# [ISO 13485:2016 Medical Devices - Quality Management Systems Standard Released](http://r20.rs6.net/tn.jsp?f=001IdabKGPJzHpoKpRUVOo9_jjZysYgo_5Xs_LMmv0az_dG829_jhMIdWXeMxGLf6qJaXrq-pS6V4vkK7CyGP0Jtc-8hzcrIDZWXYJG9XrKWyYK890aCiDLss7u7QSpbGA1QE0OX1kvlVj_XW_sEpZPrf8SG3j4JkK4YcvRwTofAJw3Ph5J5VzyKoPGgASlFY0nXONlI9vCc_Opo8Lr7BnfllUSX6M58ikbB-23Ch2qTz1tS3r0BFs3Mu99M1ElZyMILCJurHjRn09OLpKwFConZw==&c=73Fbqf0RR3t8nDsOSSZbUSbPY4afgn22yDobgtk7BFI4wG7Tqh8oGA==&ch=Ed2VEEUfLz2b8tOU6MoT2QvSjHcAPKM9NtnOD94lxg56kHAmCjb1rw==" \t "_blank)

The International Organization for Standardization (ISO) published the updated ISO 13485 medical devices quality management systems standard on March 1, 2016.

ISO 13485:2016 identifies the requirements for a quality management system (QMS) in which an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet both customer and regulatory requirements. Organizations seeking certification may be involved in any portion of the medical device product lifecycle, which includes design and development, production, storage and distribution, installation, or servicing of a medical device or provision of associated activities (e.g. technical support). ISO 13485:2016 can also be used by suppliers or external parties that provide product, materials or service, including quality management system-related services to such organizations.

NSF International Strategic Registrations (NSF-ISR) will be working to ensure a smooth transition to the new international standard for medical device quality management systems. We are committed to developing useful tools, webinars and publications to assist your organization with the transition process.  Similar publications were produced by NSF-ISR for the ISO 9001:2015 transition and can be viewed on our [ISO 9001 webpage](http://r20.rs6.net/tn.jsp?f=001IdabKGPJzHpoKpRUVOo9_jjZysYgo_5Xs_LMmv0az_dG829_jhMIdXV2csfJc-CHM1D8sG58xLMS0HzVNaNqaNq8oWTi9gqucMMURF9XC24ZlBuODcc8xh3n1_W2YiNpricxcH4iUJEB62QbdvC6hsub3mWN7KREqywfmAct9xHTnm13xih6pyUGiQD7pRa5paCi2WY4L60CIueIUFdaeFsCQx2dVIzqNk13_7J3bDmEZTO7PeVwf0DToi_8vLDOhLQ1_H_gluQ=&c=73Fbqf0RR3t8nDsOSSZbUSbPY4afgn22yDobgtk7BFI4wG7Tqh8oGA==&ch=Ed2VEEUfLz2b8tOU6MoT2QvSjHcAPKM9NtnOD94lxg56kHAmCjb1rw==" \t "_blank).

Key improvements in the 2016 version include:

* Expansion of the standard's applicability to include all organizations involved in the lifecycle of the product, from inception to end of life
* Greater focus on post-market surveillance (including complaint handling)
* Improved alignment with regulatory requirements
* Increased focus on risk management
* More emphasis on implementing the appropriate infrastructure, particularly for the production of sterile medical devices

There will be a 3-year period for current NSF-ISR clients registered to ISO 13485:2003 to transition to the 2016 version of the standard.  NSF-ISR will be working with ANAB to determine the transition requirements in order to provide your organization with detailed information relating to the new version of the standard and how to best create a positive, seamless transition experience to ISO 13485:2016.

The updated standard can be purchased through the [NSF Bookstore](http://r20.rs6.net/tn.jsp?f=001IdabKGPJzHpoKpRUVOo9_jjZysYgo_5Xs_LMmv0az_dG829_jhMIdXV2csfJc-CHEVTM4cjZeZCNmXoOiYCYQntDVajl649zRywNIRGgBW8W2KNxlAOwDodr7oEHgIZaho84KkIl37XRln0I1e_pDjo_t_QD_jhUxyjHdyyNedG_OHSChvIaB2qy6MWGn9FQEvba016mkuE59douSL5vug==&c=73Fbqf0RR3t8nDsOSSZbUSbPY4afgn22yDobgtk7BFI4wG7Tqh8oGA==&ch=Ed2VEEUfLz2b8tOU6MoT2QvSjHcAPKM9NtnOD94lxg56kHAmCjb1rw==" \t "_blank).

