ISO 13485:2016
MEDICAL DEVICES QMS
TRANSITION GUIDE

ISO 13485, OVERVIEW

ISO 13485 sets regulatory requirements or, when specified, customer requirements for a management system for medical devices or services. The primary objective of ISO 13485 is to harmonize medical device regulatory requirements for quality management systems. The standard is specific to organizations providing medical devices or services, regardless of the type or size of the organization. Based on the ISO 9001 process approach to quality management, ISO 13485 focuses on what manufacturers must do to provide safe and effective medical devices.

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.

The International Organization for Standardization (ISO) published the updated ISO 13485 medical devices quality management systems standard on March 1, 2016 – it can be purchased through the NSF Bookstore.

KEY BENEFITS OF ISO 13485

The benefits of ISO 13485 certification include demonstration of regulatory compliance and more effective risk management. Certification aids compliance to national or international regulatory requirements. Certification also confirms to customers, suppliers and other stakeholders that the organization is in a state of control over its operations.

Third-party certification is preferred in many international markets, and is the accepted basis and starting point to achieve the medical device CE mark. It can also be used as a bench mark to meet good manufacturing practice (GMP) compliance in the United States. An ISO 13485 certified quality management system can aid access to U.S. and international markets.

In addition, certification:

- Provides confidence of quality risk management and good manufacturing practices within the medical device supply chain throughout the medical device product life cycle
- Provides assurance that appropriate regulatory requirements are implemented within your organizational processes
- Provides confidence that best practice validation and GMP have been implemented and evaluated

TRANSITION TIMELINES

The transition is underway for ISO 13485 - NSF-ISR is fully accredited to ISO 13485:2016 and business development and account management personnel have begun to provide quotes to registered clients requesting an upgrade to ISO 13485:2016.

- **January 18, 2017**: NSF-ISR is fully accredited to ISO 13485:2016, clients can begin transitioning.
- **September 14, 2018:** ISO 9001:2015 transition deadline. Organizations that have ISO 9001 with ISO 13485 may need to separate their audits.
- **November 30, 2018**: All ISO 13485 clients will have until this date to complete their upgrade audit. A review will be conducted for clients who have not upgraded their medical devices certificate to determine the extent of their recertification status.
- **February 28, 2019**: Deadline for all NSF-ISR clients registered to ISO 13485:2003 will be required to upgrade to the 2016 standard.
- **March 1, 2019**: Clients certified to ISO 13485:2003 will be dropped from the NSF-ISR system on if they have failed to upgrade their certification by this date.

NSF-ISR offers two options to upgrade to ISO 13485:2016:

1. If an existing, or new transfer client provides a completed Delta Checklist, Recertification time will be used.
2. If an existing, or new transfer client does not provide a completed Delta Checklist, Initial Audit time (Stage 1 and Stage 2) time will be used.

A client may choose to transition to the revised standard (13485:2016) at the time of recertification and/or surveillance audits.

KEY IMPROVEMENTS TO ISO 13485

Key improvements in the 2016 version include:

More emphasis on implementing the appropriate infrastructure, particularly for the production of sterile medical devices	Improved alignment with regulatory requirements	Expanded 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)	Increased focus on risk management

ISO 13485:2016 HAS BEEN PUBLISHED… *What Should You Do?*

Become Informed

- Begin to understand ISO 13485:2016
- Understand differences between ISO 13485:2003 and ISO 13485:2016

Begin Planning

- All NSF-ISR clients registered to ISO 13485:2003 will be required to "upgrade" by February 28, 2019.
- All ISO 13485 clients will have until November 30, 2017 to complete their upgrade audit. Clients for ISO 13485:2003 will be dropped from the NSF-ISR system on March 1, 2019 if they have failed to upgrade their certification by that date.

Communicate

- Team, Top Management, Organization, Interested Parties
- Questions, needs or suggestions? Contact NSF-ISR at information@nsf-isr.org

THINGS TO CONSIDER

1. Do you have a copy of the new ISO Standard?
2. Have you read it?
3. Do you have a good understanding of the requirements?
4. Would you like guidance in developing a road map for your organization?
5. Have you began to communicate changes?
6. Does Top Management understand their role?
7. Has your organization identified risks, opportunities, consequences, and a plan to manage risks?

HOW NSF-ISR CAN HELP YOU WITH THE TRANSITION

NSF-ISR is a leader in management systems registration and can provide the latest information to clients on updates to the standard. We work with clients to ensure they fully understand the requirements and timing of the standard changes. Upon request, we can provide a gap analysis.

Through webinars, email updates, web content, presentations, and white papers, NSF-ISR is here to ensure that customers are equipped with the tools they need for registration. Our knowledgeable auditors are trained and our systems calibrated in preparation for the ISO 13485 launch.

Whether you are currently registered and would like to gain efficiency by consolidating your audits, or are looking to newly register, we have to tools and knowledge you need to succeed. NSF-ISR has developed, or is in the process of developing, the following tools for customers looking to register to ISO 13485. As they are developed, you can find them on our transition webpage, www.nsf.org/info/iso-updates.

We hope that this transition guide is helpful as your organization transitions to the new ISO 13485:2016.

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