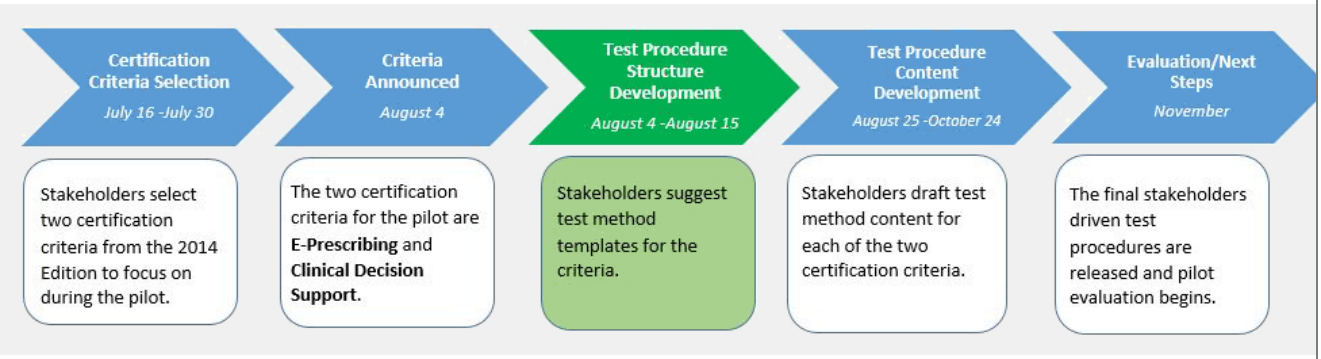
Open Test Method Development - Template Design

Open Test Method Development Pilot Program

ONC's *Open Test Method Development Pilot Program* builds on our continued commitment to collaborate with health IT stakeholders and to enhance stakeholder engagement in ONC's Health IT Certification Program. This pilot program is open to all stakeholders willing to contribute their expertise towards the development of the test methods that could ultimately be used by accredited testing laboratories (ATLs) for health IT testing. This pilot program is designed to provide stakeholders with an expanded opportunity to apply their in-the-field experience to test method development (including test procedures, test data, and test tools) to support improvements to the nation's health care system.

The pilot program will be limited to two 2014 Edition EHR certification criteria and, at its conclusion, will be evaluated for feasibility, efficiency, and scalability relative to future certification criteria editions.

The pilot program will follow the process below and aims to complete the development of two test methods by October 31, 2014



If you have questions about the Open Test Development Pilot Program Email Us

Existing Test Method Template (Unit-based)

This template is provided as a starter template. If you have feedback for this template, please provide it below.

Test Procedure for §170. 314(_)(#) Name of Criterion

This introductory section is identical in all 2014 Edition Test Procedures. It describes the purpose of the document and cites relevant regulatory policy and stakeholders. This is typically boilerplate content, but may require changes in the future as policy and the ONC certification program evolve.

CERTIFICATION CRITERIA

The first paragraph of this section cites the ONC Certification Criteria for EHR Technology, 2014 Edition Final Rule and is standard across all Test Procedures. The second paragraph then quotes verbatim from the 2014 Edition Final Rule. The third and final paragraph explains whether the Criterion is new, revised, or unchanged from the 2011 Edition. See existing Test Procedures for standard language corresponding to each of the three aforementioned options.

Guidelines

1. It is acceptable to contribute to only a portion of this test method, e.g. only the test data.
2. The test method should meet only the requirements of the Final Rule (45 CFR Part 170, September 4, 2012) for the certification criteria. Conversely, no requirements should be added.
3. The test procedure should align with the test data and vice versa.
4. There may or may not be a need for a conformance tool for the test method.
5. Referenced standards are called out by the Final Rule and cannot be ignored or changed.
6. Concentrate on the "what" and not the "how." That is, do not try to lead the tester through the process in a step-by-step or prescriptive manner.
7. Do not tie the test method to a particular clinical practice workflow. (Note: If you are proposing a test scenario involving multiple unit tests, then clinical practice workflow must be described. However, do not make the workflow overly specific, thereby making it plausible in only a very restricted and prescribed environment.)
8. Provide enough detail so that a determination of pass /fail can be made. That is, make a clear statement of the expected outcome for each step (or group of steps).