For more information, please email NSF-ISR at [information@nsf-isr.org](mailto:information@nsf-isr.org" \t "_blank) and check our website, [www.nsf-isr.org](http://r20.rs6.net/tn.jsp?f=001IdabKGPJzHpoKpRUVOo9_jjZysYgo_5Xs_LMmv0az_dG829_jhMIdbkr7mi05duY67D4mwRLsddYQyATm2o2UTNUvq61rJfAdCgUo9eepcz813C1uMriHbw0QzmGehCbjQx_5zVf5DjZ2xmm5i1nxyWUvUfMz2LKuJa-bZBY_xY=&c=73Fbqf0RR3t8nDsOSSZbUSbPY4afgn22yDobgtk7BFI4wG7Tqh8oGA==&ch=Ed2VEEUfLz2b8tOU6MoT2QvSjHcAPKM9NtnOD94lxg56kHAmCjb1rw==" \t "_blank), for regular updates about the standard, including webinars, transition guides and more

**ISO 13485: 2016 Planner and Delta Checklist**

**Annex A (Informative) Comparison of content between**

**ISO 13485:2003 and ISO 13485:2016**

**Instructions:**

1. Highlighted areas are to be completed by the Client Organization prior to the off-site review, or on-site Gap Analysis or Upgrade Audit, and submitted to the NSF-ISR Lead Auditor for review.
2. The **Annex A - ISO 13485: 2016 vs. ISO 13485: 2003 Comparison Table** has been provided at the end of this document for information and reference purposes only.
3. Completion by the Client Organization should include the final statement of readiness for Upgrade by the Top Management of the Client Organization.
4. The columns for “Planned Completion Date” and Responsibility” may be used by the Client Organization to develop their plan for upgrading their QMS to the requirements of ISO 13485: 2016.
5. All other areas of the Checklist are required to be completed by the NSF-ISR Lead Auditor to confirm the effective implementation of the Client Organization’s ISO 13485: 2016 Quality Management System.
6. The Lead Auditor shall sign the appropriate sections at the end of the Checklist to indicate: whether the Client Organization is Ready/Not Ready for Upgrade Audit (Off-site review), **AND** the final approval of the QMS in meeting the requirements of ISO 13485: 2016 (during the on-site Upgrade Audit)
7. This checklist shall be submitted by the NSF-ISR Lead Auditor as one of the records of the ISO 13485: 2016 Upgrade for the Client Organization.

|  |  |
| --- | --- |
| **Organization Name:** |  |
| **Organization Address:** |  |
| **Number of Personnel:** | **1st Shift :**  **2nd Shift :**  **3rd Shift :**  **Temp. / Part-time :** |
| **Other locations included in this registration:** |  |
| **Management Contact:** |  |
| **Name and Revision Status of QMS documentation:** |  |
| **FRS Number:** |  |
| **Off-site Review Date (Desk Audit):** |  |
| **Audit Dates (on-site):** |  |
| **Lead Auditor / Audit Team:** |  |
| **Scope of Registration:** |  |
| **ISO 13485: 2016 Clauses that are Not Applicable to the scope of the QMS :Reference ISO 13485: 2016 (E) Medical devices — Quality management systems —**  **Requirements for regulatory purposes: Scope, Section 1** |  |
| **The interval between the client Delta Review and the Upgrade Audit should not exceed 90 days.** | |

**NOTE: Please ensure that your Organization’s registered ISO 13485:2003 QMS remains compliant with that version of the Standard until the Transition to ISO 13485: 2016 is complete and verified by the NSF-ISR Lead Auditor.**

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| **Question / Requirement** | **Level of Completion**  0=Not Started  10=Completed & Implemented | **QMS Process Related to Requirement**  *(Process Name)* | **Planned Completion Date** | **Responsibility** | **Reference Document**  (Name / Rev. Level)  ***OR***  **Records** | **NSF-ISR Lead Auditor Review Comments** |
| **QMS Documentation**  **Clause 4.1 – General requirements**  Updates required:  **•** Documentation  **•** Increased regulatory and risk based approach;  **•** Outsourced processes;  **•** Change management;  **•** Validation of software. |  | **ALL** |  |  |  |  |
| **Clause 4.2 – Documentation requirements**  Updates required:  **•** Clauses 6, 7 and 8;  **•** Medical device file;  **•** Controls related to document and record amendment, security and integrity |  |  |  |  |  |  |
| **Clause 5 – Management Responsibility**  **•** Increased focus on regulatory requirements;  **•** Documented procedures for management review; documented planned intervals |  |  |  |  |  |  |
| **Evidence of : Clause 6.2 – Human resources**  Updates required:  **•** Documented processes for competence, awareness and training  **•** Risk based training effectiveness |  |  |  |  |  |  |
| **Evidence of : Clause 6.3 – Infrastructure**  Updates required:  **•** Processes for preventing product mix-up;  **•** Information systems infrastructure;  **•** Maintenance intervals for production or monitoring equipment. |  |  |  |  |  |  |
| Evidence of: **Clause 6.4 – Work environment**  Updates required:  **•** Documentation requirements for work environment;  **•** Contamination controls for sterile medical devices. |  |  |  |  |  |  |
| **Evidence of : Clause 7.1 – Planning of product realization**  Updates required;  **•** Processes for risk management;  **•** Requirements for storage, handling, distribution and traceability. |  |  |  |  |  |  |
| Evidence of **: Clause 7.2 – Customer related processes**  Updates required:  **•** Requirement and availability for any user training;  **•** Documented processes for communicating with stakeholders, including regulatory authorities. |  |  |  |  |  |  |
| **Clause 7.3 – Design and development**  Updates required:  **•** Traceability of design inputs to outputs;  **•** Required resources, including competence of personnel involved in design projects;  **•** Additional details and documentation for verification and validation plans, including statistical techniques, sampling  rationale and representative product and records;  **•** Documented procedures for design transfer and design change;  **•** Design and development files. |  |  |  |  |  |  |
| **Clause 7.4 – Purchasing**  Updates required:  **•** Increased focus on supplier monitoring and risk;  **•** Documented agreements for prior notification of changes to supplied product;  **•** Linkage between verification of purchased product and change control. |  |  |  |  |  |  |
| Evidence of**: Clause 7.5 – Production and service provision**  Updates required:  **•** Qualification of infrastructure;  **•** Analysis of service records;  **•** Documented procedures for validation including statistical techniques, sampling rationale, revalidation;  **•** Validation requirements for processes that cannot or are not subsequently monitored;  **•** Procedures for risk based software validation;  **•** Documented procedure for product identification/status during production; this may be Unique Device Identification (UDI),  **•** Validation of sterile barrier systems;  **•** Suitability of packaging systems;  **•** Recording of measuring equipment adjustments. |  |  |  |  |  |  |
| Evidence of:: Clause 8 – Measurement, analysis and improvement  **Clause 8.2 – Monitoring and measuring**  Updates required:  **•** Linkages from customer feedback into risk management;  **•** Documented processes for ascertaining whether customer requirements have been met;  **•** Procedures for complaint handling;  **•** Processes for informing third parties of complaints;  **•**  Plans for internal audits at defined intervals;  **•** Processes for the identification of test equipment. |  |  |  |  |  |  |
| **Clause 8.3 – Control of non-conforming product**  Updates required:  **•** Processes for communication with external parties regarding non-conforming product;  **•**  Controls for managing concessions;  **•** Linkages between rework and regulatory requirements. |  |  |  |  |  |  |

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| **Question / Requirement** | **Level of Completion**  0=Not Started  10=Completed & Implemented | **QMS Process Related to Requirement**  *(Process Name)* | **Planned Completion Date** | **Responsibility** | **Reference Document**  (Name / Rev. Level)  ***OR***  **Records** | **NSF-ISR Lead Auditor Review Comments** |
| : **Clause 8.4 – Analysis of data**  Updates required:  **•** Sources of data for analysis, such as service records and audits;  **•** Procedures that cover the application of statistical techniques;  **•** Linkages between the analysis and improvement processes. |  |  |  |  |  |  |
| :**Clause 8.5 – Improvement**  Updates required:  **•** Actions are taken without undue delay;  **•** Evaluation of actions for adverse effects on regulatory requirements and product safety and performance. |  |  |  |  |  |  |
| **Organization confirmation that the QMS now complies with all requirements of ISO 13485: 2016 (refer to Annex A).**  *(e.g. Quality Manual or Documented Information addresses all clauses of the Standard).* |  |  |  |  |  |  |
| **Other Client Organization-specific information** about the QMS (as determined by the Client Organization)  Note: This section is optional, and may be completed if there are unique aspects of the QMS that the Client deems important in demonstrating compliance to the ISO 13485: 2016 Standard. |  |  |  |  |  |  |

