Verification Audits: Checking products, services and processes

By JP Russell

Introduction:

Probably, many more product, service and process audits are conducted than system audits. Generally, system audits verify compliance versus product/process audits validate conformance. Product, process, and service audits focus on defect reduction or prevention. 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 opposed to the "big Q" (quality assurance or management systems). System thinking is important but we cannot lose sight of the everyday tools necessary to ensure processes are controlled and risks are identified as well as monitored. 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. Other reasons for performing product and process audits are due to a change 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 verifications[i] and validations[ii] are integrated into design, manufacturing or service delivery processes and are performed by operators, inspectors, technicians, engineers or those performing the service. Auditors can verify processes and product and service verification (inspection) activities. Verification audits may verify or validate: inspection methods, delivery of services, compliance with contracts, critical product or service characteristics, or process/product performance. In the AS9100, aviation, space and defense organizations standard, verify and validate have two distinctively different objectives.

Need:
ISO 9001, clause 8.4.2, Type and Extent of Control, states that organizations must determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet 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 and validated, 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.

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.

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 (asset value) of the organization. Organizations purchase sophisticated or specialized services that require special equipment or individuals with an expertise or trade. Based on make or buy decisions, a greater reliance is increasing on second-party services to reduce overhead costs, free up resources and space, or to procure services that are not an organization's strength. Organizations carry out projects to design, develop, construct, assemble or build. Designing may require seeking special expertise for various design nuances. 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).

High risk activities are 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 8.5.1 Control of Production and Service Provision requires organizations to validate, and periodically revalidate, the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement. 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 and validation audits. Verification audits can be a product audit, a process audit or a combination of both. The scope is narrowly focused with a purpose to verify or validate that a product or service meets a specified criteria or requirements. Product and process audits are also 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 it is an internal or external audit as well as the performance history of the process, product or service.

First-party audit objectives:

- verify or validate a process: The process may be an activity that cannot 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.

The process and product/service to be audited must be understood. Reviewing the procedure, specifications and records is a good starting point. If there is no procedure, the auditee may need to be asked to provide a description of the process or processes.

Several tools are available to help understand the process. They include:

- process flow diagrams, flowcharts or process mapping
- training documents
- CE diagrams, turtle diagrams
- tree diagrams
- FMEA results
- inspection checklists

There may be criteria for product and service inputs. A product may include services (set up, maintenance, and disposal) and services may include products or facilities to perform the service.

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

- specifications, lists
- test procedures
- drawings, pictures, diagrams
- planned arrangements for process approval
- approved equipment and qualification/certification of personnel
- inspection method sheets
- first-article inspections
- contract or regulatory requirements

Research process/product history to verify:

- 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

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, meet with the manager/supervisor to review the audit plan.

If product as well as the process is to be checked, the sampling method must be determined. Sample selection and inspection and test procedures may be observed.

The primary strategies for process audits are tracing and process strategies (*The Auditing Handbook*, 4th edition). A procedure may exist, but auditors need to test the weaknesses as well as verify the strengths of a process or series of processes. Open-ended questions should be used 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. The auditor should also consider performing reverse traces during product or service audit, since more verifiable linkages are throughout a process or processes. Tracing can include process settings, material traceability, personnel training, nonconformance handling, material handling and storage, shelf-life controls, process equipment, measurement system, supplier control. Going back to the start, purchase orders, contracts, regulatory or internal requirements may be verified.

If included in the audit objectives and purpose, verification audits can include error-proofing or mistake-proofing to improve process effectiveness and efficiency. An auditor may also observe opportunities for improvement as well as report-identified weaknesses 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 as 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.

My belief is that since a service cannot be verified as conforming prior to delivery to customer, all services should be validated. Since verification of product characteristics are not always a true indicator of product performance, processes should be validated, especially when changed or altered.

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

Results come from checking, not expecting[iii].

JP Russell provides training at www.qualitywbt.com. He is an ASQ CQA, Fellow of ASQ, a voting member of the American National Standards Institute/ASQ Z1 committee, and a member of the U.S. Technical Advisory Group to Technical Committee 176; the body responsible for the ISO 9000 standard series. Russell is a former RAB and IRCA lead auditor, and 15 years as columnist for Quality Progress. He is the author of the pocket guides: *Process Auditing Techniques, Internal Auditing Basics*, *Continual Improvement Assessment* and the *ISO Lesson Guide 2008*, editor of *The ASQ Supply Chain Management Primer* and editor of *The ASQ Auditing Handbook.* Russell is a trainer, auditor, consultant, and instructional designer.

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[i] 1) Confirmation, through the provision of objective evidence that specified requirements have been fulfilled (ISO 9000, 3.8.12). 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