The Medical Device File

ISO 13485:2016, clause 4.2.3 has the requirements for the Medical Device File (MDF). This article describes these requirements as well as the requirements from EN ISO 13485:2016 as it relates to the Medical Device Directive (MDD) Annex II.

General Requirements from the Standard

The section starts with a general description of the medical device file followed by a list of specific requirements. The first paragraph includes some sentences worthy of analysis. Starting at the beginning, the medical device file applies to either each medical device type or to medical device family. The standard doesn't define medical device type, but clause 3.12 has a definition for medical device family.

> *Medical Device Family* means a group of medical devices manufactured by or for the same organization and having the same basic design and performance characteristics related to safety, intended use, and function.

Determining Families

To set up the medical device file for a family the first step determines which devices are in the family. One method uses a matrix with potential family members listed in the first column. Subsequent columns include safety, intended use, and function. The final column list the family name for each device in the first column.

The rows list the basic design and performance characteristics of the device. This method identifies devices that share the same basic characteristics.

Establish and Maintain

The manufacturer will establish and maintain one or more medical device files. The interesting issue here is the lack of the word "document". Clause 0.2 Clarification of concepts, third indent says, "When a requirement is required to be "documented", it is also required to be established, implemented, and maintained". The medical device file is not implemented, only established and maintained. Since the medical device file contains procedures, work instructions, *etc*. presumably they are implemented. As a result the full meaning of the word documented doesn't apply – only two of the three attributes.

One or More Files

It appears the standard would allow more than one file for the same device type or device family. This is not usually a good idea; there is advantage in keeping all of the information about a device type or device family together.

Documents to Demonstrate Conformity

The medical device file includes documents that generate conformity to the standard and to regulatory requirements. One of the requirements of the standard asks the manufacturer to

determine the manufacturer's roles each regulatory region, identify the requirements, and establish the necessary processes. As a result, there are two sets of requirements to consider.

The requirements from the standard are listed in the clause. Additionally, regulatory regions create specific requirements. For the EU, EN ISO 13485:2016 is an example. Another source is the regulatory requirements cited in the MDSAP Audit Document. This identifies the requirements in the MDSAP geographic areas: Australia, Brazil, Canada, Japan, and the US. A subsequent section looks at these requirements.

Containing or Referencing Documents
The medical device file includes the documents necessary to show both kinds of conformity: conformity to the standard and conformity to regulatory requirements. The documents, or at least copies of them, could be collected into the medical device file. There was a time when they would all be in a three ring binder. Today they could be collected in an electronic file. Alternately, there could be an electronic file with pointers to the documents. Both methods are satisfactory, but the manufacturer should decide to use only one.

It would be useful, regardless of the method selected, to identify each document by its role. A document could satisfy a requirement of the standard, a regulatory requirement, or both.

Specific Requirements from the Standard

The standard lists six specific requirements. Some of these elements include multiple requirements.

General Description
Section 4.2.3.a says that the medical device file includes a general description of the medical device, the intended use/purpose, and the labeling (including any instructions for use).

The general description describes the device, and should include the device characteristics, method of operation, functional requirements, *etc*. For a device family the general description should include the basic design and performance characteristics related to safety, intended use, and function that define the family.

The intended use or purpose is part of the general information about the device, but often overlaps with regulatory requirements for an intended use statement.

In many regulatory areas, labeling is important and potentially has many meanings. It will certainly include the label that goes on the device package or the device itself. Notice that the requirement here is that labeling includes any instructions for use.

Product Specifications
Section 4.2.3.b requires specifications for the product. Think of this as the specific requirements for the device in contrast with the general description. Often these are the product specifications

included in the final acceptance criteria. These are the characteristics to verify before the device is released for distribution.

Specifications and Procedures
Section 4.2.3.c includes the specifications or procedures for manufacturing, packaging, storage, handling, and distribution.

This is a long list of requirements for procedures or specifications. Typically, the manufacturer implements procedures for each of these characteristics.

Manufacturing procedures include all of the procedures and work instructions for production, product verification, process validation, identification, inspection status, *etc.*

Packaging procedures cover device packaging and may include packaging that protects the device storage or transit. It could also include sterile barrier systems.

Storage procedures explain the requirements for the device while it is in the stockroom. For example a device may require storage under controlled conditions such as temperature or humidity.

Handling procedures may also include specific requirements such as the use of specific equipment.

Distribution procedures cover the device while in the distribution channel; the period of time from leaving the manufacturer until arriving at the customer's site.

Measuring and Monitoring
Section 4.2.3.d requires procedures for measuring and monitoring.

ISO 9000:2015 includes definitions of measuring and monitoring.

