

<b>Base Standard Program</b>		
<b>ISO 13485 Medical Devices CB Application for Accreditation</b>		
AUTHORITY: Accreditation Manager	EFFECTIVE DATE: 09 September 2011	DOCUMENT NUMBER: <b>FA 2014.09</b>

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

CB name:

Street address:

City:

State/province:

Postal code:

Country:

Name of person completing application:

E-mail:

ISO 13485 application fee: \$5,000

### **Fees are payable when purchasing application**

Application and all supporting documents shall be submitted in English.

Instructions on application process are at [www.anab.org](http://www.anab.org); click on Become a Certification Body.

Application shall be obtained through ANAB's Enterprise Quality Manager (EQM) database at <http://anab.remoteauditor.com> and completed electronically (including submission of all supporting evidence) and submitted to ANAB via EQM. Instructions on how to obtain and upload the application in EQM can be found at [www.anab.org](http://www.anab.org); under Documents, select Heads Up and click on issue 72.

If the completed application is not accepted by ANAB after three reviews, the application will be declined. The CB may re-apply (including payment of application fees) after 60 days.

## Section 2: ISO/IEC 17021 Requirements for CBs Not ISO/IEC 17021 Accredited by ANAB

Provide evidence that the CB's certification system includes the requirements of ISO/IEC 17021.

\_\_\_ Not applicable – mark X at left if CB is already an applicant or accredited by ANAB for another program and proceed to Section 3.

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Reference to Supporting Document(s) Including Specific Section References	Comment/Response	Comment/Response
1. Execute (signed) <a href="#">ANAB CB Applicant Agreement</a> , which can be found in EQM under Reference Documents.  An electronic signature is acceptable but a typed name is not. If the signature is handwritten, scan the signed document and attach to application electronically.	<b>Initial Response</b>		Approved?
	<b>Second Response</b>		Approved?
	<b>Final Response</b>		Approved?
2. Completed <a href="#">ISO/IEC 17021:2011 Requirement Matrix</a> , which can be obtained through the EQM application process.	<b>Initial Response</b>		Approved? ANAB-specific comments will be included on completed ISO/IEC 17021 Requirement Matrix
	<b>Second Response</b>		Approved?
	<b>Final Response</b>		Approved?
3. Completed impartiality analysis of relationships to other parts of the company and to other organizations and/or individuals.  Requirement: <a href="#">ANAB Accreditation Rule 10</a>	<b>Initial Response</b>		Approved?
	<b>Second Response</b>		Approved?
	<b>Final Response</b>		Approved?
4. Evidence that the impartiality analysis (referenced in 3, above) was reviewed by the committee responsible for impartiality.  Requirement: <a href="#">ISO/IEC 17021, 6.2</a>	<b>Initial Response</b>		Approved?
	<b>Second Response</b>		Approved?
	<b>Final Response</b>		Approved?
5. Provide names of members on committee established to safeguard impartiality, including key interest group each person represents. It is the CB's responsibility to notify ANAB of any changes.  Requirement: <a href="#">ISO/IEC 17021, 6.2</a>	<b>Initial Response</b>		Approved?
	<b>Second Response</b>		Approved?
	<b>Final Response</b>		Approved?

6. Current list of organizations to which the CB out sources work associated with management systems certification.  Requirement: <a href="#">ISO/IEC 17021, 7.5</a>	<b>Initial Response</b>	
		Approved?
	<b>Second Response</b>	
		Approved?
7. Copy of enforceable arrangements with each organization.  Requirement: <a href="#">ISO/IEC 17021, 7.5</a>	<b>Initial Response</b>	
		Approved?
	<b>Second Response</b>	
		Approved?
	<b>Final Response</b>	
	Approved?	

### Section 3: ISO 13485 CB Requirements

Provide evidence that the CB's certification system includes the requirements of ISO 13485.

Requirement	To Be Completed by CB		To Be Completed by ANAB
	Reference to Supporting Document(s) Including Specific Section References	Comment/Response	Comment/Response
1. Provide revised <a href="#">ISO/IEC 17021 Requirement Matrix</a> , with document references revised to address this program highlighted. (The 2006 version can be found in EQM under Reference Documents. The 2011 version must be obtained through the EQM application process.) Also include copy of documents that were revised.  Note: Disregard if provided in Section 2 above.	<b>Initial Response</b>		
			Approved?
	<b>Second Response</b>		
			Approved?
1. For purposes of ANAB accreditation oversight, provide branch, regional, and/or country offices of CB that will be authorized to (a) conduct ISO 13485 certification audits and (b) issue ISO 13485 certificates. Provide basis on which such authorization is or will be granted.	<b>Initial Response</b>		
			Approved?
	<b>Second Response</b>		
			Approved?
2. Does CB have relationship with existing notified body for purpose of issuing European CE mark?	<b>Initial Response</b>		
	If yes, which body?		Approved?
	<b>Second Response</b>		
			Approved?
3. Provide competency analysis completed for medical devices, including for auditors and other expertise	<b>Initial Response</b>		
			Approved?
	<b>Second Response</b>		
			Approved?

in the process.	<b>Second Response</b>	
		Approved?
	<b>Final Response</b>	
4. Provide evidence (based on competency analysis) for technical experts designated to represent medical device industry on basis of medical device industry experience.	<b>Initial Response</b>	
		Approved?
	<b>Second Response</b>	
5. Provide evidence (based on competency analysis) for all auditors and contract and/or permanent staff used by CB for ISO 13485.	<b>Initial Response</b>	
		Approved?
	<b>Second Response</b>	
6. Provide model of certificate to be issued to ISO 13485 certified organizations, including example of relevant scope of certification statement.	<b>Initial Response</b>	
		Approved?
	<b>Second Response</b>	
7. Management system documentation for any supplemental auditor guidelines, training, checklists, or other tools available to audit team.	<b>Initial Response</b>	
		Approved?
	<b>Second Response</b>	
	<b>Final Response</b>	
		Approved?
	<b>Final Response</b>	
	Approved?	

#### Section 4: ISO 13485 initial Audits

ANAB requires initial full-system stage 1 and stage 2 witnessed audits for accreditation for ISO 13485 certification.

#### Section 5: CB Management 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.remoteauditor.com>). Instructions on how to upload the application and supporting evidence to EQM can be found at [www.anab.org](http://www.anab.org); under Documents, select Heads Up and click on issue 72.
3. The initial (off site) document review takes approximately two weeks.

4. The CB will be notified when the review is complete.

CB management who completed the application and determined that the information meets all applicable requirements:

Name:

Title:

Date: