


Base Standard Program		
ISO 13485:2016 Transition CB Application		
FA 5009	Authority: Accreditation Manager	

Section 1: CB Name, Contact Information, and Processing Fees

CB name:

Street address:

City:

State/province:

Postal code:

Country:

Name of person completing application:

Email:

Transition application fee: \$625 (Additional fess may apply if multiple reviews are required.)

Fees are payable when purchasing application

Application and all supporting documents shall be submitted in English.

Application shall be obtained through ANAB's Enterprise Quality Manager (EQM) database at <http://anab.jadian.com>. Existing EQM users can select Applications, Access to Applications, and follow steps 2 through 4 as for any application process. Select ISO 13485:2016 in the standard dropdown menu under step 2.

This application is for CBs already accredited by ANAB for ISO 13485. CBs applying for initial ANAB accreditation for ISO 13485 shall follow the initial accreditation process outlined at <http://anab.org/programs/isoiec-17021/ms-accreditation-programs/quality-iso-13485/>.

The CB is required to submit evidence to support its [ISO 13485:2016](#) transition process.

Section 2: Transition Plan

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Refer to Supporting Evidence	Comment/Response	Comment/Response
1. Provide CB's transition plan including at a minimum: <ul style="list-style-type: none"> • Process for transitioning existing clients to ISO 13485:2016 to meet the three-year deadline of 2019/03/01 • Communication plan with existing clients (including timeline, means of communication, and determination of effectiveness) • Internal changes necessary to implement an effective and efficient transition process • Timeline to deem personnel (including auditors and other relevant personnel) competent to new standard • Revisions in current processes to manage the ISO 13485 certification program Requirement: IAF Resolution 2015-13	Initial Response		
			Approved?
	Second Response		
			Approved?
	Final Response		
			Approved?

Section 3: Transition Process

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Refer to Supporting Process Including Specific Section References	Comment/Response	Comment/Response
1. Provide updated CL 5300 highlighting processes revised to support the ISO 13485:2016 certification program. Note: ANAB will review key processes to support ISO 13485:2016 transition in response to item 2 below.	Initial Response		
			Approved?
	Second Response		
			Approved?
	Final Response		
			Approved?
2. Provide processes that were revised and referred to on CL 5300 in item 1 above as it relates to transition. Note: During transition review, ANAB will focus on process revisions for management of ISO 13485:2016 transitions. There will be limited review to support processes to manage the ISO 13485:2016 certification program going forward; these processes will be reviewed in detail and evaluated for implementation during office assessments throughout the three-year transition period.	Initial Response		
			Approved?
	Second Response		
			Approved?
	Final Response		
			Approved?

<p>3. Provide process by which CB will ensure that auditors will be deemed competent for ISO 13485:2016 prior to any transition or new certification audit being performed by the auditors.</p> <p>Requirement: ISO/IEC 17021, 7.1.2, or ISO/IEC 17021-1, 7.1.2; ISO/IEC TS 17021-3, 5; and IAF MD 9, 7.2, Annex B, and Annex C</p>	Initial Response			Approved?
	Second Response			Approved?
	Final Response			Approved?
<p>4. Provide process by which CB will ensure that all other relevant personnel will be deemed competent for ISO 9001:2015 prior to any task performed as it relates to transition or new certification activities. Skills and knowledge should be tailored and delivered to all relevant functions of the CB.</p> <p>Requirement: ISO/IEC 17021, 7.12, or ISO/IEC 17021-1, 7.1.2; ISO/IEC TS 17021-3, 6; and IAF MD 9, 7.1 and Annex B</p>	Initial Response			Approved?
	Second Response			Approved?
	Final Response			Approved?
<p>5. Provide process for managing preliminary visits with clients (e.g., gap analysis, informational visit). If not offering preliminary visits, please mark NA for not applicable.</p>	Initial Response			Approved?
	Second Response			Approved?
	Final Response			Approved?
<p>6. Provide process for audit duration for ISO 13485:2016 transition audits, including separate transition audits and transition audits conducted with a surveillance or recertification audit.</p> <p>Requirement: ISO/IEC 17021, 9.1.4.1, or ISO/IEC 17021-1, 9.1.4.1; IAF MD 9, 9.1.4.1 and Annex D (IAF MD 5 and IAF MD 11) may be applicable if integrated audit and processes are different)</p>	Initial Response			Approved?
	Second Response			Approved?
	Final Response			Approved?
<p>7. Provide process for managing control of certificates to the new standard, specifically issuing certificates to ISO 13485:2016 only after the client has been audited and ANAB management staff has made transition decision for the CB's accreditation.</p>	Initial Response			Approved?
	Second Response			Approved?
	Final Response			Approved?
<p>8. Provide process for managing certifications to ISO 13485:2003 which expire after the transition deadline including managing certifications to ISO 13485:2003 that do not transition by the deadline.</p>	Initial Response			Approved?
	Second Response			Approved?
	Final Response			Approved?

9. How many ISO 13485:2016 certificates have been previously issued with another AB's accreditation symbol or unaccredited (specify each)? Does the CB plan to reissue the certificates with ANAB's accreditation symbol after transition? If yes, provide the plan for reissuance.	Initial Response	
		Approved?
	Second Response	
		Approved?
	Final Response	
		Approved?

Section 4: Transition Evidence

Sample size is specified for each item. ANAB should be able to confirm effective implementation with this sample. Additional evidence will be reviewed and verified for effective implementation during future assessments.

If the CB prefers to have evidence reviewed on site (e.g., during an upcoming office assessment), contact the ANAB coordinator and EATL to determine timeframes prior to submitting the application. If an acceptable timeline is not possible, section 4 shall be completed prior to submitting the completed application.

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Refer to Supporting Evidence	Comment/Response	Comment/Response
1. Provide evidence of ISO 13485:2016 knowledge to support auditors' competence (item 3 in section 3 above). Provide evidence for fewer of two auditors or all ISO 13485 auditors.	Initial Response		
			Approved?
	Second Response		
			Approved?
	Final Response		
			Approved?
2. Provide evidence of ISO 13485:2016 knowledge to support personnel competence (item 4 in section 3 above). Provide evidence for fewer of two certification personnel responsible for transition activity (e.g., application review, audit team and duration determination, report review, certification decision) or all individuals involved with the ISO 13485 certification programs.	Initial Response		
			Approved?
	Second Response		
			Approved?
	Final Response		
			Approved?
3. Provide evidence, including justification, of how audit duration for an ISO 13485:2016 transition audit was determined (item 6 in section 3 above). Include evidence for one transition audit scheduled to be conducted alone and one transition audit scheduled to be conducted with a surveillance or recertification audit.	Initial Response		
			Approved?
	Second Response		
			Approved?
	Final Response		
			Approved?
4. Provide evidence for one new certificate issued to ISO 13485:2003 after publication of ISO 13485:2016 to demonstrate management of the expiration date	Initial Response		
			Approved?
	Second Response		
			Approved?

(item 8 in section 3 above). If a certificate has not yet been completed, mark NA.	Final Response		Approved?
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Section 5: CB Personnel Endorsement

Submission steps:

1. Verify responses to all questions are complete and all required information (attachments) is included.
2. Upload application to EQM (<http://anab.jadian.com>). Existing EQM users can select Applications, Access to Applications, and follow step 4 as for any application process.
3. The transition (off-site) application review takes approximately two weeks from assignment and will be conducted by the CB's EATL or ISO 13485 technical assessor.
4. The CB can request an office assessment for the evidence review (section 4); contact ANAB for scheduling.
5. The CB will be notified when the review is complete.
6. Implementation will be verified at the next office assessment and ISO 13485:2016 witnessed audit unless additional assessments are required per section 6 below.

CB personnel who completed the application:

Name:

Title:

Date:

CB management who reviewed the information and determined that it meets all applicable requirements and application requests prior to submission to ANAB:

Name:

Title:

Date:

Section 6: Additional Assessments (to be completed by ANAB reviewer)

If the CB's transition process, including evidence, cannot be verified during the application review, ANAB's reviewer shall recommend an office or witness assessment, and ANAB will work with the CB to expedite scheduling of the assessment.

Is the application information, including evidence, sufficient to recommend transition to ANAB management?

If not, include the type of assessment required and any other relevant detail.

Reviewer Name and Date: