



Organization of this manual is the same as the sectional organization of ISO 13485:2003. Close correspondence between the manual and the standard helps to demonstrate compliance of the system and ensures that all clauses and requirements have been addressed systematically.

Note that each section of the manual is an independent document with its own page numbering, approval and release signatures, and revision level.

You have probably noted that some sections have titles that are not exactly the same as in the standard. The changes are intentional, to better describe the content of the section, or to use a more established and traditional terminology.

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SCOPE			
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1.1 QUALITY POLICY

QUALITY POLICY

AAA Inc. is committed to meeting customer requirements and enhancing customer satisfaction through continual improvement of its products, services and the quality management system.

This policy is too general, and it should not be considered as an example of a proper policy. It is included here only to illustrate how the policy could be presented in the manual.

1.2 INTRODUCTION

This section includes an introduction, a definition of operations and products to which the quality system applies, and statement of any exclusions of ISO 13485 requirements (per Clause 1.2 of the standard).

- 1.2.1 AAA Inc. developed and implemented a quality management system to demonstrate its ability to consistently provide product that meets customer and regulatory requirements, and to address customer satisfaction through the effective application of the system, including continual improvement and the prevention of nonconformity.

The introductory paragraph is taken from ISO 9001:2000 Section 1.1. If you don't need to comply with ISO 9001 and only with ISO 13485, delete the second part of the sentence that refers to customer satisfaction and continual improvement.

- 1.2.2 The quality system complies with the international standard ISO 13485:2003.

List any other standards with which your quality system complies, for example, ISO 9001, 21 CFR Part 820 (FDA's QSR), other national regulations, etc..

- 1.2.3 The manual is divided into eight sections modeled on the sectional organization of the ISO 13485:2003 standard. Sections are further divided into several subsections

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representing main quality system processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant operational procedures and other documents.

- 1.2.4 The purpose of this manual is to define and describe the quality system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system.
- 1.2.5 Another purpose of this manual is to present the quality system to customers, suppliers, regulators and other external interested parties, and to inform them what specific controls are implemented at AAA Inc. to assure quality.

1.3 APPLICATION

Define the products (medical devices) and services for which this quality system applies. Where applicable, in addition to manufacture and delivery you may add design, development, distribution, installation, servicing, etc., of the products. If you don't apply the system to all categories of products, name specifically these products to which the system applies. Here, you can also directly use the scope of your ISO 13485 certification.

- 1.3.1 The quality management system defined in this manual applies to the design, manufacture and distribution of medical devices offered by AAA Inc.

Instead of "medical devices" name the products specifically (or generally by categories or types of products).

1.4 EXCLUSIONS

This section pertains to ISO 13485 Clause 1.2, Application, allowing for claiming exclusions from certain requirements of the standard. Under previous editions, organizations could choose between ISO 13485 and ISO 13488, depending on the nature of their operations and needs. Now there is only one specification of requirements, ISO 13485, but organizations may claim exclusions from various requirements that do not apply to their operations.

The intention is primarily to allow exclusions of design control requirements where there are no design activities (old ISO 13488). But you can also exclude other requirements that don't apply, for example, 7.5.4, Customer property.

Note that in some countries you may be able to exclude design control requirements even when you design products. Contact your registrar or regulatory agency to find out if this would apply in your situation.

This clause starts with a short procedure explaining briefly the rules for taking exclusions, who makes these determinations and who approves them, and how exclusions are documented. Although not explicitly required, the procedure helps to demonstrate that there is a deliberate process for identifying applicable exclusions, and thus adds credibility to the validity of the claimed exclusions.

- 1.4.1 The quality management system shall be relevant to the nature of our organization and

products, and to customer and regulatory requirements. For this reason, those requirements of ISO 13485 that do not apply are excluded from the scope of our quality system.

- 1.4.2 An ISO 13485:2003 requirement may be excluded only when the following three conditions are met:

The following two conditions are identical to those stated in ISO 13485 Clause 1.2.

- The requirement must be within ISO 13485 Clause 7, Product Realization;
- The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets specified requirements; and
- The exclusion may not affect our ability to carry out corrective action.

- 1.4.3 Processes which are applicable to the medical device(s), but which are performed by outside contractors, do not qualify for exclusion. They are accounted for in the quality system to ensure control over such outsourced processes.

- 1.4.4 The QA Manager is responsible for identifying those requirements of ISO 13485 that do not apply to our organization or products, and to propose to the top management that such requirements be excluded from the scope of the quality system.

- 1.4.5 Top management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Operational Procedure QOP-56-01, Management Review).

Formal approval of exclusions by the top management is not explicitly required in the standard. Thus, you may delete this paragraph if you feel that it is not appropriate, or does not apply in your company. I included it here because decisions regarding the scope of the quality system are often important enough to warrant direct involvement of the top management, and because these decisions may have direct bearing on the compliance status of the company.

- 1.4.6 Any exclusions taken are documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

CLAIMED EXCLUSIONS

If all requirements of ISO 13485 Section 7 apply, write here "No exclusions taken." You still need this section in the manual to define how exclusions will be identified, should this become relevant in the future.

If you identified any exclusions, document them as in the two examples below. The first example illustrates how an ISO 13488:1996 or ISO 9002:1994 company may justify exclusion of design and development requirements. The second example may be relevant to a company that does not receive any products or documents from its customers.

- I. **Exclusion:** ISO 13485 (2003) Section 7.3, Design and Development, including all subsections

Justification: AAA Inc. does not design or develop products. All principal product characteristics are specified by the customers or their consultants. Our engineering activities are limited to developing methods and means of production, fabrication, or installation.

- II. **Exclusion:** ISO 13485 (2003) Section 7.5.4, Customer Property

Justification: AAA Inc. does not receive from customers any tangible or intellectual property that is intended for incorporation into, or in any way associated with the medical device(s).



REFERENCE DOCUMENTS

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In the ISO 13485 standard this section is for listing normative references.

Here in the quality manual, you should list any quality system related regulations, standards and guidelines that you use or must comply with (such as international, national, regulatory, or industry-specific standards, guidelines and manuals).

2.1 REGULATORY REQUIREMENTS

Reference here your national, regional and international regulations.

Part 820 of Title 21 of the Code of Federal Regulations (CFR) - Quality System Regulation(QSR)

2.2 STANDARDS AND GUIDELINES

ISO 9000-2000: Quality Management Systems- Fundamentals and Vocabulary

ISO 14971-2000: Medical Devices- Application of Risk Management to Medical Devices

Only the first two standards, ISO 9000 and ISO 14971, are mandatory for you to reference. All the other standards below are just a random list. Include only standards that you actually use.

ISO 9004-2000: Quality Management Systems- Guidelines for Performance Improvements

ISO 10013-1995: Guidelines for Quality Manuals

ISO10006-1997: Quality Management - Guidelines to Quality in Project Management

ISO10007-1995: Quality Management - Guidelines for Configuration Management

ANSI/ASQC M1-1996: American National Standard for Calibration Systems

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TERMS AND DEFINITIONS

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The definitions below are taken directly from ISO 13485. You should change them if definitions in your national regulations are materially different (for example 21 CFR Part 820.3). The national regulations take precedence.

If your devices are not sterile, implantable, or active, you can delete those definitions that don't apply.

In addition to the official definitions, you may define in this section anything else you want. For example, you could define some selected terms from ISO 9000:2000, such as quality, nonconformity, process, etc. And you could define internally used abbreviations and acronyms. If you need to comply with 21 CFR 820 you should also include at least some definitions from CFR 820.3, Definitions. There is really no established practice as to how detailed this section should be. Some companies just include five to ten official definitions, but it is also quite common to see 50 to 100 definitions. How many you include has no bearing on compliance. You are doing this for yourself.

- 3.1 **Active implantable medical device:** active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.
- 3.2 **Active medical device:** medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.
- 3.3 **Advisory notice:** notice issued by the organization, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what corrective or preventive action should be taken in:
 - the use of a medical device,
 - the modification of a medical device,
 - the return of the medical device to the organization that supplied it, or
 - the destruction of a medical device.
- 3.4 **Customer complaint:** written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.
- 3.5 **Implantable medical device:** medical device intended to be totally or partially introduced into the human body or a natural orifice, or to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention.

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NOTE This definition applies to implantable medical devices other than active implantable medical devices.

- 3.6 **Labeling:** written, printed or graphic matter affixed to a medical device or any of its containers or wrappers, or accompanying a medical device, related to identification, technical description, and use of the medical device, but excluding shipping documents.
- 3.7 **Medical device:** any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
 - investigation, replacement, modification, or support of the anatomy or of a physiological process,
 - supporting or sustaining life,
 - control of conception,
 - disinfection of medical devices,
 - providing information for medical purposes by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.
- 3.8 **Sterile medical device:** category of medical device intended to meet the requirements for sterility.

If you must also comply with 21 CFR Part 820, you should also include definitions from 820.3 Definitions.



6.1 PROVISION OF RESOURCES

As the standard does not prescribe any specific methods for determining resource requirements and provision of resources, this section tries to be as general and noncommittal as possible. If you are a small company and do not use any specific methods for formal identification and allocation of resources, this section should be sufficient as is. However, if you have formal systems for managers to request additional space, equipment, personnel, etc., and/or a formal process for establishing budgets, this is the place to document such systems.

