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Vocabulary and Definitions

Any profession has a set of technical terms and specialized vocabulary. The quality profession is no different. In terms of management standards, as opposed to, say, statistical methods, there are a series of documents that provide the vocabulary.

Since many standards have a basis in ISO 9001, using the terms and definitions in that family can help communication. This is particularly true when a word or term has both a colloquial meaning and a technical meaning.

QMS Standards

The first place to start is the specific standard. Here, we consider two standards in particular: ISO 9001:2008 as a general standard and ISO 13485 as a specific standard for medical devices.

For ISO 9001:2008 Clause 3 contains terms and definitions. It doesn't define any terms, relying on ISO 9000:2005, but clarifies that the term "product" can also mean "service".

For ISO 13485:2003 Clause 3 also relies on ISO 9000:2005 but also contains terms and definitions that are more specific to medical devices. For example, Clause 3.7 defines a medical device and Clause 3.4 defines a customer complaint. Both of these terms have a specific meaning for medical devices that may not apply in other product areas.

Technical Vocabulary

Both ISO 9001:2008 and ISO 13485:2003 include ISO 9000:2005 as a normative reference. ISO 9000:2000 *Quality management systems — Fundamentals and vocabulary* provides the technical vocabulary that applies across many management systems. In particular, it applies to both ISO 9001:2008 and ISO 13485:2003.

Unlike a conventional dictionary, organized in alphabetical order, ISO 9000:2005 organizes terms into related areas:

- Quality
- Management
- Organization
- Process and product
- Characteristics
- Conformity
- Documentation
- Examination
- Audit

- Quality management or measurement processes

A nice feature of this organization is the concept diagrams in Annex A. The concept diagrams are a graphical representation among the terms defined in a specific category.

For example the concept diagram related to Management divides Quality Management into four parts: Quality Planning, Quality Control, Quality Assurance, and Quality Improvement. The concept diagram also provides the definitions for the terms.

The main body of ISO 9000:2005 gives the definitions, explanatory notes, and references to other terms included in the definition.

Common Vocabulary

The ISO website also contains definitions of common terms, *Guidance on Some of the Frequently Used Words Found in the ISO 9000 Family of Standards*. The guidance location is http://www.iso.org/iso/iso_catalogue/management_standards/iso_9000_iso_14000/iso_9001_2008.htm#support_package

This guidance offers the terms in alphabetical order and includes the part of speech (noun, verb, etc.) and the definition. It also includes the location where ISO 9001:2008 or ISO 9004:2009 uses the term.

An Example

Both ISO 9001:2008 and ISO 13485:2003 have the same requirements for customer property. Clause 7.5.4 requires, “The organization shall identify, verify, protect, and safeguard customer property provided for use or incorporation into the product.” This string of verbs – identify, verify, protect, and safeguard – obligates the manufacturer. The issue is to determine what they mean and how they differ. This is clearly a case to clarify with definitions.

ISO 9001:2008 provides part of the answer.

Verification is “confirmation, through the provision of objective evidence, that specified requirements have been fulfilled”

The ISO Guidance provides the rest.

Identify means “establish the identity of someone or somebody”

Protect means “keep safe from damage”

Safeguard means “protect or prevent something undesirable (from happening)”

With an understanding of the terms (both technical and common), we can quickly move from potential confusion to a clear understanding of the requirements. Now, creating conforming process in a QMS has become easier.