a verification audit. Verification audits are part of what Joseph Juran called the “little q” (quality control, tactical tools) as apposed to the “big Q” (quality assurance or management systems). System thinking is very important but we can not lose sight of the everyday tools necessary to ensure processes are controlled and risks minimized. Supply chain management, outsourcing, process/product complexity and sophistication, certified suppliers and operators, global economies, and risk of field failures, have all increased the need for ongoing verification. Additionally, verification audits need to be performed when there are routine changes in suppliers, equipment, process settings, methods, requirements or personnel.

Verification Methods:

Standards require verification of products and activities to ensure control. It is part of the PDCA model. For example: The ISO 13485 medical device standard uses the words verification and validation over 100 times. Most verificationsⁱ and validationsⁱⁱ are integrated into design, manufacturing or service delivery processes and are preformed by operators, inspectors, technicians, engineers, service providers and auditors.

Need:

ISO 9001, clause 7.4.3, Verification of purchased product, states that organizations must establish and implement activities to ensure purchased product meets specified requirements. If risks of nonconformity or failure are low, verification may be a simple inspection. However, if risks are higher, supplier processes may be verified, contract requirements affirmed, and product/service characteristics and performance checked. Risks could be higher due to: complexity, low confidence levels in the supplier, sole sourcing, criticality of the product/service, the high levels of revenue being transacted, material, or safety, health, or environmental consequences. Based on the news reports and my personal experiences, it seems to me that number of defective products, contaminated foods and recalls are increasing.

The benefits and market advantages of outsourcing has increased reliance on other organizations for important products and services. The organizations that provide the outsourced products and services are run by managers with different goals, skills and abilities, values and cultures. Increased oversight is needed to ensure supplier organizations provide what they promised and will be able to provide the same products and services in the future. ISO 9001, 4.1 General Requirements allows outsourcing of any process but the organization must ensure control over

such processes and retains responsibility for conformity to all customer, ISO 9001, statutory and regulatory requirements.

Many organizations do a good job of verification of materials and components but not so good on services or processors. Supplier services or processors may in fact have the greatest impact on an organization (for example: clinical trials, heat treating, welding, knelling, annealing, special packaging, special solutions, trades and so on).

A global economy gives management more options to ensure the organization is effective and efficient and able to survive competitive pressures or increased demands for their industry or public sector. However, the advantages could be negated due to failure costs, delays, or risks to the wealth of the organization (assets).

Some organizations purchase sophisticated or specialized services that require special equipment or individuals with an expertise or trade. In other cases organizations are becoming more reliant on second party services to reduce overhead costs, free up resources and space or procure services that are not an organization's strength.

Organizations carry out projects to design, development, construct, assemble or build. Designing may require seeking special expertise for various design nuances external to the organization. For example, if you are designing a tower, you may need a wind expert. If you are constructing a building you may need a foundation expert for a given site. The performance of design, development, construction, assembly or building activities may require performance of tasks by suppliers that represent a high risk to the successful outcome of the project (for example: design calculations or modeling, quality of concrete and pour method for a bridge, and setting up terminals or shops to perform specialized services).

There are high risk activities performed by organization-trained personnel that need oversight. Due to consequences of failure, some risks must be mitigated by verification and validation. ISO 9001, clause 7.5.2 requires organizations to validate any processes for production and service provision where the resulting output cannot be verified. For example, there may be sophisticated equipment that must be operated and calibrated, welding, inspection of pharmaceuticals and medical devices, containerization of dangerous materials, and so on.

One way to mitigate negative consequences of high risk product use or process is to conduct verification audits. Verification audits can be a product audit, a process audit or a combination of both. Product and process audits are considered preventive actions, a form of quality assurance versus inspection, which traditionally has been thought of as quality control.

Preparing:

Once the need of the audit is determined, standard audit preparation activities should be carried out. You will need to know the audit objectives, criteria and scope.

There could be several audit objectives depending on whether is it an internal or external audit as well as the performance history of the process, product or service.

First-party audit objectives:

- verify/ validate a process. The process may be an activity that can not be verified by inspection or test. The process may be a special test or procedure requiring special expertise or equipment.
- verify project implementation activities such as in construction or new product or services
- verify product characteristics or validate performance requirements
- verify that defects and nonconformities have been addressed
- verify training, equipment capabilities, process settings

Second-party audit objectives:

- verify supplier organization process or processes used to provide a product or service
- verify supplier product or service characteristics or validate performance requirements
- verify supplier process capabilities
- verify conformance to contract requirements
- verify material sources and traceability
- verify that defects and nonconformities have been addressed

Third-party audit objectives:

- approve/disapprove process for license or certification
- approve/disapprove product or service for license or certification

Next the scope needs to be established. The scope may be an internal or supplier process or product. There may be one process, processes in series or parallel processes that need to be verified. There may be one product/service or several products/services that need to be verified.