In this quality system, matters regarding resources are periodically reviewed and determined in the framework of management reviews. This is at no cost to the system, as Clause 5.6.3.c) already requires that management review output must include decisions regarding resource needs.

- 6.1.1 Resources required for implementing, maintaining and improving the quality management system, and for addressing customer satisfaction, include personnel, infrastructure, work environment, process equipment, materials, information, and financial resources.

If you only need to comply with ISO 13485 (no ISO 9001), you can change "...for implementing, maintaining and improving the quality system, and for addressing customer satisfaction ." to "...for implementing the quality management system and maintaining its effectiveness and for meeting regulatory and customer requirements "

- 6.1.2 Determination of resource needs for specific activities is integrated with the process of defining and initiating the activity. It may take the form of personnel assignments, allocation of space or equipment, training, procurement decisions, budgets, etc.

- 6.1.3 Depending on the type and nature of the operation or activity, resource requirements are defined in:

- Quality manual, operational procedures and work instructions (***QOP-42-01 Document Control***);
- Product and process drawings and specifications (***QOP-42-02 Device Master Record***);
- Production plans (***QOP-75-01 Production Work Order and History Record***);
This reference is specifically to the work order or traveler, where human/equipment/process resources are called out for every operation.
- Job descriptions, competence matrixes, and training programs (***QOP-62-01 Competence, Awareness and Training***);
- Minutes of management reviews, quality objective records, and corrective and preventive action requests (***QOP-56-01 Management Review, QOP 85-04 Corrective and Preventive Action***).

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- 6.1.4 Top management has the responsibility and authority for provision of resources.
- 6.1.5 Management reviews of the quality system are the principal forum for determining resource requirements and providing resources for maintaining and improving the quality system, and for enhancing customer satisfaction. Operational Procedure ***QOP-56-01 Management Review*** defines this process.

If you only need to comply with ISO 13485 (no ISO 9001), you can take out any references to "improvement" and to "customer satisfaction".

6.2 HUMAN RESOURCES

This section of the manual consists basically of some general verbiage paraphrasing Clause 6.2 of the standard, assignment of general responsibilities, and a reference to operational procedure QOP-62-01, Training and Awareness. Make sure that you edit the assignment of responsibilities (6.2.1.2 and 6.2.1.3) to fit your company.

6.2.1 General

- 6.2.1.1 Personnel performing work affecting product quality are competent. Competence is determined on the basis of appropriate education, training, skills and experience.
- 6.2.1.2 Human Resources department is responsible for training and awareness programs for company-wide participation, such as: general orientation, rules and regulations, quality system, safety, and other company-wide systems and issues.
- 6.2.1.3 Departmental managers are responsible for identifying competency requirements and for providing training in their departments. Departmental training is primarily focused on increasing the level of skills in operating equipment and processes, conducting inspections and testing, using analytical and statistical techniques, and other such skills as appropriate for particular positions and jobs.

6.2.2 Competence, awareness and training

- 6.2.2.1 Processes for ensuring adequate competency and awareness of personnel are defined in Operational Procedure ***QOP-62-01 Competence, Awareness and Training***. The procedure addresses issues related to:
- Determining competency requirements,
 - Identifying training needs,
If you don't need to comply with CFR 820, you can delete this bullet.
 - Providing training,
 - Evaluating the effectiveness of training,
 - Ensuring quality awareness, and
 - Maintaining training records.

6.3 INFRASTRUCTURE

ISO 13485 Clause 6.3 applies only to those facilities, equipment and supporting services that have direct bearing on the organization's ability to ensure product conformity. In other words, the clause applies only when inadequacy or deterioration of a facility, or breakdown of a service could directly result in nonconforming product.

Obviously, production process equipment and product delivery services would almost always fall into this category. Examples of other types of facilities and services that could be relevant are buildings, warehouses, workstations, utilities, ventilation and air filtering systems, communication, IT services, etc.

This documentation takes the usual, minimalist approach, assuming that infrastructure issues are rather routine and, for most part, are taken care of by external vendors and subcontractors, such as utilities, telephone companies, courier services, etc. At AAA Inc. only production equipment maintenance and operation of the IT system are performed in-house.

6.3.1 Buildings, workspace and associated utilities

6.3.1.1 Infrastructure and facilities, such as buildings, workspaces and associated utilities, etc., are appropriate and are properly maintained to achieve conformity to product requirements.

6.3.1.2 Departmental managers are responsible for identifying the need and requirements for new, and/or modification or repair of existing infrastructure and facilities in their departments. Requests for changes and/or expansions of facilities are submitted to the top management for review and approval.

6.3.1.3 Maintenance of buildings and facilities is performed by external contractors. This includes regularly scheduled maintenance of lighting systems, air conditioning and heating systems, landscaping, and cleaning. Repairs of buildings and other such facilities are contracted as needed. Purchasing is responsible for coordinating and managing maintenance contracts.

