



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



According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0990-XXXX. The time required to complete this information collection is estimated to be either 4.5 hours or 400.5 hours depending on the applicant's current conformance to the application requirements. These estimates include the time to review instructions, gather the required data and perform the necessary conformance analyses. If you have comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: U.S. Department of Health & Human Services, OS/OCIO/PRA, 200 Independence Ave., S.W., Suite 336-E, Washington D.C. 20201, Attention: PRA Reports Clearance Officer.

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



<input type="checkbox"/>	Control of data	Section 5.4.7
<input type="checkbox"/>	Equipment	Section 5.5
<input type="checkbox"/>	Measurement traceability	Section 5.6
<input type="checkbox"/>	General	Section 5.6.1
<input type="checkbox"/>	Specific Requirements	Section 5.6.2
<input type="checkbox"/>	Reference standards and reference materials	Section 5.6.3
<input type="checkbox"/>	Sampling	Section 5.7
<input type="checkbox"/>	Handling of test and calibration items	Section 5.8
<input type="checkbox"/>	Assuring the quality of test and calibration results	Section 5.9
<input type="checkbox"/>	General	Section 5.10.1
<input type="checkbox"/>	Test reports and calibration certificates	Section 5.10.2
<input type="checkbox"/>	Test report	Section 5.10.3
<input type="checkbox"/>	Calibration certificates	Section 5.10.4
<input type="checkbox"/>	Opinions and interpretations	Section 5.10.5
<input type="checkbox"/>	Testing and calibration results obtained from subcontractors	Section 5.10.6
<input type="checkbox"/>	Electronic transmission of results	Section 5.10.7
<input type="checkbox"/>	Format of reports and certificates	Section 5.10.8
<input type="checkbox"/>	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: _____

¹http://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
<input type="checkbox"/> General Provisions	Section 4.1
<input type="checkbox"/> Organization	Section 4.2
<input type="checkbox"/> Subcontracting	Section 4.4
<input type="checkbox"/> Quality Systems	Section 4.5
<input type="checkbox"/> Conditions and procedures for granting, maintaining, extending, suspending and withdrawing certification	Section 4.6
<input type="checkbox"/> Internal audits and management reviews	Section 4.7
<input type="checkbox"/> Documentation	Section 4.8
<input type="checkbox"/> Records	Section 4.9
<input type="checkbox"/> Confidentiality	Section 4.10
Certification Body Personnel	Section 5
<input type="checkbox"/> General	Section 5.1
<input type="checkbox"/> Qualification Criteria	Section 5.2
Changes in certification requirements	Section 6
<input type="checkbox"/> Changes in the certification requirements	Section 6
Appeals, complaints, and disputes	Section 7
<input type="checkbox"/> Appeals, complaints and disputes procedures	Section 7.1
<input type="checkbox"/> Application for certification	Section 7.2
Application for Certification	Section 8
<input type="checkbox"/> Information on the procedure	Section 8.1
<input type="checkbox"/> The application	Section 8.2
Preparation for Evaluation	Section 9
<input type="checkbox"/> Maintain records	Section 9.1
<input type="checkbox"/> Prepare plan for evaluation activities	Section 9.2
<input type="checkbox"/> Assign evaluation personnel	Section 9.3
<input type="checkbox"/> Provision of working documents to personnel	Section 9.4
Evaluation	Section 10
<input type="checkbox"/> Evaluation	Section 10
Evaluation Report	Section 11
<input type="checkbox"/> Evaluation Report	Section 11
Decision on Certification	Section 12
<input type="checkbox"/> Decision on certification	Section 12.1
<input type="checkbox"/> Delegation of authority	Section 12.2
<input type="checkbox"/> Certification documents	Section 12.3
Surveillance	Section 13
<input type="checkbox"/> Documented surveillance procedures	Section 13.1



<input type="checkbox"/>	Product changes and modification updates	Section 13.2
<input type="checkbox"/>	Documentation of surveillance activities	Section 13.3
<input type="checkbox"/>	Periodic evaluation to confirm conformance of marked products	Section 13.4
Use of licenses, certificates and marks of conformity		Section 14
<input type="checkbox"/>	Control over ownership, use and display of licenses, certificates and marks of conformity	Section 14.1
<input type="checkbox"/>	Guidance on use of certificates and marks	Section 14.2
<input type="checkbox"/>	Action in response to misrepresentation of certification systems, licenses, certificates and marks	Section 14.3
Complaints to suppliers		Section 15
<input type="checkbox"/>	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: _____

²http://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	
<input type="checkbox"/>	Operate a certification program in accordance with ISO/IEC Guide 65:1996 and testing program in accordance with ISO/IEC 17025:2005.
<input type="checkbox"/>	Maintain an effective quality management system which addresses all requirements of ISO/IEC 17025:2005.
<input type="checkbox"/>	Attend all mandatory ONC training and program update sessions.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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: <ol style="list-style-type: none">(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.
<input type="checkbox"/>	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.
<input type="checkbox"/>	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: <ol style="list-style-type: none">(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.
<input type="checkbox"/>	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: _____

