Form Approved
OMB No. 0990-XXXX
Exp. Date XX/XX/20XX

APPLICATION FOR ONC-AUTHORIZED TESTING & CERTIFICATION BODY (ONC-ATCB) STATUS: PART I

Application Instructions

Please complete all sections of the application form and submit the completed application and requested supporting documentation to the National Coordinator for Health Information Technology.

A complete Part I of the application will include the following components:

Application Components for Part I	Action Required
General Identifying Information	Provide Information
Designated Point of Contact for ONC-ATCB Applicant	Provide Information
ISO/IEC 17025:2005 Self-Audit Conformance Checklist	Complete Self-Audit
Proof of Conformance to ISO/IEC 17025:2005	Document Conformance
ISO/IEC Guide 65:1996 Self-Audit Conformance Checklist	Complete Self-Audit
Proof of Conformance to ISO/IEC Guide 65:1996	Document Conformance
Agreement to Adhere to the Principles of Proper Conduct for ONC-ATCBs	Sign Original Agreement

Submission Instructions

Preferred Method – Electronic Submissions:

For electronic submissions, applicants must return a completed application, including all documents, in PDF to ATCBapplication@hhs.gov.

If submitting the completed application form by e-mail, please include the applicant's name and the date in the subject line. In addition, in the body of the mail, please include a list of the names of all the attachments submitted with the e-mail, indicating to which application requirement each attachment applies. All supporting documents must be clearly labeled with a document title and the organization name.

Alternate Method – Postal Mail Submissions:

Paper applications must be submitted to the following address. Two (2) copies of submitted documentation are required for postal mail submission.

Office of the National Coordinator for Health Information Technology
Attention: Certification Programs
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave, S.W., Washington, D.C. 20201

U.S. Department of Health & Human Services
Office of the National Coordinator for Health Information Technology

Questions?

Please review all information contained within the application form carefully before submission.

For inquiries and questions about the application process or how to complete the application form, please contact the Office of the National Coordinator for Health Information Technology:

Office of the National Coordinator for Health Information Technology
Attention: Certification Programs
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave, S.W., Washington, D.C. 20201

Phone: (202) 690-7151
E-mail: ATCBapplication@hhs.gov (Application Questions)
Email: ONC.Certification@hhs.gov (General Questions)

Application Form

Part I

General Information

Applicant Name(s):

Address:

City, State: Zip Code:

Homepage URL:

Designated Point of Contact for ONC-ATCB Applicant

Name (Last, First): Title:

Phone: Cell:

E-mail:

ISO/IEC 17025:2005 Self-Audit Conformance Checklist

Please check each box as appropriate. If you believe that a particular requirement of ISO 17025 does not apply to your application for authorization as an ONC-ATCB, please clearly identify the requirement and attach a detailed explanation for why the requirement should not apply.

Management Requirements	Section 4
☐ Organization	Section 4.1
☐ Management System	Section 4.2
☐ Document Control	Section 4.3
☐ General	Section 4.3.1
☐ Document approval and issue	Section 4.3.2
☐ Document changes	Section 4.3.3
☐ Review of requests, tenders and contracts	Section 4.4
☐ Subcontracting of tests and calibrations	Section 4.5
☐ Purchasing services and supplies	Section 4.6
☐ Service to the customer	Section 4.7
☐ Complaints	Section 4.8
☐ Control of nonconforming testing and/or calibration work	Section 4.9
☐ Improvement	Section 4.10
☐ Corrective action	Section 4.11
☐ General	Section 4.11.1
☐ Cause analysis	Section 4.11.2
☐ Selection and implementation of corrective actions	Section 4.11.3
☐ Monitoring of corrective actions	Section 4.11.4
☐ Additional audits	Section 4.11.5
☐ Preventive action	Section 4.12
☐ Control of records	Section 4.13
☐ General	Section 4.13.1
☐ Technical records	Section 4.13.2
☐ Internal audits	Section 4.14
☐ Management reviews	Section 4.15
Technical Requirements	**Section 5**
☐ General	Section 5.1
☐ Personnel	Section 5.2
☐ Accommodation and environmental conditions	Section 5.3
☐ Test and calibration methods and method validation	Section 5.4
☐ General	Section 5.4.1
☐ Selection of methods	Section 5.4.2
☐ Laboratory-developed methods	Section 5.4.3
☐ Non-standard methods	Section 5.4.4
☐ Validation of methods	Section 5.4.5
☐ Estimation of uncertainty of measurement	Section 5.4.6

☐	Control of data	Section 5.4.7
☐	Equipment	Section 5.5
☐	Measurement traceability	Section 5.6
☐	General	Section 5.6.1
☐	Specific Requirements	Section 5.6.2
☐	Reference standards and reference materials	Section 5.6.3
☐	Sampling	Section 5.7
☐	Handling of test and calibration items	Section 5.8
☐	Assuring the quality of test and calibration results	Section 5.9
☐	General	Section 5.10.1
☐	Test reports and calibration certificates	Section 5.10.2
☐	Test report	Section 5.10.3
☐	Calibration certificates	Section 5.10.4
☐	Opinions and interpretations	Section 5.10.5
☐	Testing and calibration results obtained from subcontractors	Section 5.10.6
☐	Electronic transmission of results	Section 5.10.7
☐	Format of reports and certificates	Section 5.10.8
☐	Amendments to test reports and calibration certificates	Section 5.10.9

Proof of Conformance to ISO/IEC 17025 2005 (ISO 17025) [1]

Please provide copies of the following documents as evidence of conformance.

