



DEVICE MASTER RECORD

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ISO 13485 requires that for each type or model of medical device the organization shall "establish and maintain a file either containing or identifying documents defining product specifications..."

CFR 820.181 requires the same kind of file or index, called Device Master Record (DMR), and in addition, explicitly requires that this index be itself a controlled document that is reviewed, approved and released in accordance with CFR 820.40.

Although ISO 13485 is not as detailed and explicit as 820.181, one should conclude that the requirements are quite identical, and thus this procedure applies equally to both standards.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for establishing and maintaining Device Master Records (DMR).

II APPLICATION

This procedure applies to technical/engineering documentation for each type or model of medical device.

III PROCEDURE

1 General

1.1 Device Master Record is an index (a table of contents) of device-specific documentation required for procurement of materials and components, manufacture, and evaluation of the device.

In this procedure the DMR is just an index, and not a physical file or binder with the actual documents. The advantage of this approach is that documents don't need to be copied and maintained in special files. It is also easier to implement revision control and other document control requirements. But if you prefer to maintain physical DMR files, you can easily change this procedure (in particular this section and section 3) to describe how the physical files are established, maintained and controlled. There is really not much difference. You would still need a table of contents (in effect an index) for each binder or file folder.

Physical DMR files may be more practical for relatively simple devices and in small companies. The advantage is that all documents are being kept together and thus are easy to manage.

1.2 DMR is also a current record and status of the physical configuration of the device.

1.3 Unique DMR is established for each type or model (family) of medical device manufactured by AAA Inc.

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2. Documents included in DMR

2.1 For each type or model of medical device the DMR includes the following types of documents:

This list is based on 21 CFR Part 820.181, Device Master Record, but it also fully applies to ISO 13485. Edit this list carefully to delete any items that are not applicable (installation or sterilization, for example), and to add any documents that are relevant but are not included. Be sure to use the actual document names and designations as applicable for your type of products and processes (for example, blending versus assembly, etc.).

2.1.1 Device Specifications (DS):

- product trade and common names;
- intended uses;
- performance characteristics and theory of operation;
- physical characteristics;
- environmental limitations, product stability and storage requirements;
- user safety characteristics;
- component, subassembly and assembly drawings and specifications;
- bills of materials (or lists of ingredients);
- compositions;
- formulations;
- wiring and piping diagrams;
- software specifications.

2.1.2 Manufacturing Process Specifications (MP):

- process flow charts;
- process/assembly lines diagrams;
- equipment, tools, molds;
- manufacturing environment specifications;
- setup procedures;
- operator instructions;
- equipment maintenance procedures;
- validation reports for special processes;
- sterilization specifications, procedures, and validation reports;
- blank work orders, nonconforming product/process forms, and other reporting forms.

2.1.3 Quality assurance procedures and specifications (QA):





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- quality system manual (QM);
- quality system operational procedures (QOP);
- quality system forms (QF);
- process control specifications/charts;
- control plans, instructions and acceptance criteria for incoming, in-process, and finished device inspection and testing;
- procedures and acceptance criteria for the verification of packaging, labeling, installation, and servicing activities;
- blank work order forms for recording inspection/testing activities, traceability, and other data for device history records;
- device release review/evaluation checklists.

2.1.4 Packaging and labeling specifications (PL):

- package drawings and specifications;
- filling/packaging procedures;
- label/labeling drawings;
- instruction manuals.

2.1.5 Installation, maintenance and servicing specifications (IMS):

- installation, specifications and instructions;
- maintenance instructions;
- servicing specifications and manuals.

2.2 Not all types of documents specified in this section are relevant for each type or model of device. For a particular device, the Chief Engineer, Production Engineer, Production Manager, and QA Manager decide jointly which specific documents are to be included in the DMR.

Edit to accurately assign the responsibilities for determining the contents of the DMR.

3 **Format of the DMR Index**

3.1 DMR is maintained on computer in the form of an Excel spreadsheet. The model of the spreadsheet is provided in Form QF-42-02-1, Device Master Record Index.

3.2 Individual documents referenced in the DMR Index are identified by:

- code/number,
- title (or description),
- releasing/approval authority,
- placement/custodian of the original/master document,

You probably noted that the DMR does not identify the effective date, revision level or



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distribution of its documents. The reason is that the same document may be referenced in several DMRs, and thus tracking of the revision status and distribution of this document would have to be done in several lists at once - A REAL NIGHTMARE. Instead, you want to have a document master list (refer to procedure QOP-42-01) that identifies the revision and distribution status for all documents, irrespective of whether they are included in any DMR or not, and have the DMRs just reference the document. Another advantage is that with this system the DMRs would not have to be updated every time a document is changed to a higher revision level.