2014 EDITION PREAMBLE LANGUAGE

This section contains a list of selected statements from the 2014 Edition Preamble that support decisions made in the development of the Test Procedure, particularly with respect to interpretation of the relevant Criterion. If applicable, some Test Procedures include statements from the 2011 Edition Preamble as well if it provides relevant historical context.

INFORMATIVE TEST DESCRIPTION

This section provides an informative description of how the Test Procedure is organized and conducted. "Normative" statements, step-by-step instructions for meeting certification requirements, are included in a later section. The Informative Test Description may address such items as ONC or vendor-supplied test data, noteworthy standards, and differences in testing between ambulatory and inpatient settings. Diagrams or other visual aids are also appropriate in this section. All content must be based on the precise language of the Certification Criterion and relevant preamble language in the 2014 Edition Final Rule. See existing Test Procedures for examples. This section provides an informative description of how the test procedure is organized and conducted. It is not intended to provide normative statements of the certification requirements.

REFERENCED STANDARDS

In this section, referenced standards from the Certification Criterion should be listed and organized by their respective regulatory numbers (i.e., §170.205). See existing Test Procedures for examples. The following formatting rules should be applied:

- Each regulatory number for a standard should have its own table.
- Tables should be organized in ascending order (i.e., §170.205, §170.207, §170. 209).
- Rows within tables should be organized in alphabetical, ascending order (i.e., (a)(3), (a)(5), (b)(2)).

§170.XXX [Insert title of standard 1]	Regulat
Insert introductory language to the standard if available. This is found directly after the standard's title in the Final Rule and typically starts with "The Secretary adopts…"	
[Insert description of referenced standard directly as written in the Final Rule, starting with the certification criterion letter/number (i. e., (a)(3)), all the way to the period.]	If a regulatory stand standard to the lef If this is not applicab
Insert each additional standard in its own row, following the same format.	

Definitions

Derived Test Requirements - describes a specific portion of the certification criterion which will be addressed in the test procedure. To provide traceability, each is denoted using the following form: DTR [FR certification criterion number] – [Sequence number]

Required Vendor Information - describes the information needed from the Vendor in order to perform the test procedure. To provide traceability, each is denoted using the following form: VE [FR certification criterion number] – [Sequence number]

Required Test Procedure – describes the test activities required to be performed by the Tester. To provide traceability, each is denoted using the following form: TE [FR certification criterion number] – [Sequence number]

Inspection Guide – provides additional guidance to the Tester on how to evaluate conformance to the certification criterion. To provide traceability, each is denoted using the following form: IN [FR certification criterion number] – [Sequence number]

Test Story – an English language description of a clinical situation that gives context to the test data. It can describe the patient-physician interactions or the physician-lab interactions, for instance. They may be very simple and short or long and complex.

NORMATIVE TEST PROCEDURES – [IDENTIFY AMBULATORY /INPATIENT SETTING (IF APPLICABLE)]

The Normative Test Procedure outlines the test steps that will be performed by the Vendor and Tester to demonstrate compliance with the certification criterion. This portion of the Test Procedure builds off of the Informative Test Description. The purpose of this section is to evaluate whether the EHR possesses the technical capabilities to comply with the certification criterion. As this is often the longest, most complex portion of a Test Procedure, Test Procedure authors should review existing Test Procedures to gain a better understanding of tone, level of detail, formatting, and organization.