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| **Approval** | **Name / Title** | **Signature** | **Date** |
| **NSF-ISR Lead Auditor** confirmation of Readiness (Pre-planning). |  |  |  |
| **NSF-ISR Lead Auditor** Approval of Compliance to ISO 134485: 2016 at **On-site Upgrade Audit.** |  |  |  |
| ***The completed Checklist shall be submitted by the NSF-ISR Lead Auditor as a supplement to the ISO 13485:2016 Audit Report*** | | | |

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| **Table A.1 — Comparison of content between ISO 13485:2003 and ISO 13485:2016** | |
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| **Clause in ISO 13485:2016** | **Clause in ISO 13485:2016 Comment on change compared with ISO 13485:2003** |
| Foreword | Foreword — Clarifies the effect of the third edition of this International Standard |
| Introduction  0.1 General | — Includes substantially more detail related to the nature of the organization covered by this  International Standard’s requirements and the life-cycle stages covered.  — Explains that the requirements can be used by suppliers or other external parties either  voluntarily or as a result of contract arrangements.  — Alerts organizations about their obligations related to regulatory requirements focused  on quality management systems.  — Alerts organizations about differences in local regulation definitions and their obligation  to understand how these definitions will affect their quality management system.  — Adds the obligation to meet the organization’s own quality management system requirements.  — Specifically calls out the focus on the necessity to “meet customer and applicable regulatory  requirements for safety and performance.”  — Emphasizes that the product requirements that are important are those related to safety  and performance.  — Adds two influences on the nature of the quality management system that were not in the  original listing (organizational environment and regulatory requirements).  — Clarifies that the organization does |
| 0.2 Clarification of concepts | — Adds two additional criteria associated with the description of appropriate requirements:  — compliance with regulatory requirements;  — the requirement is necessary for the organization to manage risks.  — Limits application of risk to the safety or performance requirements of the medical device  or meeting applicable regulatory requirements.  — Clarifies that the term “documented” includes the need to establish, implement and  maintain.  — Clarifies that the term “product” applies to outputs that are intended for, or required by, a  customer, or any intended output resulting from a product realization process |
| 0.3 Process approach | Explanation of process approach extended |
| 0.4 Relationship with ISO 9001 | — States the relationship between ISO 13485:2016 and ISO 9001.  — Indicates the structural relationship between ISO 13485:2016 and ISO 9001:2015 will be  outlined in Annex B.  — The use of italic text within standard to indicate changes from ISO 9001:2008 has been  eliminated. |
| 1. Scope | — Indicates the applicability of this International Standard to organizations that are involved  in one or more stages of the life-cycle of a medical device.  — Indicates that this International Standard can also be used by suppliers or external parties  that provide product, including quality management system-related services to medical  device organizations.  — Specifically calls out the responsibilities for monitoring, maintaining, and controlling  outsourced processes.  — Expands requirements that can be not applicable to those in Clauses 6 and 8.  — Clarifies that the term “regulatory requirements” includes statutes, regulations, ordinances  or directives and limits the scope of the “applicable regulatory requirements” to  those requirements for the quality management system and the safety or performance of the  medical device. |
| 3 Terms and definitions | — Several new definitions added and some existing definitions refined. |
| 4 Quality management system  4.1 General requirements | — Added requirement to document the role(s) of the organization.  — Requires the determination of processes “taking into account the roles undertaken by the  organization.”  — Requires the application of a “risk based approach to the control of the appropriate processes  needed for the quality management system.”  — Adds requirements related to changes to processes.  — Added requirements related to validation of the application of computer software used in  the quality management system. |
| 4.2 Documentation requirements | Includes control of records within the document control requirements.  Lists the documents that would be included in the medical device file.  New requirement related to protection of confidential health information.  New requirement related to deterioration and loss of documents |
| 5.6 Management review | — Includes requirement for the documentation of one or more procedures for management  review and the requirement for management reviews at “documented planned intervals”.  — Lists of inputs and outputs of management review have been expanded. |
| 6.2 Human resources | — New requirement for documentation processes of establishing competence, providing  needed training and ensuring awareness of personnel. |
| 6.3 Infrastructure | — Adds requirement that infrastructure prevents product mix-up and ensure orderly handling  of product.  — Adds information system to the listing of supporting services. |