- 3.3 To determine the effective date, revision level, and distribution of a document included in the DMR, the DMR Index is cross-referenced with the appropriate Document Control Master List, where the document status information is maintained (refer to Operational Procedure QOP-42-01, Control of Documents).

4 Review, approval and change control

- 4.1 The initial DMR Index, and any subsequent addition or deletion of documents form the index, are reviewed and approved by the QA Manager.

Note that the DMR Index is reviewed and approved only for its completeness (to satisfy regulatory requirements) and not for the correctness of individual documents. Thus, the function that approves the index does not need to be very technical in any specific area, but must be "multidisciplinary" and aware of the regulatory requirements.

- 4.2 The review and approval of the DMR Index is for ensuring the completeness and relevance of the index, rather than for the correctness of the individual DMR documents. Individual documents in the index are independently reviewed and approved by their issuing authority, in accordance with Operational Procedure QOP-42-01, Control of Documents.
- 4.3 DMR review, approval, change control, distribution control, retention of obsolete copies, and other document control requirements are the same as apply generally to controlled documents, as specified in Operational Procedure QOP-42-01, Control of Documents.

V ASSOCIATED DOCUMENTS

- Form QF-42-02-1, Device Master Record Index
- Operational Procedure QOP-42-01, Control of Documents
- Operational Procedure QOP-42-03, Control of Records

VI ASSOCIATED RECORDS

- **Device master record (DMR) index:** An index (a table of contents) of device-specific documentation required for procurement of materials and components, manufacture, and evaluation of the device. Based on Form QF-42-02-1, Device Master Record.



INTERNAL QUALITY AUDITS

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This procedure represents a classic and well-established approach to internal auditing, however, being true to the minimalist approach of this whole documentation, it may be somewhat light in the areas of auditor training and audit checklists. Try to strengthen these areas if you can.

If internal auditing is new in your company and you don't have any established practices, you should incorporate this procedure without too many changes, and then review it, say, a year later when you get your own experience with operating this system.

I PURPOSE

The purpose of this procedure is to provide for a system and instructions, and to assign responsibilities for conducting internal audits of the quality management system.

II APPLICATION

This procedure applies to all processes and activities of the quality management system, and to all areas where the quality system is implemented.

III PROCEDURE

1 Audit plan

1.1 Planning of internal audits is based on the Quality System Process Map diagram and the Quality System Process Matrix documented in the Quality Manual Section 4, Quality Management System, Clause 4.1.1, Process Approach. The quality system process map and matrix define all major quality system processes and for each process:

- Define component sub-processes,
- List pertinent sections of the quality manual and the operational procedures,
- Specify areas to be audited, and
- Reference relevant sections and clauses in the ISO 13485 standard (for auditing of compliance).

1.2 Quality Assurance is responsible for planning and scheduling internal audits of the quality system, manufacturing processes and products. Audit frequency is based on the status and importance of the processes, products and areas to be audited, as well as results of previous audits, internal/external nonconformities, and customer complaints. Each quality system process is audited at least once a year.

An audit plan where all processes and activities are audited with the same frequency (for example, annually) is not acceptable. There must be some variation in audit frequency to demonstrate that audits are scheduled on the basis of the status and

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importance of the audited area or activity.

- 1.3 Internal audits cover all quality management system processes and sub-processes; are conducted in all relevant departments, functions and areas; and cover all relevant shifts.

Be sure that your audit plan reflects this requirement for covering all shifts.

- 1.4 Quality system audit plan and schedule is documented in a matrix, a model of which is provided in Form QF-82-02-1, Internal Audit Plan. The vertical side of the matrix lists processes of the quality system to be audited and the horizontal side lists audit dates and assigned auditors. More detailed scope and reference for the audit, to include relevant sub-processes, procedures, areas/functions and reference clauses of ISO 13485 standard, are provided in the Quality System Process Map diagram and the Quality System Process Matrix documented in the Quality Manual Section 4.

Note that QF-82-02-1 is actually just the schedule component of the internal audit plan. The actual scope and reference for the internal auditing program are defined in the Quality System Process Map diagram and the Quality System Process Matrix.

- 1.5 Internal audit plans and cycles are synchronized with management reviews of the quality system (refer to Operational Procedure QOP-56-01, Management Review), so that complete results from the full auditing cycle are available in time for the management review meeting.

2 Audit team

- 2.1 The QA Manager is responsible for qualifying, training and assigning internal auditors. Personnel assigned to carry out internal audits are independent of those having direct responsibility for the audited activity.

Edit this as appropriate to your company, but be sure to clearly communicate the requirement for objectivity and impartiality of the auditor.