Notes :

- 170. **XXX** corresponds to the regulatory number assigned to the Final Rule (i.e., §170. **314** , §170. **315**)
- The certification criterion letter and number are assigned in the Final Rule
- The total number of DTR sections should align with the number of sections outlined in the Informative Test Description (ITD)
- The title of each DTR section should slightly expand upon the high level sections outlined in the ITD
- The Normative Test Procedure can be organized by Ambulatory and Inpatient Settings, only if the certification criterion is different in each setting. A certification criterion that is the same for both care settings will only have one Normative Test Procedure section.

TEST DATA

This section contains introductory language about test data. Describe whether the Test Data is ONC or Vendor supplied, and describe the scope of the test data. See existing Test Procedures for examples.

CONFORMANCE TEST TOOLS

The National Institute of Standards & Technology (NIST) and ONC have developed a number of conformance test tools supporting certification testing for certain criteria. Test tools may be submitted by individuals and organizations for ONC approval for use in certification testing. If applicable, relevant test tools should be described in this section. Descriptions for each individual test tool are largely identical between Test Procedures, but some variation may exist. See existing Test Procedures for examples.

Suggest a Template

If you would like to suggest a template, please keep in mind that a template could be used for a large number of criteria and unit or scenario based testing. While ONC recognizes that this program may result in two different templates for two different criteria, it encourages the industry to suggest one template that could address both. The existing template above is meant to serve as a starting point. Suggested templates will be posted and made available for feedback as they are received and reviewed.

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8/12/14 Work Group	**Overall goal**: Aim for one template and add sections or mark sections as "non-applicable" as appropriate for specific criteria, with the understanding that this template may adapt during full content build.
	
	Work Group Feedback:
	
	• Currently, there are multiple sections with the same information that may make the procedures confusing. Should consolidate the info and move the test narrative to the top, so that people can get right to what they need to do.
	• Build a flexible template model that fits with all of the criteria and potential test methods, but isn't too complex.
	• Don't remove content from the existing template, just think about restructuring it so that:
	  ◦ More of what needs to be DONE is at the beginning
	  ◦ Descriptions/additional information is at the end
	  ◦ Update the Standards section so that as standards get revised, there is clear documentation of versioning (i.e. list the 2011 standards and effective dates, the 2014, etc.)
	  ◦ Consider adding the following sections to the existing template:
	  ▪ Special considerations/potential "curveballs"
	  ▪ Technical requirements
	  ▪ Dependencies on other test criteria
	  ▪ Attestation (as a test method)
	  ▪ Consider clarifying how the system is meant to be used vs. how it is used within the test method or in the reporting of test results.

8/15/2014 Feedback	First off, we wanted to mention that the test method template itself hasn't been problematic for us in the past; it's the content within the template that's been the most problematic. We look forward to giving feedback as the group adapts the ePrescribing and clinical decision support measures to the new template. Similar to the feedback on the template given by the work group on 8/12, we agree that the template could be consolidated. Certain sections of the template are duplicative. For example, the testing tools being used for a given test are described in the informative test description and again in the testing tools section. We'd like to see the testing tools be included as a sub-point in the informative test description section to consolidate the document. The template also contains extraneous info that applies to all templates such as "This introductory section is identical in all 2014 Edition Test Procedures. It describes the purpose of the document and cites relevant regulatory policy and stakeholders". Since this is on every template, we get used to seeing it and skip over it. Could these sections be moved to a central document that applies to all test procedures to make the test procedure documents themselves more concise? We've found the certification criteria, preamble language and informative test description sections to be the most helpful. The certification criteria and preamble language minimize the cross-referencing we need to do between documents and the informative test procedure gives us an overview of the test before getting into the details. The referenced standards section is also helpful and necessary to keep everyone on the same page, but we would suggest moving it to the end of the document so that it doesn't break up the flow between "general description of test" and the detailed "test procedure".

