SUBJECT: Accreditation Program for ISO 15378

APPLIES TO: ISO 15378 ANAB Accredited and Applicant Certification Bodies

PREFACE
This Accreditation Rule is to inform certification bodies (CBs) of ANAB requirements for accreditation to certify organizations for management systems conforming with ISO 15378, which defines harmonized primary packaging material requirements and specifies good manufacturing practices for pharmaceutical packaging materials.

ACCREDITATION RULE
1. Requirement Documents (current versions unless specified)
   1.1. ISO 15378, Primary packaging materials for medicinal products – Particular requirements for the application of ISO 9001:2015, with reference to good manufacturing practice (GMP)
   1.2. ISO/IEC 17021-1, Conformity assessment – Requirements for bodies providing audit and certification of management systems
   1.3. MA 5000, ANAB Accreditation Manual, and applicable ANAB Accreditation Rules
   1.4. IAF Mandatory Documents, as applicable
2. Prerequisites
   2.1. The CB shall be accredited by ANAB or attain ANAB accreditation concurrently to certify organizations for ISO 9001 quality management systems.
   2.2. If the CB’s accreditation for ISO 9001 is suspended or withdrawn, the CB’s accreditation for ISO 15378 also shall be suspended or withdrawn.
3. Application Process
   3.1. CBs can obtain applications for informational use at www.anab.org.
   3.2. The application process outlined at www.anab.org must be completed via ANAB’s Enterprise Quality Manager (EQM) database when the CB is ready to apply for accreditation.
   3.3. The application fee includes the cost of one assessor day for the off-site documentation review.
4. Initial Assessments for Accreditation
   4.1. An ANAB accreditation assessor shall conduct a full documentation review.
   4.2. After the documents are found acceptable, ANAB shall conduct an office assessment and required witness audits.
      4.2.1. The office assessment shall be conducted on site or remotely (at ANAB’s discretion) and is conducted to ensure the CB’s certification process for ISO 15378 conforms with ISO/IEC 17021-1 and is effective.
      4.2.2. ANAB shall witness the CB conducting a two-stage audit process (stages 1 and 2).
         4.2.2.1. The ANAB assessment team shall have the same number of members as the CB audit team.
         4.2.2.2. ANAB may use an ISO 15378 upgrade audit (to ISO 9001) as the initial witness audit.
5. Surveillance Assessments

5.1. ANAB shall conduct an annual office assessment and annually witness a CB team conducting an ISO 15378 audit.

5.1.1. When possible, the office assessment shall be conducted concurrently with assessments for other ANAB accreditation programs for which the CB is accredited.

5.1.2. During the accreditation cycle, ANAB shall evaluate the CB’s full system audit process during at least one annual witnessed audit (stages 1 and 2 certification audit or recertification). The additional witnessed audits required in the accreditation cycle are based on the CB’s audit activity and management system findings, and include audit types such as surveillance, special, multi-site, scope expansion, transfer, integrated. ANAB Accreditation Rule 18 outlines the witnessed audit scheduling process and the process for potentially altering the types of audits witnessed.

6. Re-accreditation Assessments

6.1. ANAB shall conduct a document review and an on-site full system office assessment at approximately six months prior to the expiration of accreditation.

7. End User Expected Outcomes for Accredited Certification to ISO 15378

7.1. End users can expect an organization with a certified ISO 15378 management system to conform with ISO 9001 and GMPs applicable to primary packaging materials for a quality management system. An organization with a certified ISO 15378 management system will consistently demonstrate its ability to conform with applicable customer requirements, regulatory requirements, and international standards.

7.2. The CB shall have processes to ensure that its auditors and other certification personnel are knowledgeable of the expected outcomes and consistently reinforce them with the CB’s clients.