<u>प्रबंध पद्धति प्रमाणन विभाग</u>

हमारा संदर्भ: एमएससीडी/29:1 24 जनवरी 2018

विषय: आईएस/आईएसओ 13485:2016के कार्यान्वयन के लिए दिशानिर्देश

आईएस/आईएसओ 13485का पुनरीक्षित संस्करण अर्थात् 2016 संस्करण के कार्यान्वयन हेतु दिशानिर्देश संलग्न हैं।

ये तत्काल प्रभाव से कार्यान्वित किए जाएं और इसके बारे में सभी संबंधितों को सूचना दी जाएं। आवेदकों/लाइसेंसियों/भावी ग्राहकों/अन्य संबंधितों को भेजी गई संप्रेषण की प्रति रिकॉर्ड हेतु हमें भेजी जाएं।

(संजय गोस्वामी)
वैज्ञानिक ई एवं प्रमुख (एमएससीडी)

सभी एमएससीओआर

प्रतिलिपि

1. सभी डीडीजीआर
2. डीडीजी (एमएससीडी)
3. सभी शाखा कार्यालय प्रमुख

MANAGEMENT SYSTEMS CERTIFICATION DEPARTMENT

Our Ref: MSCD/29:1 24 January 2018

Subject: Guidelines for implementation of IS/ISO 13485:2016

Please find attached herewith the guidelines for implementation of revised version of IS/ISO 13485, i.e. 2016 version.

These may be implemented with immediate effect and may be brought to the notice of all concerned. The copy of communication being sent to applicants/licensees/prospective clients/other concerned may please be sent to us for records.

(Sanjay Goswami)
Sc. E & head (MSCD)

All MSCORs

Copy to

1. DDGRs
2. DDG (MSCD)
3. All BO Heads

Management systems Certification Department

Our Ref: MSCD/29:1 **23 January 2018**

Subject: Guidelines for Implementation of IS/ISO 13485: 2016

1. The revised standard for Medical Device Management System has been published by ISO on 1st March 2016 as ISO 13485: 2016 and Indian Standard, IS/ISO 13485: 2016, is published in August 2017. The outline of changes in the revised standard IS/ISO 13485: 2016 as compared with IS/ISO 13485: 2003 are enclosed at Annex I.

2. For continuing with Certification for IS/ISO 13485, our licensees/ applicants are required to comply with the requirements of IS/ISO 13485:2016. In order to implement the changes the organisations need to:

• Identify organisational gaps which need to be addressed to meet new requirements

• Develop an implementation plan

• Provide appropriate training and awareness for all parties that have an impact on the effectiveness of the organisation

• Update the existing medical device management system (MDMS) to meet the revised requirements and provide verification of effectiveness

• Keep BIS informed of the transition.

3. Implementation plan for IS/ISO 13485: 2016 –

3.1 Date of Implementation

3.1.1 The revised standard IS/ISO 13485: 2016 would be implemented with immediate effect.

3.1.2 As the changeover period permitted by IAF is 3 years from the date of publication of the ISO standard, the existing standard IS/ISO 13485: 2003 would remain valid till February 2019.

3.1.3 The important timelines for implementation of transition to the revised standards has been tabulated and enclosed at Annex II.

3.2 Applications

3.2.1 After 30 April 2018, BIS would accept new applications for Grant of licence only as per the revised version of the standard i.e. IS/ISO 13485: 2016.

3.3 Licences

3.3.1 Changeover of existing licence to revised standard shall be permitted only after assessment through surveillance or recertification audit. Existing licensee shall be

informed about the date and advised to complete the changeover process as per the time line.

3.3.2 Licensee would need to apply for changeover to revised standards before 30 September 2018 to enable surveillance audit by BIS for transition to the revised standards before 31 December 2018.

4. Auditing and reporting

4.1 As the assessment to revised standards would be made during a routine surveillance/ recertification audit, the documentation shall also be assessed and reported as per the revised standards. Additional time of 1 Man day required for carrying out the verification of documentation and changes which shall be added to the surveillance time or the recertification audit time and charges to be collected accordingly.

4.2 A surveillance audit conducted before 30 June 2018 will also be used to assess the preparedness of the licensee for transition to the revised standards and the transition plan of the licensee should be adequately communicated in the auditor's report.

5. Training

NITS has been requested for Transition Training of MDMS auditors to carry out audit as per IS/ISO 13485: 2016.

(Sanjay Goswami)

Scientist-E & Head

MSCD

Annex- I

Outline of the changes in IS/ISO 13485:2016 compared with IS/ISO 13485:2003.

Clause in ISO 13485:2016	Comment on change compared with ISO 13485:2003
Foreword	— Clarifies the effect of the third edition of this Indian Standard.
Introduction 0.1 General	— Includes substantially more detail related to the nature of the organization covered by this Indian Standard's requirements and the life-cycle stages covered. — Explains that the requirements can be used by suppliers or other external parties eithervoluntarily or as a result of contract arrangements. — Alerts organizations about their obligations related to regulatory requirements focusedon quality management systems. — Alerts organizations about differences in local regulation definitions and their obligationto 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 regulatoryrequirements for safety and performance." — Emphasizes that the product requirements that are important are those related to safetyand performance. — Adds two influences on the nature of the quality management system that were not in theoriginal listing (organizational environment and regulatory requirements). — Clarifies that the organization does not have to align its documentation to the clausestructure of this Standard.
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 deviceor meeting applicable regulatory requirements. — Clarifies that the term "documented" includes the need to establish, implement andmaintain. — Clarifies that the term "product" applies to outputs that are intended for, or required by, acustomer, or any intended output resulting from a product realization process.
0.3 Process	Explanation of process approach extended.

approach	
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 — 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 involvedin 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 partiesthat provide product, including quality management system-related services to medicaldevice organizations. — Specifically calls out the responsibilities for monitoring, maintaining, and controllingoutsourced processes. — Expands requirements that can be not applicable to those in Clauses 6 and 8. — Clarifies that the term “regulatory requirements” includes statutes, regulations, ordinancesor directives and limits the scope of the “applicable regulatory requirements” tothose requirements for the quality management system and the safety or performance of themedical 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 theorganization.” — Requires the application of a “risk based approach to the control of the appropriate processesneeded for the quality management system.” — Adds requirements related to changes to processes. — Added requirements related to validation of the application of computer software used inthe 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 managementreview 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, providingneeded training and ensuring awareness of personnel.
6.3 Infrastructure	— Adds requirement that infrastructure prevents product mix-up and ensure orderly handlingof 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 particulatematter 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 differentgroups 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 validationand 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 productsin 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 developmentchanges.
7.3.10 Design and	— New sub-clause added.

development files	
7.4.1 Purchasing process	— Focuses the supplier selection criteria on the effect of the supplier performance on thequality 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 actionto 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 takenwhen 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 ofthe 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	— Added requirement for unique device identification. — New requirement for a documented procedure for product identification and regardingidentification 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 monitorand 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 afterdelivery 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 statisticaltechniques 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

Annex II

Implementation Plan for transition to IS/ISO 13485: 2016

	Important timelines
Applications	
Last date to apply as per IS/ISO 13485: 2003	01 April 2018
Processing of applications recorded as per IS/ISO 13485: 2003 to be completed	30 June 2018
Licence	
Last date to apply for changeover by existing licensees with complete documentation	30 September 2018
Last date for completing surveillance assessment as per IS/ISO 13485: 2016	31 December 2018
Last date for changeover to IS/ISO 13485: 2016	28 February 2019