Understanding the Versions of Risk Management Standards

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One common source of confusion for medical device manufacturers is the versions of quality management standards and risk management standards. The problem is particularly relevant to risk management because many people don't understand the distinction between international standards and regional standards or the naming conventions.

The issue starts with international standards. For medical devices, two standards organizations are particularly significant – ISO (International Organization for Standardization) and IEC (International Electrotechnical Commission). Each of them issues international standards. Often, national or regional standards organizations adopt the standards and change their designations. For example, the international standard for medical device risk management is ISO 14971:2007. This is the current international version. The European Union adopted the standard, added additional information, and changed the designation to EN ISO 14971:2012.

The identification of standards has three elements:

- the identity of the issuing organization
- a non-significant number for the standard
- the year it was issued

For example, in 2016 the international organization for standardization issued ISO 13485:2016 as a quality management standard for medical device manufacturers. However, the number of the standard is not significant. One cannot decode it to determine it relates either to quality management or to medical devices.

Regional or national standards organizations may adopt international standards and, in some cases, add additional information. For example, ISO 13485:2003 is an international standard for medical device quality management. While superseded by ISO 13485:2016, many medical device manufacturers have it, or variants, implemented. Common regional variants include:

- CAN/CSA 13485-03, the version adopted in Canada
- EN ISO 13485:2012, the version adopted in the European Union
- ANSI/AAMI/ISO 13485:2003, the version adopted in the United States

Risk Management Standards

Based on the discussion above, the list below provides the current risk management standards in specific regions:

- ISO 14971:2007, the international standard
- ANSI/AAMI/ISO 14971:2007, the US standard
- CAN/CSA-ISO 14971, the Canadian standard
- EN ISO 14971:2012, the EU standard

In the EU, consider CEN (European Committee for Standardization), the parallel organization to ISO. CEN develops standards, modifies ISO standards, but does not publish standards. The associated national standards organizations sell the standards. They will also a prefix to the designation. For example:

For each of the EU standards, there is national standard based on the standards body of the member states.

I.S. EN ISO 14971:2012 is the Irish version
BS EN ISO 14971:2012 is the British version
DIN EN ISO 14971:2012 is the German version

The EU Approach

The EU regulates medical devices through three directives, Medical Device Directive (MDD), Active Implantable Medical Device Directive (AIMD), and In Vitro Device Directive (IVDD). Each of these directives has Essential Requirements, which are characteristics the device must meet. The device manufacturer determines how to meet them, but most common approach uses harmonized standards. A harmonized standard typically has a table that shows the relationship between the clauses of the standard and the sections of the Essential Requirements. A device manufacturer that uses the harmonized standard to demonstrate that the device meets that Essential Requirement has a legal status (presumption of conformity).

EN ISO 13485:2012 and EN ISO 13485:2016 relates the clauses of the standards to the conformity assessment paths in the directives. EN ISO 14971:2012 explains how the requirements of the product directives are more stringent than ISO 14971:2007; a company that implements ISO 14971:2007 as written would not be able to put the CE Mark on a medical device.

The EU intends to replace the three product directives with two product regulations. The overall approach will be the same, but there will probably be two new standards: EN ISO 13485:2017 and EN ISO 14971:2017 to align with the directives.

The US Approach

In the US, the Food and Drug Administration (FDA) issues regulations. The regulations are in the *Code of Federal Regulations* (CFR), which is divided in Titles, Parts, and Sections.

The FDA device regulations are in Title 21. The quality system requirements are in Part 820. The requirements for design control are in section 820.30. The citation is 21 CFR §820.30.

The naming system doesn't include any revision information. Parts, sections, and subsections may change independently, but the various versions all have the same citation.

The History

Most companies are concerned with the international quality management system, the US system, and the EU system. Figure 1 shows the historical progression.

For the risk management system, the international version and the EU versions are the most significant. Figure 1 shows the historical progression.