1. Documentation of the Completion and Results of the Self-Audit Against All Sections of ISO 17025 (Above)
2. Copy of the Applicant's Quality System Document According To Section 4.2.2 of ISO 17025
3. Copy of Applicant's Policies and Procedures for Handling Testing Nonconformities According to Section 4.9.1 of ISO 17025
4. Copy of Qualifications of Each of the Applicant's Personnel Who Oversee Or Conduct Testing According to Section 5.2 of ISO 17025

By completing the check-boxes and signing below, I hereby attest that I have read and understood the requirements as outlined in ISO/IEC 17025:2005 and my organization is conformant with the requirements listed except as noted above and in the explained attachments.

Signature: _____

Name: _____

Date: _____

Organization: _____

[1] http://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+17025%3a2005&source=google&adgroup=iso9&keyword=iso%2Fiec%2017025&gclid=CKDg3_-XvKECFVhJ2god_AfX-w

ISO/IEC Guide 65:1996 (Guide 65) Self-Audit Conformance Checklist

Please check each box as appropriate. If you believe that a particular requirement of Guide 65 does not apply to your application for authorization as an ONC-ATCB, please clearly identify the requirement and attach a detailed explanation for why the requirement should not apply.

Certification Body	**Section 4**
☐ General Provisions	Section 4.1
☐ Organization	Section 4.2
☐ Subcontracting	Section 4.4
☐ Quality Systems	Section 4.5
☐ Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification	Section 4.6
☐ Internal audits and management reviews	Section 4.7
☐ Documentation	Section 4.8
☐ Records	Section 4.9
☐ Confidentiality	Section 4.10
Certification Body Personnel	**Section 5**
☐ General	Section 5.1
☐ Qualification Criteria	Section 5.2
Changes in certification requirements	**Section 6**
☐ Changes in the certification requirements	Section 6
Appeals, complaints, and disputes	**Section 7**
☐ Appeals, complaints and disputes procedures	Section 7.1
☐ Application for certification	Section 7.2
Application for Certification	**Section 8**
☐ Information on the procedure	Section 8.1
☐ The application	Section 8.2
Preparation for Evaluation	**Section 9**
Maintain records	Section 9.1
☐ Prepare plan for evaluation activities	Section 9.2
☐ Assign evaluation personnel	Section 9.3
☐ Provision of working documents to personnel	Section 9.4
Evaluation	**Section 10**
☐ Evaluation	Section 10
Evaluation Report	**Section 11**
☐ Evaluation Report	Section 11
Decision on Certification	**Section 12**
☐ Decision on certification	Section 12.1
☐ Delegation of authority	Section 12.2
☐ Certification documents	Section 12.3
Surveillance	**Section 13**
☐ Documented surveillance procedures	Section 13.1

☐	Product changes and modification updates	Section 13.2
☐	Documentation of surveillance activities	Section 13.3
☐	Periodic evaluation to confirm conformance of marked products	Section 13.4
Use of licenses, certificates and marks of conformity		**Section 14**
☐	Control over ownership, use and display of licenses, certificates and marks of conformity	Section 14.1
☐	Guidance on use of certificates and marks	Section 14.2
☐	Action in response to misrepresentation of certification systems, licenses, certificates and marks	Section 14.3
Complaints to suppliers		**Section 15**
☐	Complaints to suppliers	Section 15

Proof of Conformance to ISO/IEC Guide 65:1996 (Guide 65)[2]

Please provide copies of the following documents as evidence of conformance.

1. Documentation of the completion and results of the self-audit against all sections of Guide 65 (Above)
2. Copy or Description of Applicant's Management Structure According to Section 4.2 of Guide 65
3. Copy of Applicant's Quality Manual developed According to Section 4.5.3 of Guide 65
4. Copy of Applicant's Policies and Approach to Confidentiality According to Section 4.10 of Guide 65
5. Copy of Qualifications of each of the Applicant's Personnel who Oversees or Conducts Certification According to Section 5.2 of Guide 65
6. Copy of the Applicant's Evaluation Reporting Procedures According to Section 11 of Guide 65
7. Copy of Applicant's Policies for Use and Display of Certificates According to Section 14 of Guide 65

By completing the check-boxes above and signing below, I hereby attest that I have read and understood the requirements as outlined in ISO/IEC Guide 65:1996 and my organization is conformant with the requirements listed except as noted above and in the explained attachments.

