SUPPORTING STATEMENT

Collection of Information under the Temporary Certification Program for Health Information Technology

> **Final** November 19, 2010

The Office of the National Coordinator for Health Information Technology

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Office of the National Coordinator for Health Information Technology (ONC) received emergency approval from the Office of Management and Budget (OMB) under section 3507(j) of the Paperwork Reduction Act (PRA) for this collection of information on June 14, 2010. This emergency approval expires on December 31, 2010. Accordingly, ONC now seeks OMB's approval for this collection of information under section 3504(h) of the PRA.

The Health Information Technology for Economic and Clinical Health (HITECH) Act, Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA) (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created "Title XXX – Health Information Technology and Quality" (Title XXX) to improve health care quality, safety, and efficiency through the promotion of health information technology (HIT) and electronic health information exchange.

Section 3001(c)(5) of the PHSA requires the National Coordinator for Health Information Technology ("the National Coordinator"), in consultation with the Director of the National Institute of Standards and Technology (NIST), to "keep or recognize a program or programs for the voluntary certification of health information technology as being in compliance with applicable certification criteria" adopted by the Secretary under section 3004. In a notice of proposed rulemaking implementing section 3001(c)(5), ONC proposed to establish two certification programs, a temporary certification program and a permanent certification program.

The temporary certification program requires applicants that wish to become ONC-Authorized Testing and Certification Bodies (ONC-ATCBs) to respond to and submit an application, collection and reporting requirements for ONC-ATCBs, and requirements for ONC-ATCBs to retain records of tests and certifications and disclose the final results of all completed tests and certifications (i.e., provide copies of all completed tests and certifications) to ONC at the conclusion of testing and certification activities under the temporary certification program.

a. Application for ONC-ATCB Status

The application process for the temporary certification program requires the completion of an application form, submission of additional documentation as specified in the application form, and completion of a proficiency examination. Part 1 of the application (application form and submission of additional documentation) is subject to the PRA. Part 2 of the application (proficiency examination) is not considered "information" for PRA collection purposes because it falls under the exception to the definition of information at 5 CFR 1320.3(h)(7).

b. Collection and Reporting Requirements

ONC will require ONC-ATCBs to provide ONC, no less frequently than weekly, a current list of Complete EHRs and/or EHR Modules that have been tested and certified as well as certain

minimum information about each certified Complete EHR and/or EHR Module. In particular, an ONC-ATCB must provide ONC 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 criteria adopted by the Secretary; and (7) Where applicable, the certification criterion or criteria to which each EHR Module has been tested and certified.

Compliance with this collection of information is a requirement for ONC-ATCBs to maintain good standing under the temporary certification program.

c. Records Retention and Disclosure to ONC

ONC will require ONC-ATCBs to retain records related to tests and certifications for the duration of the temporary certification program and provide copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.

2. Purpose and Use of Information Collection

a. Application for ONC-ATCB Status

The information collected through the application process will be used to assess the qualifications and abilities of applicants for ONC-ATCB status under the temporary certification program. ONC will utilize the contact information provided for an applicant's authorized representative to communicate and correspond with the applicant about the application. ONC will continue to utilize the authorized representative's contact information to communicate and correspond with the applicant becomes an ONC-ATCB.

If an applicant is granted ONC-ATCB status, ONC intends to post its name and the fact that it has been granted ONC-ATCB status on ONC's website.

b. Collection and Reporting Requirements

The information collected will be used to provide the public and the Centers for Medicare & Medicaid Services (CMS) with an aggregate list of certified Complete EHRs and EHR Modules.

c. Records Retention and Disclosure to ONC

The information collected may be used for assessing compliance with temporary certification program requirements.

3. Use of Improved Information Technology and Burden Reduction

a. Application for ONC-ATCB Status

The application process includes provisions that permit the use of electronic media for communication and correspondence. Applicants are permitted and encouraged to submit applications by e-mail to ONC and to communicate with ONC via e-mail. ONC also intends to conduct most of its communications related to the application process by e-mail. These communications will include identifying any deficiencies in the application, requesting clarifications and requesting additional information.

b. Collection and Reporting Requirements

ONC anticipates that ONC-ATCBs will electronically collect and store the requested information about Complete EHRs and EHR Modules. Additionally, ONC anticipates that the information will be electronically transmitted to ONC.

c. Records Retention and Disclosure to ONC

ONC anticipates that ONC-ATCBs will electronically collect and store testing and certification records, particularly the final results of all completed tests and certifications. Additionally, ONC anticipates that the information will be electronically transmitted to ONC.

4. Efforts to Identify Duplication and use of Similar Information

a. Application for ONC-ATCB Status

The collection of information for the application process will not be duplicative of any other information collections. In addition, ONC will subsume within the temporary certification program application process the Department of Health and Human Services' application process to "recognize certification bodies" (RCB) specified in guidance issued by ONC in August 2006 entitled "Interim Guidance Regarding the Recognition of Certification Bodies." This guidance currently specifies how ONC evaluates applications for "recognized certification body" status and provides the information a body would need to apply for and obtain such status. By including the RCB application process in the temporary certification program application process ONC will be creating efficiencies and eliminating any potential duplication.

b. Collection and Reporting Requirements

The collection of information is not duplicative of any other collection of information.

c. Records Retention and Disclosure to ONC

The collection of information is not duplicative of any other collection of information.

5. Impact on Small Businesses or Other Small Entities

All three collections of information under the temporary certification program require the same collection of information from any applicant that applies, regardless of the applicant's size. ONC believes that it has established the minimum amount of information collection requirements that are necessary for it to properly assess the qualifications and abilities of

applicants for ONC-ATCB status, to obtain the information necessary to achieve its goal of expeditiously notifying the public about certified Complete EHRs and EHR Modules so that eligible professionals and eligible hospitals can confidently and quickly adopt Certified EHR Technology, and to assess compliance with the temporary certification program requirements. In this regard, if some applicants for ONC-ATCB status or ONC-ATCBs themselves could be classified as small entities, ONC does not believe that any appropriate alternatives exist to lessen the information collection burden for these entities.

6. Consequences of Collecting the Information Less Frequently

a. Application for ONC-ATCB Status

An applicant will only need to apply once under ONC's temporary certification program.

b. Collection and Reporting Requirements

If ONC were to collect this information less frequently, then eligible professionals and eligible hospitals who seek to become meaningful users under CMS' Medicare and Medicaid EHR Incentive Programs may have difficulty determining what Complete EHRs and/or EHR Modules have been certified and are available for them to adopt. ONC's proposed weekly collection of information will ensure that information about certified Complete EHRs and EHR Modules is available to the public in a timely manner.

c. Records Retention and Disclosure to ONC

An ONC-ATCB will need to only respond once, at the conclusion of testing and certification activities under the temporary certification program, to ONC's request for copies of the final results of all completed tests and certifications under the temporary certification program.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

a. Application for ONC-ATCB Status

Applicants for ONC-ATCB status may submit information they identify or consider to be proprietary, a trade secret, or other confidential information. ONC will protect the information to the extent permitted by law.

b. Collection and Reporting Requirements

ONC is requiring that the information be provided on a weekly basis so that appropriate parties and entities are fully aware of what Complete EHRs and/or EHR Modules have been certified as soon as practical. This will require the information to be prepared in less than 30 days each time it is reported. However, as previously noted, ONC anticipates that the information will be collected, stored and transmitted electronically. The use of electronic media will substantially reduce the burden on the respondents and will allow them to readily meet the weekly reporting requirements. The collection of information is otherwise fully compliant with 5 CFR 1320.5.

c. Records Retention and Disclosure to ONC

ONC-ATCBs may submit records that identify proprietary information, trade secrets, or other confidential information. ONC will protect the information to the extent permitted by law.

8. Comments in Response to the Federal Register Notice/Outside Consultations

a. Application for ONC-ATCB Status

ONC sought comment on this collection of information in a 60-day Federal Register Notice that was published in the **Federal Register** on August 16, 2010, Vol. 75, No. 157, pages 49934-35. (*see* attachment). ONC did not receive any public comments.

Outside Consultations

ONC consulted with NIST in developing the application requirements.

b. Collection and Reporting Requirements

ONC sought comment on this collection of information in a 60-day Federal Register Notice that was published in the **Federal Register** on August 16, 2010, Vol. 75, No. 157, pages 49934-35. (*see* attachment). ONC did not receive any public comments.

c. Records Retention and Disclosure to ONC

ONC sought comment on this collection of information in a 60-day Federal Register Notice that was published in the **Federal Register** on August 16, 2010, Vol. 75, No. 157, pages 49934-35. (*see* attachment). ONC did not receive any public comments.

Outside Consultations

ONC consulted with NIST in determining the industry standard for records retention and in determining the burden for providing copies of the final results of all completed tests and certifications at the at the conclusion of testing and certification activities under the temporary certification program.

9. Explanation of any Payment/Gift to Respondents

a. Application for ONC-ATCB Status

Applicants for ONC-ATCB status (respondents) will not receive any payments or gifts for applying.

b. Collection and Reporting Requirements

ONC-ATCBs will not receive any payments or gifts for collecting and reporting information on certified Complete EHRs and/or EHR Modules. Compliance with this collection of information is a requirement for maintaining good standing under the temporary certification program.

c. Records Retention and Disclosure to ONC

ONC-ATCBs will not receive any payments or gifts for providing copies of the final results of all completed tests and certifications to ONC at the conclusion of testing and certification activities under the temporary certification program.

10. Assurance of Confidentiality Provided to Respondents

ONC will protect the information to the extent permitted by law.

11. Justification for Sensitive Questions

This collection of information does not require the disclosure of any sensitive information.

12A. Estimated Annualized Burden Hours

a. Application for ONC-ATCB Status

Under the temporary certification program, an applicant who voluntarily applies to become an ONC-ATCB will be required to submit an application to the National Coordinator. ONC anticipates that there may be up to five applicants for ONC-ATCB status. ONC assumes that approximately 3 applicants for ONC-ATCB status will already be conformant with ISO/IEC Guide 65:1996 (Guide 65) and ISO/IEC 17025:2005 (ISO 17025) and will have "in hand" the documentation requested as part of the ONC-ATCB application ("conformant applicants"). ONC believes that, at most, two potential applicants may need to perform more upfront work than "conformant applicants" to prepare to apply for ONC-ATCB status. These two applicants are referred to as "partially conformant applicants" for the purposes of distinguishing them from "conformant applicants" in estimating the relevant application burden.

As to Part 1 of the application (which is the subject of this collection of information), ONC estimates that it will take approximately 10 minutes for a "conformant applicant" to provide the general identifying information requested in the application, 2 hours to complete the self audit to Guide 65 and assemble associated documentation, 2 hours to complete the self audit to ISO 17025 and assemble associated documentation, and 20 minutes to review and agree to adhere to the "Principles of Proper Conduct for ONC-ATCBs."

ONC estimates that a "partially conformant applicant" will need the same amount of time as a "conformant applicant" to provide the general identifying information requested in the application (i.e., 10 minutes) and the same amount of time to review and agree to the "Principles of Proper Conduct for ONC-ATCBs" (i.e., 20 minutes). ONC estimates, however, that a "partially conformant applicant" will need up to a maximum of 400 hours to complete the self audits to Guide 65 and ISO 17025. ONC has equally distributed the estimated 400 burden hours between the self audits to Guide 65 and ISO 17025 (i.e., 200 hours for each self audit).

ONC's burden estimates for both types of applicants are expressed in the table below.

Estimated Annualized Burden Hours

Type Form	Number	Number of	Burden Hours	Total
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of Respondent	Name	of Respondents	Responses per Respondent	per Response	Burden Hours
Conformant Applicant	ONC-ATCB Application	3	1	4.5	13.5
Partially Conformant Applicant	ONC-ATCB Application	2	1	400.5	801
Total					814.5

b. Collection and Reporting Requirements

For the purposes of estimating the potential burden, ONC assumes that all of the estimated number of applicants for the temporary certification program (i.e., five) will become ONC-ATCBs. ONC also assumes, per the requirement for no less frequently than weekly reporting, that ONC-ATCBs will report weekly (i.e., respondents will respond 52 times per year). Finally, ONC assumes that the information collection will be accomplished through electronic data collection and storage and that such collection and storage will be part of an ONC-ATCB's normal course of business. Therefore, with respect to the collection of information, the estimated burden is limited to the actual electronic reporting of the requested information to ONC. ONC's estimates are expressed in the table below.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
ONC-ATCB Testing and Certification	5	52	1	260
Results				

c. Records Retention and Disclosure to ONC

At the conclusion of testing and certification activities under the temporary certification program, each ONC-ATCB will be required to submit one copy of the final results of every completed test and certification performed under the temporary certification program. For the purposes of estimating the potential burden, ONC assumes that all of the estimated number of applicants for the temporary certification program (i.e., five) will become ONC-ATCBs. For calculation purposes, ONC also assumes that each ONC-ATCB will incur the same burden. ONC assumes that, on average, each ONC-ATCB will test and certify an equal amount of ONC's estimate of the maximum amount of Complete EHRs and EHR Modules that will be tested and certified under the temporary certification program. ONC estimated that a maximum 1,207 Complete EHRs and EHR Modules would be tested and certified to the certification criteria adopted by the Secretary and that 85% of the total number of Complete EHRs and EHR Modules would be tested and certified under the temporary certification program. Therefore, ONC estimates the equal amount of Complete EHRs and/or EHR Modules that will be tested and certified by each of the 5 estimated ONC-ATCBs to be approximately 205. Finally, ONC

assumes that either the information collection would be accomplished through an ONC-ATCB's electronic transmission of the final results of all completed tests and certifications or by sending paper photocopies of the final results of all completed tests and certifications to ONC. In either instance, ONC believes that an ONC-ATCB will spend a similar amount of time and effort in organizing, categorizing, and submitting the requested information. ONC estimates that this amount of time will be approximately 8 hours for each ONC-ATCB. ONC's estimates are expressed in the table below.

Estimated Annualized Burden Hours

Type of Respondent	Number of Respondents	Number of Responses per Respondent	Average Burden Hours per Response	Total Burden Hours
ONC-ATCB Testing and Certification Records	5	1	8	40

12B. Estimated Annualized Respondent Costs

a. Application for ONC-ATCB Status

Based on ONC assumptions and consultations with NIST, ONC believes that an employee equivalent to the Federal Salary Classification of GS-9 Step 1 can provide the general information requested in the application and accomplish the paperwork duties associated with the application and that an employee equivalent to the Federal Salary Classification of GS-15 Step 1 will be responsible for conducting the self audits and agreeing to the "Principles of Proper Conduct for ONC-ATCBs." ONC has taken these employee assumptions and utilized the corresponding employee hourly rates for the locality pay area of Washington, D.C., as published by the U.S. Office of Personnel Management, to calculate the cost estimates. ONC has also calculated the costs of an employee's benefits while completing the application. ONC has calculated these costs by assuming that an applicant expends thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. ONC has concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by the Department of Health and Human Services (HHS) for contract cost estimates.

In the table below, ONC's "Hourly Wage Rate with Benefits" for each type of respondent constitutes an hourly wage with benefits based on the average time commitment for an employee equivalent to the GS-9 Step 1 level to complete the general identifying information part of the application and the time commitment for an employee equivalent to the GS-15 Step 1 level to complete the self audits and the agreement to adhere to the Principles of Proper Conduct for ONC-ATCBs. The "Hourly Wage Rate with Benefits" differs between the type of respondent because of the different levels of commitment between employees and the average of their wages. Specifically, an employee equivalent to the GS-15 Step 1 level will commit only 4.33 hours for a "conformant applicant," while that same employee will commit 400.33 hours for a "partially conformant applicant." This disparity leads to the different "Hourly Wage Rate with Benefits" for each type of respondent when averaged with the time commitment of an employee equivalent to the GS-9 Step 1 level, which is approximately .17 hours for both "conformant

applicants" and "partially conformant applicants." ONC's estimated costs for applicants are expressed in the table below.

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Total Applicant Costs
Conformant Applicant	13.5	\$78.79	\$1,063.65
Partially Conformant Applicant	801	\$80.63	\$64,584.63
Application Totals			\$65,648.28

ONC based its cost estimates on the amount of applicants that ONC believes will apply over the life of the temporary certification program. ONC assumes that all applicants will apply during the first year of the program and thus all application costs should be attributed to the first year of the program.

b. Collection and Reporting Requirements

As previously stated, ONC anticipates requiring the reporting of this information on a weekly basis and that it will take ONC-ATCBs about an hour to prepare and electronically transmit the information to ONC each week (i.e., respondents will respond 52 times per year).

ONC believes that an employee equivalent to the Federal Classification of GS-9 Step 1 can complete the transmissions of the requested information to ONC. ONC has taken this employee assumption and utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by the U.S. Office of Personnel Management, to calculate the cost estimates. ONC has also calculated the costs of the employee's benefits while completing the transmissions of the requested information. ONC has calculated these costs by assuming that an ONC-ATCB will expend thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. ONC has concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. ONC's estimated cost for weekly reporting by ONC-ATCBs is expressed in the table below.

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Total Reporting Costs
ONC-ATCB Testing and Certification Results	260	\$30.45	\$7,917.00

c. Records Retention and Disclosure to ONC

Based on ONC assumptions and consultations with NIST, ONC believes that an employee equivalent to the Federal Classification of GS-9 Step 1 can organize, categorize, and submit the

final results of all completed tests and certifications either by electronic transmission or through paper submission of photocopies to ONC. ONC has taken this employee assumption and utilized the corresponding employee hourly rate for the locality pay area of Washington, D.C., as published by the U.S. Office of Personnel Management, to calculate the cost estimates. ONC has also calculated the costs of the employee's benefits while organizing, categorizing, and submitting the final results. ONC has calculated these costs by assuming that an ONC-ATCB will expend thirty-six percent (36%) of an employee's hourly wage on benefits for the employee. ONC has concluded that a 36% expenditure on benefits is an appropriate estimate because it is the routine percentage used by HHS for contract cost estimates. ONC's estimated cost for ONC-ATCBs to provide copies of test results and certifications is expressed in the table below.

Type of Respondent	Total Burden Hours	Hourly Wage Rate with Benefits	Total Reporting Costs
ONC-ATCB Testing and Certification Records	40	\$30.45	\$1,218.00

13. Estimates of Other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

a. Application for ONC-ATCB Status

There are no capital costs associated with this collection of information.

b. Collection and Reporting Requirements

ONC does not believe that there are any specific recordkeeping or capital costs associated with this collection of information. ONC-ATCBs will need to maintain databases that collect and store the information ONC is requesting that they report, but maintaining databases that collect and store the requested information as well as collecting and storing the information is part of the normal course of business for such entities. ONC understands from its consultations with NIST that it is standard industry practice to maintain such information related to testing and certification. Therefore, ONC believes that the only costs attributable to this collection of information are those associated with the electronic transmission of the information to ONC, which ONC has accounted for in the estimated annualized burden costs.

c. Records Retention and Disclosure to ONC

ONC does not believe that there are any specific recordkeeping or capital costs associated with this collection of information. ONC-ATCBs will need to maintain databases that collect and store the information ONC is requesting that they report, but maintaining databases that collect and store the requested information as well as collecting and storing the information is part of the normal course of business for such entities. ONC understands from its consultations with NIST that it is standard industry practice to maintain final results of testing and certification that is performed. Therefore, ONC believes that the only costs attributable to this collection of information are those associated with the submission of copies of the final results of all completed tests and certifications, which ONC has accounted for in the estimated annualized burden costs.

14. Annualized Cost to Federal Government

a. Application for ONC-ATCB Status

ONC has estimated the cost to develop Part 1 of the ONC-ATCB application to be \$1,399 based on the 20 hours it took for a Federal Salary Classification GS-14 Step 1 employee located in Washington, D.C. to perform the task. ONC anticipates that there will be costs associated with reviewing applications under the temporary certification program. ONC believes that a GS-15 Step 1 employee will review the applications and the National Coordinator (or designated representative) will issue final decisions on all applications. ONC anticipates that it will take approximately 16 hours to review and reach a decision on Part 1 of each application. This estimate assumes a satisfactory Part 1 application (i.e., no formal deficiency notifications) and includes the time necessary to verify the information provided in Part 1 of the application. ONC estimates the cost for the review of Part 1 of each application to be \$4,056. As a result, ONC estimates the Federal government's overall cost for reviewing Part 1 of the application based on 5 total applicants to be approximately \$20,280. ONC assumes that all applicants will apply during the first year of the program and thus all application review costs should be attributed to the first year of the program.

As previously noted, ONC will also post the names of applicants granted ONC-ATCB status on ONC's website. ONC believes that there will be minimal cost associated with this action and has calculated the potential cost to be approximately \$156 on an annual basis for posting and maintaining the information on ONC's website. This estimate is based on a maximum of 3 hours of work for a Federal Salary Classification GS-12 Step 1 employee located in Washington, D.C.

b. Collection and Reporting Requirements

ONC will use the reported information to post an aggregate list of certified Complete EHRs and EHR Modules on its website. ONC believes that there will be minimal cost associated with this action. ONC has calculated the potential cost, including weekly updates, to be \$5,392 on an annualized basis. This amount is based on 104 hours of yearly work of a Federal Salary Classification GS-12 Step 1 employee located in Washington, D.C.

c. Records Retention and Disclosure to ONC

ONC will simply be receiving copies of the final results of all completed tests and certifications as part of this collection of information. Therefore, ONC believes its costs will be negligible.

Overall Annual Costs

ONC estimates that the annual Federal government cost for the ONC-ACB application process, posting an aggregated list of Certified EHRs and EHR Modules, and receiving copies of the final results of all completed tests and certifications to be \$27,227.

15. Explanation for Program Changes or Adjustments

This is a new collection of information.

16. Plans for Tabulation and Publication and Project Time Schedule

a. Application for ONC-ATCB Status

ONC will publish on its website the names of those applicants that are granted ONC-ATCB status and their associated authorization for the purpose of public notification.

The temporary certification program will sunset on December 31, 2011, or if the permanent certification program is not fully constituted at that time, then upon a subsequent date that is determined to be appropriate by the National Coordinator. Therefore, ONC will no longer accept applications and collect information under the temporary certification program once the temporary certification program ceases to exist.

b. Collection and Reporting Requirements

ONC will publish all reported certified Complete EHRs and EHR Modules on its website and maintain the information on its website consistent with the specifications of the certification programs.

c. Records Retention and Disclosure to ONC

ONC may tabulate and analyze the final results of all completed tests and certifications under the temporary certification program, but ONC does not anticipate that it will publish such analyses. As previously stated, the information collected may be used for assessing compliance with temporary certification program requirements.

17. Reason Display of OMB Expiration Date is Inappropriate

ONC does not seek this exception. The OMB expiration date may be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

B. Collection of Information Employing Statistical Methods

Not applicable. The collection of information required above in part A does not require nor lends itself to the application of statistical methods.