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ICMED Transition Policy Rev.04 dt. 11-10-2021

Transition Policy for Indian Certification of Medical Devices (ICMED) Scheme for-**Level 1: ICMED 9000****Level 2: ICMED 13485**

In view of publication of the Technical Criteria(s) for Certification of Medical Devices (Issue 2/ January 2019) of Level 1: ICMED 9000 & Level 2: ICMED 13485, QCI has laid down its transition policy as defined below for all the clients of provisionally approved / accredited CBs.

Desk review or/and Office Assessment of the CBs certification system to be carried out by the Scheme Owner or delegated to the AB depending whether CB is provisionally approved or accredited. This review assessment shall cover the following:

1. A Declaration Statement from the Management as a commitment confirming that the CB is ready for and in compliance with Level 1: ICMED 9000 and/or Level 2: ICMED 13485 requirements based on an comprehensive Internal audit.
2. The inclusion of Level 1: ICMED 9000 and/or Level 2: ICMED 13485 additional requirements to be incorporated in the CB management system with particular reference to:
 - i) Transition Process Requirements pertaining to updated version of the scheme
 - ii) Dissemination of information about the transition process to all certified organizations about Level 1: ICMED 9000 and/or Level 2: ICMED 13485
 - iii) Ensuring training of all CB Personnel involved in certification process on new version of the ICMED scheme
 - iv) Upgradation of competence of auditors as per internal process covering additional requirements of new version of the ICMED scheme including requirements of MDR 2017.
3. Identified deficiencies (if any) in the CB Management system shall be documented and addressed by an appropriate action plan.
4. Following a successful Desk Review or/and Onsite Assessment, QCI shall issue an updated provisional approval certificate to the CB for the applicable scope and NACB shall issue an updated accreditation certificate for applicable scope.
5. During the next scheduled assessment visit of CB, QCI/NACB shall verify the implementation of the applicable level requirement.
6. Implementation of the requirements related to witness assessments shall commence during the next accreditation cycle of the CB.

Note:

1. QCI shall execute the requirements of this policy in case of provisionally approved CBs and NACB shall execute the requirements in case of NACB accredited CBs.
2. QCI / NACB shall conduct Desk Review or/and Office Assessment (OA) for a duration of 1 Man-day.
3. All the approved CBs and their clients must complete the transition process to new version of ICMED scheme by 31st Dec. 2021.
4. Each CB has to conform the dates of their transition assessment with NACB within 15 days from the release of this policy

