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Validation of Process for Production and Service Provision (7.5.2)

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Clause 7.5.2 of the ISO 9001:2008 standard refers to processes that are typically considered “special processes”. These processes are so called, due to their nature; there is no way to determine if deficiencies exist prior to use or delivery. For such processes, we are unable to verify the characteristics of the product during processing without destroying the product as part of our evaluation.

While not an all-inclusive list, processes that fall under this category include welding, nondestructive examination (NDE), heat treatment, as well as casting, forging, bending, forming, bonding, protective coatings and other processes. While infrequent, disagreement can arise over what is a special process, but needless to say, if the characteristics of a product can’t be 100% verified without destroying the product, this classification applies. In all cases, it is up to organization to define these processes as part of their Quality Management System and to address these processes as appropriate.

For these processes, the only alternative to destroying useable product is to ensure that the process is controlled to the degree that it is capable of producing only conforming product. To achieve this outcome, the ISO 9001 standard addresses the control of these processes by requiring the using organization to establish arrangements for the control and verification of procedures, personnel, equipment and other factors that may impact the process under consideration.

How do we address these requirements? For the sake of an example, if we were attempting to establish a methodology for a “special process” (as well as address this process within our QMS documentation) for the fictitious "XYZ Company", we may end up with something similar to the following. I’ve tried to make this as general as possible, while addressing each of the areas noted by the standard (again, this is only an example):

1. Defined criteria for review and approval of the processes:

    - Example: “Each <Process> procedure will be reviewed and approved by XYZ Company’s <Approval Authority>, to verify compliance with the requirements of <Applicable Standard>”.

2. Approval of equipment and qualification of personnel:

    - Example: “<Process> equipment used by XYZ Company will be calibrated or verified at periodic intervals (see clause 7.6 of the ISO 9001 standard also). Personnel performing <Process> will be qualified in accordance with <Applicable code, standard or specification>".

3. Use of specific methods and procedures:

- Example: “<Process> will be performed in accordance with an approved procedure that has been properly qualified in accordance with the requirements of <Applicable code, standard or specification>”.

4. Requirements for records:

- Example: “Records related to the Qualification of <Process>, <Process> personnel, equipment, facilities, etc., shall be maintained in accordance with XYZ Company’s procedure for the Control of Records”.

5. Revalidation:

- Example: “<Process> will be revalidated by XYZ Company on an as-needed basis, where process or process conformance data indicates the need exists. <Process> personnel and equipment shall be re-qualified on a periodic basis, in accordance with <Applicable code, standard or specification>.”

This should give you an idea of an approach to address this topic. The specific controls needed, as well as the specific content and extent of documentation that needs to be developed, will have to be based on the specific requirements of your organization, your customers and the requirements of any codes, standards and/or specifications that apply.

Bear in mind also, that where outsourced processes are used, the organization must retain full responsibility for ensuring that the work performed meets all specified quality requirements. This means that not only your organization, but also your suppliers, as applicable, must ensure the control and verification of the procedures, personnel, equipment, facilities, etc. that are used.

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