8/15/2014 Feedback	General Feedback for Test Procedure Template: • Set the expectation at the beginning of the document that readers should familiarize themselves with the final certification criteria edition rule as prerequisite knowledge to content contained in the test procedure. • Content within the test procedure template should be reflective of true test procedures rather than replication of content contained in the final rule. For reference to final rule citations, we suggest including links to the regulatory section of the rule possibly in a parsed out version of the final rule rather than re-inclusion of only sections of the regulatory text that may risk being out of context to the whole of the preamble and regulation found in the final rule. • Consider use of a tabular format rather than a narrative one for presenting the test procedure similar to what ATLs have provided vendors. Each section of the test procedure as appropriate for each step should contain interpretive guidance, regulatory citations, and links to conformance testing tools so that content is presented in context to the testing step. The following link provides an example from ICSA:https://icsalabs.s3.amazonaws.com/downloads/2014%20Edition%20Test%20Script.docx • The information within each section of the template should contain only what is consistent with the description of the section as stated in order to be consumed effectively. • Content within the respective ONC test procedures should be evaluated to consider whether given information could be cross-referenced in the respective CMS Technical Specification Sheets for the related meaningful use objectives. For example, content within the Informative Test Description contains information that would be helpful in the Certification and Standards Criteria section of respective Technical Specification Sheet. Testing information can always provide insight into requirements for the design of software. Preamble Language Section Feedback: • Replication of content from the final rule is not necessary. We propose either summarizing key points in a bulleted format or referencing the final rule via hyperlink. Informative Test Procedure Section Feedback: • The audience of this document should be mentioned as both vendors and testing bodies. o If this section is intended to provide guidance and clarity to ATLs regarding testing latitude, we suggest either relabeling this section or creating a distinct section summarizing testing expectations. Consideration should be taken to clarify the audience of content should it be distinct to either tester or vendor expectations. • Content should be organized in sequence of major context; thus, organized in sections of how a test script would be organized, yet not to the detailed level of test steps. o For all sections, links should be provided to reference relevant content within the final rule. Requirements should also be anchored to the respective sections of all test procedures. • It would be helpful to understand how content in this section is fully vetted to assure it fulfills the regulatory intent without exceeding it. o For example, the 2014 test procedure for 170.314(c)(1)-(3) originally indicated only a complete EHR model of certification and testing could include testing to all three of the clinical quality measure criteria which was incorrect and not substantiated by the 2014 criteria edition final rule. • This section would be more user-friendly if formatted in a tabular fashion similar to test scripts formatted by ATLs. • Testing expectations should be written explicitly to the degree possible in order to leave little room for interpretation or negotiation between vendors and ATLs to debate regulatory intent or acceptable testing approaches. We encourage further guidance in this section so there is less debate between vendors and ATLs to address fewer matters of interpretation. o For example, in the test procedure for 170.314(a)(8), it was not entirely clear from the informative test procedure section if it would be permissible to show one user undertaking an action that would cause a CDS intervention to occur that may be directed to a second user or if both triggering action and response had to be interactive to the same user • Maintain a section including the changes from the previous rule to the current rule, but be more detailed in the description. We would request a more detailed section, perhaps including a table that includes one column with text from the previous rule with the second column containing content from the current rule.
8/15/2014 Feedback	One of the most useful tools I have found in developing and building testing scenarios is the use of flow diagrams - technical and, this case, clinical. It is extremely helpful for everyone to have a visualization of the different people, technology, and processes involved. It helps determine at what point the testing failed and how the workflows were modified, through refinements visualization and iterative illustrations, to determine the proper path or to exhibit where potential may, or actual failure did, occur.

8/15/2014 Feedback	Limit the amount of historical MU criterion information. Focus on the specific goal of the MU criterion as it appears in the respective cycle/stage (MU 2014) being tested towards. It clutters the space and confuses the reader.

