



NATIONAL ACCREDITATION BOARD FOR CERTIFICATION BODIES (NABCB)

Quality Council of India (QCI), 2nd Floor, Institution of Engineers Building, Bahadur Shah Zafar Marg, New Delhi – 110002

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Accreditation Procedure
For Certification as per ISO 15378
Primary packaging materials for medicinal products - Particular requirements
for the application of ISO 9001, with reference to Good
Manufacturing Practice (GMP)

BCB 201A (QMS-02)- Dec 2023



Effective: Immediate



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0. Scope

- 0.1 NABCB has decided to undertake accreditation of certification bodies (CBs) for ISO15378, *primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001 which* would be an addition to the existing QMS accreditation.
- 0.2 ISO 15378 incorporates in a single document the quality management requirements of ISO 9001 together with the Principles of Good Manufacturing Practice (GMP) for the design, manufacturing, and supply of primary packaging materials for medicinal products
- 0.3 This document describes the procedure to be followed by the National Accreditation Board for Certification Bodies (NABCB) in processing applications from Certification Bodies (CBs) seeking accreditation for certification to ISO 15378, *Primary packaging materials for medicinal products* or applying for extension of scope of their accreditation to cover ISO 15378.

1. Application

- 1.1 Any certification body interested in the accreditation of NABCB for the purpose of ISO15378 certification may apply to NABCB.
 - 1.1.1 The new certification body shall send an application using NABCB format BCB: F 001.
 - 1.1.2 Already accredited CB for Quality Management Systems Certification shall send an application for scope extension with an administrative fee as prescribed for scope extension in the accreditation procedure BCB 201 (Q & E) using NABCB format BCB F036.
- 1.2 The completed application form for NABCB accreditation shall be duly signed by the CEO/authorized representative/s of the CB seeking accreditation. Request for extension shall be either e-mailed by authorized person or letter sent shall be duly signed by the authorized person.
- 1.3 CB shall clearly indicate the scope they wish to get accreditation for under ISO 15378 i.e. there are different packaging materials used for packaging of medicinal products for e.g. glass, plastics, etc

2. Assessment

- 2.1 A new applicant certification body shall undergo accreditation process as per NABCB accreditation procedure for Quality Management Systems certification bodies, BCB 201(Q & E).
- 2.2 In case a certification body is already accredited by NABCB for Quality Management Systems, then a one manday onsite assessment including document review will be conducted by NABCB assessment team. Manday(s) for technical expert would be charged extra as applicable.
- 2.3 On successful completion of above assessment, NABCB shall conduct witness one initial/recertification audit before granting the required scopes which have already been assessed in office. The certification body may offer 2 surveillance audits for witnessing in lieu of the above. The audit shall normally be of 3 mandays duration with a 2 member team.



3. Decision

Based on the outcome of the above assessments, decision on extension of scope/s would be taken and the applicant certification body will be granted accreditation or extension to ISO 15378 for specific scopes where it has demonstrated competence.



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Amendment Record

<u>Date</u>	<u>Auth. by</u>	<u>Description of Amendment</u>
Dec 2023	CEO	Minor edits based on internal review