> *Measurement* means a process to determine a value. [ISO 9000:2015, 3.11.4]
>
> *Monitoring* means determining the status of a system, a process, a product, a service, or an activity. [ISO 9000:2015, 3.11.3]

Often, measurement is associated with product verification activities. Monitoring is often associated with process control. For example, in SPC, the operator would measure a product characteristic on the items in the subgroup, plot them on the charts, and use the information to monitor whether the process is in control.

Installation Requirements
Section 4.2.3.e covers installation. However, some devices don't require installation.

Installation activities usually include installation instructions, verification checks for correct installation, and data sheets to record the results.

Be sure to cover all the requirements in Clause 7.5.3.

Servicing Procedures
Section 4.2.3.f covers servicing. However, some devices don't require servicing.

Servicing could be done internally, under contract to the manufacturer, or by a third party.

If servicing is required, then the procedures include service record analysis.

Be sure to cover all the requirements in Clause 7.5.4.

Medical Device Directive Annex II

The MDD Annex II has quality system requirements. Sometimes they are covered by the clause of ISO 13485:2016. EN ISO 13485:2016 Table ZB.1 provides the specific information. More than one clause could cover a requirement, so they are listed as well.

3.1, 2nd sentence, 4th indent
The manufacturer applies to a Notified to assess the QMS. The application must include the documentation on the quality system.

Applicable clauses: 4.1.1, 4.1.2, 4.1.3, 4.1.4, 4.1.6, 4.2.1, 4.2.2, 4.2.3, 4.2.4, 4.2.5

Comments/Qualifying remarks: Covered. The documentation required in this European Standard covers the quality system documentation meant in 3.2 of Annex II when the explicit legal requirements are incorporated into the quality system documentation.

3.2, 3rd paragraph (a)
Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. It shall include in particular an adequate description of the manufacturer's quality objectives.

Applicable clauses: 4.2.3, 5.1, 5.3, 5.4.1

Comments/Qualifying remarks: Covered.

3.2, 3rd paragraph (c), 1st indent
Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. It shall include in particular an adequate description of the procedures for monitoring and verifying the design of

the products, including the corresponding documentation, and in particular a general description of the product, including any variants planned, and its intended use(s).

Applicable clauses: 4.2.3, 7.2, 7.3.3, 7.3.4, 7.3.10

Comments/Qualifying remarks: Covered provided that the documentation containing a general description of the medical device includes any variants.

3.2, 3rd paragraph (c), 5th indent
Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. It shall include in particular an adequate description of the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device.

Applicable clauses: 4.2.3

Comments/Qualifying remarks: Covered provided that the quality management system documentation includes a statement indicating whether or not the medical device incorporates, as an integral part, a substance or a human blood derivative and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the medical device.

3.2, 3rd paragraph (c), 6th indent
Application of the quality system must ensure that the products conform to the provisions of this Directive which apply to them at every stage, from design to final inspection. It shall include in particular an adequate description of the procedures for monitoring and verifying the design of the products, including the corresponding documentation, and in particular a statement indicating whether or not the device is manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC (1).

Applicable clauses: 4.2.3

Comments/Qualifying remarks: Covered provided that the quality management system documentation includes a statement indicating whether or not the device is manufactured utilizing tissues of animal origin as referred to in Commission Directive 2003/32/EC.

MDSAP Audit Tasks

MDSAP is divided into processes and further subdivided into tasks. The tasks have reference to requirements, so it is interesting to look at the tasks that refer to ISO 13485:2016, clause 4.3.2.

Process: Design and Development Task 7
Review medical device specifications to confirm that design and development outputs are traceable to and satisfy design input requirements. Verify that the design and development outputs essential for the proper functioning of the medical device have been identified. Outputs include, but are not limited to, device specifications, specifications for the manufacturing process, specifications for the sterilization process (if applicable), the quality assurance testing, and device labeling and packaging.

Process: Design and Development Task 13
Verify that design and development changes were controlled, verified (or where appropriate validated), and approved prior to implementation. Confirm that any new risks associated with the design change have been identified and [reduced] to the extent practical.

Process: Design and Development Task 16
Determine if the design was correctly transferred to production.

Process: Production and Service Controls Task 4
Determine if the organization has established documented requirements for product cleanliness including any cleaning prior to sterilization, cleanliness requirements if provided non-sterile, and assuring that process agents are removed from the product if required.

Process: Production and Service Controls Task 16
Determine if the manufacturer has established and maintained a file for each type of device that includes or refers to the location of device specifications, production process specifications, quality assurance procedures, traceability requirements, and packaging, labeling specifications, and when applicable requirements for installation and servicing. Confirm that the manufacturer determined the extent of traceability based on the risk posed by the device in the event the device does not meet specified requirements.