Signature: _____

Name: _____

Date: _____

Organization: _____

[2] http://webstore.ansi.org/RecordDetail.aspx?sku=ISO%2fIEC+Guide+65%3a1996&source=google&adgroup=iso10&keyword=iso%2Fiec%20guide%2065&gclid=CL-5_L-XvKECFRRM5Qod0QigAw

Agreement to Adhere to the Principles of Proper Conduct for ONC-ATCBs

Please confirm that you have read, understand, and agree that your organization(s) will adhere to the following Principles of Proper Conduct by checking the box next to each Principle of Proper Conduct and signing and dating the attestation below.

Principles of Proper Conduct for ONC-ATCBs
☐ Operate a certification program in accordance with ISO/IEC Guide 65:1996 and testing program in accordance with ISO/IEC 17025:2005.
☐ Maintain an effective quality management system which addresses all requirements of ISO/IEC 17025:2005.
☐ Attend all mandatory ONC training and program update sessions.
☐ Maintain a training program, consistent with the ISO/IEC standards that include documented procedures and training requirements to ensure its personnel are competent to test and certify Complete EHRs and/or EHR Modules.
☐ Use test tools and test procedures approved by the National Coordinator for the purposes of assessing Complete EHRs and/or EHR Modules compliance with the certification criteria adopted by the Secretary of the U.S. Department of Health and Human Services.
☐ As set forth in 45 CFR, Part §170.423; Final Rule (the Rule) Report to ONC within 15 days any changes that materially affect its: (1) Legal, commercial, organizational, or ownership status; (2) Organization and management, including key testing and certification personnel; (3) Policies or procedures; (4) Location; (5) Facilities, working environment or other resources; (6) ONC authorized representative (point of contact); or (7) Other such matters that may otherwise materially affect its ability to test and certify Complete EHRs and/or EHR Modules.
☐ Allow ONC, or its authorized agents(s), to periodically observe on site (unannounced or scheduled) during normal business hours, any testing and/or certification performed to demonstrate compliance with the requirements of the temporary certification program.
☐ Provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified which includes, at a minimum: (1) The vendor name (if applicable), (2) The date certified, (3) The product version, (4) The unique certification number or other specific product identification; (5) The clinical quality measures to which a Complete EHR or EHR Module has been tested and certified; (6) Where applicable, any additional software a Complete EHR or EHR Module relied upon to demonstrate its compliance with a certification criterion or several certification criteria adopted by the Secretary of the U.S. Department of Health and Human Services; and (7) Where applicable, the certification criterion or certification criteria to which each EHR Module has been tested and certified.
☐ Retain all records related to tests and certifications according to ISO/IEC Guide 65:1996 and ISO/IEC

17025:2005 for the duration of the temporary certification program and provide copies of the final results of performed tests and certifications to ONC at the sunset of the temporary certification program.

☐ Promptly refund any and all fees received for:

(1) Requests for testing and certification that are withdrawn while its operations are suspended by the National Coordinator;

(2) Testing and certification that will not be completed as a result of its conduct; and

(3) Previous testing and certification if its conduct necessitates the recertification of Complete EHRs and EHR Modules it previously certified.

☐ Ensure adherence to the following requirements when issuing a certification to Complete EHRs and/or EHR Modules:

(1) All certifications must require that a Complete EHR or EHR Module developer conspicuously include the following text on its website and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification:

(i) i. "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant and has been certified by an ONC-ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments."; and

(ii) ii. The information an ONC-ATCB is required to report to the National Coordinator under paragraph (h) of this section.

(2) A certification issued to an integrated, bundle of EHR Modules shall be treated the same as a certification issued to a Complete EHR for the purposes of paragraph (k)(1) of this section except that it must also indicate each EHR Module that comprises the bundle.

(3) All certifications must require that a Complete EHR or EHR Module developer conspicuously include the following text on its website and in all marketing materials, communications statements, and other assertions related to the Complete EHR or EHR Module's certification: "This [Complete EHR or EHR Module] is 201[X]/201[X] compliant and has been certified by an ONC-ATCB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services or guarantee the receipt of incentive payments.";

(4) A certification issued to an EHR Module must also include an indication as to the specific certification criterion or certification criteria to which it has been tested and certified; and

(5) A certification issued to an integrated, bundle of EHR Modules shall be treated the same as a certification issued to Complete EHR for the purposes of the above requirement, except that its label must also indicate each EHR Module that comprises the bundle.

Further, I acknowledge and agree to abide by the regulatory requirements listed in 45 CFR, Part 170; § 170.465, *Revocation of Authorized Testing and Certification Body Status*.

As the applicant ATCB's **Authorized Representative**, I agree and am bound to the above conditions for authorization. Further, I attest that all statements made in this application are correct to the best of my knowledge and are made in good faith.

Signature: _____

Name: _____

Date: _____

Organization: _____