You need to understand the process and product/service you are going to audit. Reviewing the procedure, specifications and records is a good starting point. If there is no procedure, you may need to ask the auditee to provide a description of the process or processes. Ask questions, talk to people to get the information you need.

There are several tools available to help you to understand the process. They include:

- process flow diagrams, flowcharts or process mapping
- CE diagrams, turtle diagrams
- Tree diagrams
- FMEA results
- Training documents
- Inspection checklists
- Procedures
- Bill of materials, quantities, specifications

There must be some type of process input/output criteria. Criteria may include:

- specifications, lists,
- drawings, pictures, diagrams
- planned arrangements for process approval

- approved equipment and qualification/certification of personnel
- test procedures
- inspection method sheets
- first article inspections
- contract or regulatory requirements

Find out about process/product history. Things you will want to know are:

- nonconformance reports and trend analysis
- internal and field failures
- corrective actions
- process/product changes, date and nature of changes
- operator/technician changes
- revalidation history
- customer complaints

The process elements to be considered for a verification audit are summarized in a spider diagram. Such diagrams can be used as a tick off the areas verified and can be customized for your situation. A comprehensive diagram is available online in PowerPoint format (www.QualityWBT.com/FYI)

Performing:

Follow standard auditing protocols for conducting the verification audit. If internal, briefly make contact with the manager or supervisor before starting the audit. If external, you will need a short meeting with the manager/supervisor to review the audit plan.

If you are to check product as well as the process you will need to determine your sampling method. You may choose to observe sample selection, inspection and test procedures.

The primary strategies for process audits are tracing and process strategies (The Auditing Handbook, 3rd edition, pages 80-81). Auditors need to test the weaknesses as well as verify the strengths of a process or series of processes. Collect information by using open-ended questions to gather data about process inputs, outputs and the process elements (people, environment, equipment, material, measuring and method).

The primary strategy for the product/service audit is using the requirements or element/clause strategy. This method is used in system audits to determine if an organization conforms to requirements specified in clauses or elements in a standard. This same strategy is used in product/service audits to determine if product conforms to specified requirements that are in a clause or element of a standard, specification or condition document. A product audit can include verification of product characteristics as well as performance requirements.

Verification audits are perfect opportunities to perform reverse traces, since there are more verifiable linkages throughout a process or processes. The traces can include but are not limited to process settings, personnel training, material traceability, nonconformance handling, material handling and storage, shelf life controls, process equipment, measurement system, supplier

control; going back to the start, the requirements such as purchase orders, contracts, regulatory or internal requirements.

If included in the audit objectives and purpose, verification audits can include error-proofing or mistake-proofing to improve process effectiveness and efficiency. Identified weaknesses can be a potential source of a nonconformity if not addressed. An auditor may also observe opportunities for improvement that can be reported if included in the audit purpose.

Report and Follow-up:

Reports are normally brief and address the audit objectives. Reports should describe the items reviewed, whether they are characteristics, processes or documents and the audit results based on the requirements or expectations. The report should also define the requirements for corrective action and preventive action when appropriate. Audit results may be followed-up through communication of records showing that findings have been addressed or by a subsequent audit.

Conclusion:

Verification audits are part of a robust risk-management process to mitigate potential unacceptable losses. The frequency of verification audits depends on degree of risk and performance history.

Processes and/or their environments are constantly changing. Verification audits are key tools (“little q”) to ensure sustainability of the management system (“Big Q”).

Results come from checking, not expectingⁱⁱⁱ.

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ⁱ 1) Confirmation, through the provision of objective evidence that specified requirements have been fulfilled (ISO 9000, 3.8.4). 2) The act or process of verifying or the state of being verified; the authentication of truth or accuracy by such means as facts, statements, citations, measurements, or attendant circumstances [Merriam-Webster Unabridged Dictionary, accessed 10/2003 at <http://unabridged.merriam-webster.com>].

ⁱⁱ 1) Confirmation that a product or service will perform as expected or specified (for example: pump performance test, vehicle road testing, try out software features). 2) Confirmation, through the provision of objective evidence that the requirements for a specific intended use or application have been fulfilled [ISO 9000].

ⁱⁱⁱ Russell, JP; *Continual Improvement Assessment Guide: Promoting and Sustaining Business Results* Quality Press 2003