| 6.4 Work environment and contamination  control | — Added documentation requirements for work environment.  — Added requirement related to control of contamination with microorganism or particulate  matter for sterile medical devices. |
| 7.1 Planning of product realization | — Added requirements to list. |
| 7.2 Customer-related processes | — Added requirements to list.  — New requirement related to communication with regulatory authorities. |
| 7.3.2 Design and development planning | — Added requirements to list.  — Eliminated the requirement related to the management of the interfaces between different  groups involved in design and development. |
| 7.3.3 Design and development inputs | — Added requirements to list.  — Added requirement that the requirements shall be able to be verified or validated. |
| 7.3.5 Design and development review | — Added details of the contents of records. |
| 7.3.6 Design and development verification | — Added requirement for documentation of verification plans and interface considerations.  — Requirement added for records of verification. |
| 7.3.7 Design and development validation | — Added requirement for documentation of validation plans, product to be used for validation  and interface considerations. Requirement added for records of validation. |
| 7.3.8 Design and development transfer | — New sub-clause added. |
| 7.3.9 Control of design and development  changes | — Adds the requirement that the evaluation of the change effect should be made on products  in process and on the outputs of risk management and product realization processes  — Added detail to consider in the determination of the significance of a design and development  changes. |
| 7.3.10 Design and development files | — New sub-clause added. |
| 7.4.1 Purchasing process | — Focuses the supplier selection criteria on the effect of the supplier performance on the  quality of the medical device, the risk associated with the medical device, and the product  meeting applicable regulatory requirements.  — New requirements added related to monitoring and re-evaluation of suppliers, and action  to be taken when purchasing requirements are not met.  — Provides addition details related to the content of the records. |
| 7.4.2 Purchasing information | — New requirement added to include notification of changes in purchased product. |
| 7.4.3 Verification of purchased product | — New requirements added on the extent of verification activities and action to be taken  when the organization becomes aware of any changes to the purchased product. |
| 7.5.1 Control of production and service  provision | — Adds details related to the controls for carrying out production and service provision. |
| 7.5.2 Cleanliness of product | — Added a requirement to the list. |
| 7.5.4 Servicing activities | — New requirement for analysis of records for servicing activities. |
| 7.5.6 Validation of processes for production  and service provision | — Added requirements to the list  — Adds details related to situations requiring procedures.  — Relates the specific approach to software validation to the risk associated with the use of  the software.  — Adds requirements related to the validation records. |
| 7.5.7 Particular requirements for validation  of processes for sterilization and  sterile barrier systems | — Added requirements for sterile barrier systems. |
| 7.5.8 Identification | 7.5.8 Identification — Added requirement for unique device identification.  — New requirement for a documented procedure for product identification and regarding  identification and product status during production |
| 7.5.11 Preservation of product | — Adds details as to how preservation can be accomplished. |
| 8.2.1 Feedback | — Indicates that feedback should come from production and post-production activities.  — Adds a requirement to utilize feedback in risk management processes in order to monitor  and maintain product requirements. |
| 8.2.2 Complaint handling | — New sub-clause. |
| 8.2.3 Reporting to regulatory authorities | — New sub-clause. |
| 8.2.6 Monitoring and measurement of  product | — Adds requirement to identify the test equipment used to perform measurement activities. |
| 8.3 Control of nonconforming product | — Added details related to kinds of controls that shall be documented.  — Generalized the requirement to include any investigation and the rationale for decisions.  — Adds requirements related to concessions.  — Separated requirements for nonconformities detected before delivery, detected after  delivery and rework.  — Adds requirements for records related to the issuance of advisory notices. |
| 8.4 Analysis of data | — Adds the requirement to include determination of appropriate methods, including statistical  techniques and the extent of their use.  — Adds detail to list of inputs. |
| 8.5.2 Corrective action | — Adds the requirement to verify that the corrective action does not have an adverse effect.  — Added requirement for corrective action to be taken without undue delay. |
| 8.5.3 Preventive action | — Adds the requirement to verify that the preventive action does not have an adverse effect. |
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**Appendix A**

**ISO 13485: 2016 vs. ISO 13485: 2003 Comparison Table**

**Amendment Record**

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| **Version #** | **Submitted Date** | **Summary of Changes** |
| 1 | 10/2016 | Initial issue |
| 2 |  |  |
| 3 |  |  |