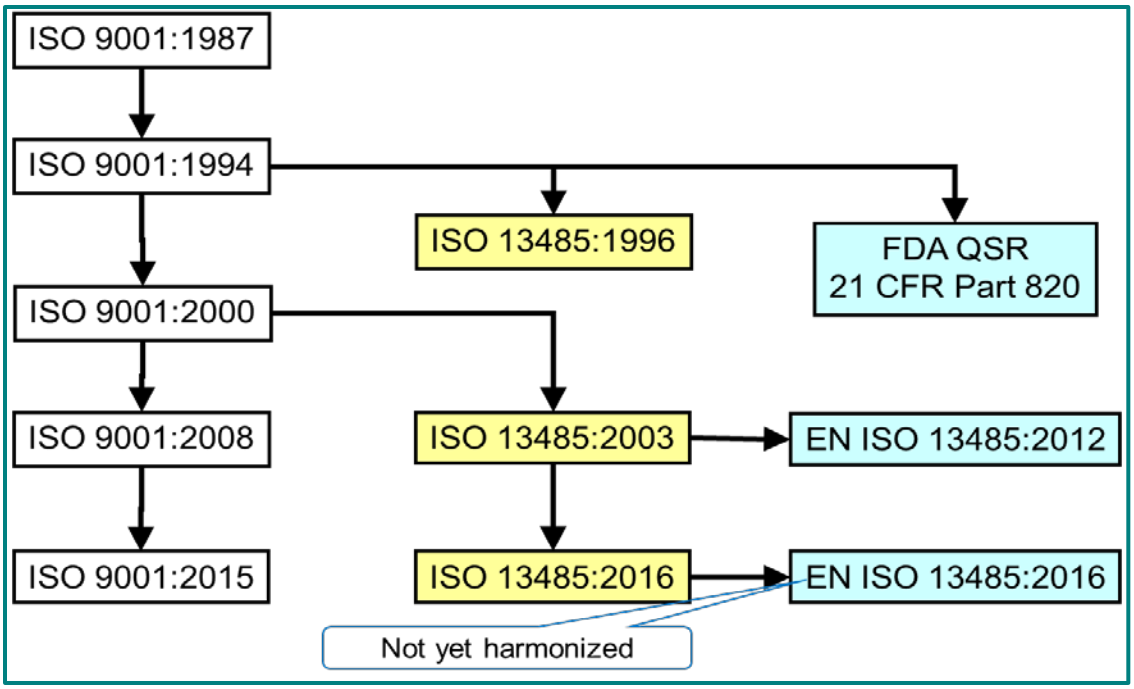

Figure 1 QMS Standards

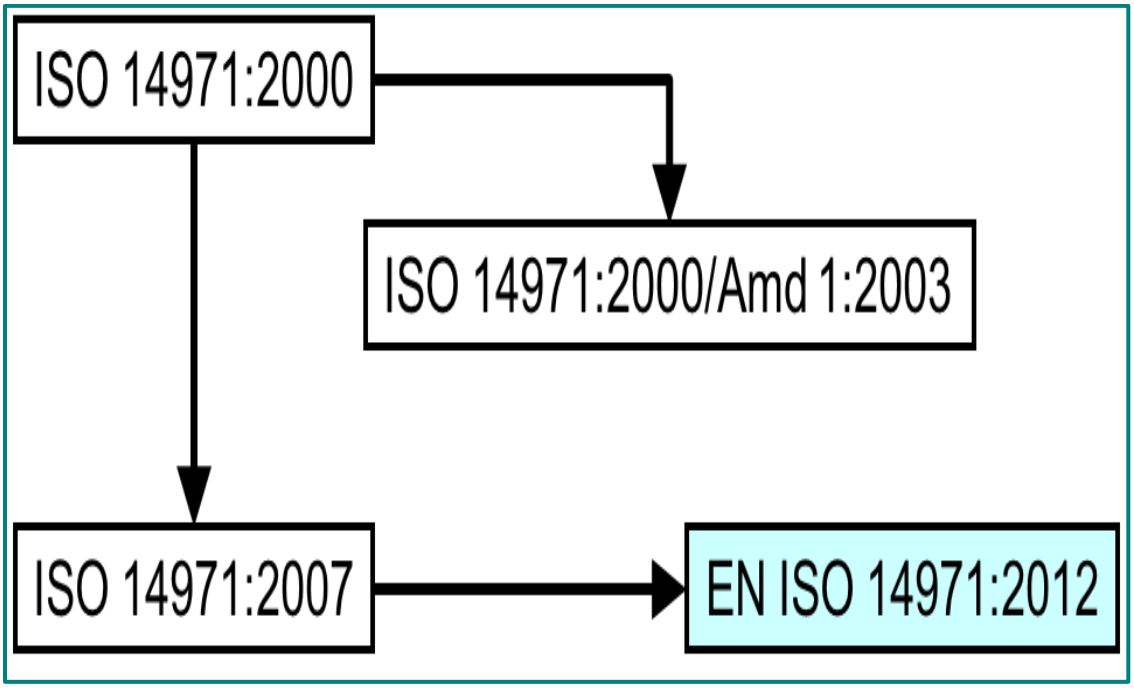

Figure 2 RMS Standards

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