Verification vs Validation

The design requirements (section 7.3) for ISO 9001:2000 require that designs be verified and validated. This requirement has been in the ISO 9000 series requirements from their inception. It has also been a source of confusion. To discuss the subject we will nee some definitions.

> **Verification** is the conformation that a product meets identified specifications.

> **Validation** is conformation that a product appropriately meets its design function or the intended use.

So far the distinction is just words and not helpful determining what to do. The following example may be helpful. One of our clients makes an epoxy material that is used to form the head gasket of an engine. There are a variety of specifications including formulation, specific gravity, flow characteristics, and temperature resistance that apply to the epoxy. Testing that assures conformance to these specifications is verification. When the epoxy is applied to an engine properly it must withstand the working pressures of an engine and perform as a head gasket. If the epoxy leaked when the engine was pressurized it would fail validation. It may have met all the material specifications (verification) but it did not work as a head gasket (validation).

Obviously, almost all properly designed products will pass validation testing if they pass verification testing. But, some products are difficult or impossible to verify by the manufacturer. For example, the engine mounts on a car. Their design function is to physically support the engine and decouple engine vibration from the chassis. The only way to validate the engine mount is to assemble it in a car and determine if it isolates engine vibration. None of the specification testing (verification) can absolutely assure that the mount will provide sufficient vibration decoupling (validation).

The engine mount manufacturer cannot perform validation testing because they usually do not have access to a test vehicle. The vehicle manufacturer is reticent to take responsibility for the validation activity and provide objective evidence of the validation process even though they are the only organization that can validate the product.

In a ISO/QS-9000 registered system this leads to difficulty. There is a clear requirement for validation but it may be impossible for the manufacturer to perform. In the case of the engine mount, even if the manufacturer could get a test vehicle, their judgment about the adequacy of the vibration decoupling would usually not satisfy the customer; the customer would want to make that judgment (perform the validation).

Although the distinction may now be clear, a solution may not be evident in cases where the manufacturer does not have the ability to perform validation. One solution would be to consider the final customer as a subcontractor for the purpose of design validation. This would require customer agreement. A second solution would be to identify verification testing that is logically linked to the specific design characteristics that require validation. Establish a test series beyond verification testing that logically would cause you to have confidence that the usage requirements can be met. This approach is also difficult, because, strictly speaking, it only approximates validation. You will need to convince the registrar that this is appropriate and all that is possible.

I believe most of the confusion between verification and validation does not result from a lack of understanding of the difference as much as the difficulty of implementing appropriate validation in some circumstances.

Bio:

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