6.3.2 Process equipment

6.3.2.1 Procurement of new, and/or modification of existing process equipment (including hardware and software) are planned in conjunction with development of manufacturing processes, as defined in this manual in **QM 7.1 Planning of Product Realization** and Operational Procedure **QOP-71-01 Production Planning and Risk Management**.

6.3.3 Supporting services

6.3.3.1 Supporting services required by AAA Inc. include transportation, communication, and IT services:

- Transportation services are purchased from parcel delivery and courier services, and

from trucking or other transportation companies or consolidators, as required. Transportation services are purchased in accordance with Operational Procedures *QOP-74-01 Supplier Evaluation and Monitoring*, and *QOP-74-02 Purchasing*.

- Communication services are provided by various telephone, wireless, and internet access companies. Purchasing is responsible for administrating and coordinating these contracts.
- IT systems are designed and implemented by external consultants, while the day-to-day operating of the systems is the responsibility of the Information Technology (IT) Manager. The IT Manager is responsible for selecting IT consultants and for administrating IT contracts.

This clause is based on the assumption that supporting services and maintenance of facilities are mostly subcontracted, and their management is not terribly complicated or important. Most companies will not fit this minimalist assumption, and will have to further develop this section to describe their actual arrangements. For example, if you operate your own fleet of delivery vehicles you should describe in more detail how this activity is managed and how is it integrated into the quality system. Even if your company generally fits this description, you should edit this section to ensure that it exactly describes how these things are actually done in your company.

6.3.4 Equipment Maintenance

- 6.3.5 Key process equipment, machines, hardware, and software are regularly maintained in accordance with maintenance plans specified by equipment manufacturers or departmental managers responsible for the equipment. Requirements for the maintenance of production equipment are specified in Operational Procedure *QOP-63-01 Equipment Maintenance*.

6.4 WORK ENVIRONMENT

6.4.1 Human factors

This section addresses general requirements for work environment as they are usually interpreted for an ISO 9001 system. In 13485 the emphasis is shifted to controlling the physical environment in production areas rather than "workplace" environment. If you don't need to comply with ISO 9001 you can delete this section.

- 6.4.1.1 Human Resources and departmental managers are responsible for ensuring suitable physical, social and psychological conditions in the workplace. This is to include such aspects as temperature, lighting, and cleanliness; as well as language and interaction between employees.
- 6.4.1.2 Production and Quality Assurance are responsible for identifying those operations where extreme environmental conditions could impact quality performance of personnel and result in product nonconformities. Where appropriate, limits of exposure and/or mitigating measures are defined and implemented for these operations.

These conditions may be extremely low or high temperature, excessive noise, or other

such factors which, although legally acceptable, may adversely impact quality performance. Mitigating measures would be limits on the time of exposure, more frequent breaks, protective gear and equipment, automation of the process, etc. Delete this whole clause if it isn't relevant.

- 6.4.1.3 Health and safety management system is independent form the quality management system. It is administrated by Human Resources and is documented in the Health and Safety (H&S) manual.

For legal and compliance reasons, it is always a good idea to keep Health and Safety (H&S) management system separate from quality management. Although it may be tempting to combine the two systems to improve administrative efficiency, the problem is that H&S is, at least in the US, regulated by law, with potentially legal consequences. Edit this section to accurately describe how H&S is administrated in your company.

6.4.2 Work environment in production and storage areas

The highlighted aspects of environmental control are rephrased ISO 13485 clauses 6.4 a) through d). Delete any of the items that don't apply at all to your company. But don't go too far. Such issues as general cleanliness, clothing, and contamination control apply pretty much everywhere. Coordinate with procedure QOP-64-01.

- 6.4.2.1 Work environment is properly controlled in areas where environmental conditions could have an adverse effect on product quality. Operational Procedure QOP-64-01 Production and Work Environment defines the management system for environmental control. The following aspects are controlled:

- **Health, cleanliness and clothing of personnel:** If contact between personnel and the product or work environment could adversely affect the quality of the product, requirements for health, cleanliness and clothing of personnel are established and documented;
- **Work environment conditions:** If work environment conditions can have an adverse effect on product quality, requirements for the work environment conditions and procedures to monitor and control the environment are defined and documented. Environmental control systems are periodically inspected to verify that the system, including necessary equipment is adequate and functioning properly;

The last sentence is from CFR 820.70(c).

- **Contaminated product:** If appropriate, special arrangements are established and documented for the control of contaminated or potentially contaminated product in order to prevent contamination of other product , the work environment or personnel.
- **Training:** Personnel who work under special environmental conditions are appropriately trained. Personnel who must work temporarily, or for any other reason enter environmentally controlled areas are also trained in appropriate procedures or are supervised by a trained person.