- 2.2 Internal auditors are qualified on the basis of their education, experience and training. Minimum requirements are:

- **Education:** High School graduation
- **Experience:** Two years in the industry
- **Training:** 16 hours external or in-house training

The training can be by an external course or seminar provided by a qualified institution (such as a registrar, accredited training organization, etc.), or in-house training provided by a qualified consultant/trainer. If training is provided in-house, the trainer must have documented qualifications as a Lead Auditor.

The standard explicitly requires that internal auditors must be qualified, but does not state any particular qualification criteria. The criteria defined in this clause are just an example.

3 Preparing for audit

Being true to the minimalist approach of this documentation, this procedure does not require auditors to use formal checklists. There should be no problem, as long as the auditors can demonstrate that they prepare for the audit, and that they keep notes during the course of the audit.

However, if you want your internal audits to be meaningful and effective, you should not let inexperienced auditors to go out without a comprehensive checklist. Only seasoned, professional auditors can be trusted to cover the whole scope and properly pace an audit without the help of a checklist.

3.1 Auditors prepare for an audit by:

- Reviewing the Quality System Process Map diagram and the Quality System Process Matrix (documented in the Quality Manual Section 4),
- Identifying relevant clauses in the ISO 13485 standard and in applicable regulatory requirements (21 CFR 820),
- Refreshing their knowledge of the quality manual and relevant operational procedures,
- Reviewing nonconformity reports, customer complaints, and corrective action files, and
- Preparing questions and checklists.

4 Conducting and reporting the audit

4.1 The manager responsible for the area scheduled for audit is contacted at least one week in advance with the proposed audit date. The manager responds with a confirmation, or proposes an alternative date.

4.2 While conducting the audit, auditors seek objective evidence demonstrating whether the audited activities conform to the requirements of the documented quality system, and whether the system is effectively implemented and maintained. When a nonconformity is noted, it is brought to the attention of, and discussed with, the responsible manager. Before the end of the audit each noted nonconformity is documented using the Audit Nonconformity Report form (a model of the form is provided in QF-82-02-2, Audit Nonconformity Report). Auditors fill out only the first part of the form, describing the noted nonconformity. The form is then handed over to the responsible manager who uses its second part to propose a corrective action.

5 Corrective action and follow up

In this procedure, the process for requesting and implementing corrective actions resulting from audit findings is incorporated into the Audit Nonconformity Report form. Thus, the general Corrective and Preventive Action procedure and form do not apply to audits. While, in theory, the general Corrective and Preventive Action system could be used for internal audit findings, it is not a good idea. Audit findings must always be addressed as a priority, and within a specified time frame; because an open



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finding means that the quality system is technically in default.

- 5.1 Once a nonconformity is identified and documented, further processing of the nonconformity report is similar to the corrective action requests (Operational Procedure QOP-85-03, Corrective and Preventive Action). Upon receiving the report, the responsible manager investigates the cause of the problem noted as a nonconformity, proposes a corrective action to be taken, and indicates the date by which the corrective action will be fully implemented. The auditor reviews and approves the proposed action.
- 5.2 On, or immediately after the due date for implementation of corrective action, the auditor follows up with an inquiry or an audit to determine if the corrective action has been implemented and if it is effective. When there is objective evidence that the corrective action is effective, the nonconformity report is closed out. If more work is needed to fully implement the action, a new follow-up date is agreed upon.

6 Documentation and records

- 6.1 Internal audits, implementation of resulting corrective actions, and follow-up audits are documented using the Audit Nonconformity Report form, a model of which is provided in Form QF-82-02-2, Audit Nonconformity Report.
- 6.2 The first block of the form contains a description of the nonconforming condition, the second block contains the proposal for a corrective action, and the third block is reserved for the follow-up audit and close-out of the report.
- 6.3 Pending nonconformity reports are kept by the auditor who initially issued the report. Closed-out nonconformity reports are kept by Quality Assurance.
- 6.4 At the end of an auditing cycle, all nonconformity reports established during the cycle are compiled and analyzed, and are presented at the management review meeting (refer to Operational Procedure QOP-56-01, Management Review).

IV ASSOCIATED DOCUMENTS

- Form QF-82-02-1, Internal Audit Plan
- Form QF-82-02-2, Audit Nonconformity Report
- Operational Procedure QOP-85-04, Corrective and Preventive Action
- Operational Procedure QOP-56-01, Management Review
- Operational Procedure QOP-42-03, Control of Records

V ASSOCIATED RECORDS

- **Internal audit plans:** Plans for quality management system audits. Based on Form QF-82-02-1, Internal Audit Plan.
- **Audit notes and checklists:** Filled out checklists, notes, and comments/references made by auditors during the audit.



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- **Audit Nonconformity Reports:** Reports with audit findings and records of corresponding corrective actions. Established by auditors using Form QF-82-02-2, Audit Nonconformity Report.