Suggested Templates:

Suggested Test Method Template 8-13-2014

Test Procedure for §170. 314(_)(#) Name of Criterion

This introductory section is identical in all 2014 Edition Test Procedures. It describes the purpose of the document and cites relevant regulatory policy and stakeholders. This is typically boilerplate content, but may require changes in the future as policy and the ONC certification program evolve.

Dependency Requirements

Include information related to additional requirements such as automated measure reporting or safety enhanced design.

Test Data

This section contains introductory language about test data. Describe whether the Test Data is ONC or Vendor supplied, and describe the scope of the test data.

Scenario Testing

This section would include product testing such as entering medications. The data should be designed so that the number of patients used and data entered helps to build historic data for other criteria, if applied for certification. To help cut down on confusion, recommend outlining a testing order. For modular products, where vendors are not applying for criteria that helps to build the test data, vendors could preload some data prior to the test. However keep this very simple. The derived test requirement sections should not contain repetitive content, for example vendor information (VE), test procedure (TE), and inspection test guide (IN) all repeat the requirements; however, sometime also contain additional requirements, which is confusing. Also, would remove or be careful how the terms vendor, tester, and proctor are used since they are not currently consistent. It may be best to take a step back and not be as prescriptive related to who performs which actions, and focus more on the system functionality that is validated against the requirements. Also recommend that when creating the content, be careful about how the requirements for certification are outlined versus meeting meaningful use to help educate vendors, providers, and hospitals. There is a difference between the two, and this is currently a big gap.

Conformance Test Tools and System Requirement Testing

Validation of files and attestation (vendor supplied documentation) such as the standards used, QMS, hashing information, etc. We need make the testing /certification process more streamline and way more efficient, one of the main complains related to the 2014 edition criteria so hopefully we could use this section to improve the process.

REFERENCED STANDARDS

There may be a better format for how the standards are listed in the table. Also would be great if we could come up with a way to keep the standards up to date with current innovation, but keep a log of the evolution of the changes, to help the providers/hospitals understand updates and timeframe of the updates (and not in the document history).

Special Considerations

Contain notes related to third-party vendors used during testing and clarifications related to testing.

INFORMATIVE TEST DESCRIPTION

Same as the current template.

2014 EDITION PREAMBLE LANGUAGE

Potentially condense or insert hyperlinks to the preamble language.

CERTIFICATION CRITERIA

Put this section at the end and condense or insert hyperlinks to the rule.

CHANGES FROM 2011 TO 2014 EDITION

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Feedback

8/14/2014 Feedback	I believe this template for a scenario based testing method is more desirable than the template for unit based testing method. It should permit EHR technology vendors to demonstrate compliance with the certification criteria in a way that more closely resembles a typical workflow in a clinical setting. One of the more significant challenges we have faced in delivering 2014 CEHRT to our clients has been to adapt the methodology used to achieve certification into workflows that meet the needs of our clients. It is one thing to demonstrate an EHR technology's capability to meet a specific certification criterion as the unit based testing method requires. It is quite another to do so with comprehensive clinical workflows appropriate to the setting and applicable to the certification criteria. Our clients routinely seek our guidance on how to best implement our CEHRT to meet their meaningful use objectives and often want to follow the exact methods we followed to achieve certification, only to find that while the unit based testing method verified our capability, it did not always do so in a context meaningful to clinical workflows they could implement. Unit-based testing, by design, does not foster the holistic approach to developing meaningful clinical workflow design for use in certification testing. Scenario based testing should permit this and should help speed delivery of workable certified solutions to our clients.
8/15/2014 Feedback	We have a few concerns with the newly proposed scenario-based template. While scenario-based testing is capable of certifying you in multiple criteria at once, we anticipate difficulties surrounding vendors who aren't certifying on all criteria. The number of potential combinations of certification criteria and how they could interact with each scenario could be difficult to account for. We also believe that test data is more straightforward when it's linked to a specific criterion and would therefore suggest sticking with the criteria-based template to allow vendors greater flexibly in the criteria they certify on and to avoid introducing additional complexity.