

**Implementation, Certification and Testing (ICT) Workgroup**

**Certification NPRM Comment Template – Group 2**

**Proposed 2015 Edition Electronic Health Record (EHR) Certification Criteria, 2015 Edition Base EHR Definition, and ONC Health IT Certification Program Modifications**

| [**Base EHR Definitions**](http://www.federalregister.gov/a/2015-06612/p-102) **p.240** | |
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| **Preamble FR Citation**: 80 FR 16870 | **Specific questions in preamble?** *No* |
| Public Comment Field:  We have the following comments relative to the Base EHR concept as proposed by ONC in the 2015 Criteria Edition NPRM.   1. We recommend that the security criteria 170.315(d)(1)-(8) be included explicitly in the base EHR scope. We are concerned that their removal could cause confusion, and in fact they are collectively required by other criteria included in the Base EHR proposed definition anyway. Their inclusion should not cause any issue for ONC’s proposal for how security criteria are to be certified on a modular basis. 2. We believe that it is premature to propose that the UDI and the Implantable Device List be included in the Base EHR definition. We offer the following observations:    1. The current state of the market is that implantable device information is most often recorded in surgical perioperative documentation or in other systems and not directly first recorded within direct patient care EHR systems and so may not be available to CEHRT at least for the kinds of products typically thought of as CEHRT.    2. The current level of adoption for communicating UDI/Implantable Device information from a source surgical or other system to a direct patient care EHR as the kind of structured data contemplated by the proposed criteria for UDI and for implantable device information in the CCDA is not sufficient to make this information available without redundant transcription of the information into CEHRT.    3. The ability to make use of manually transcribed data for supporting other requirements such as invoking a GUDID service to obtain device description information needed for inclusion in a CCDA document is problematic at best without specific guidance for how the device data is to be captured in CEHRT. Current standards focus on the UDI string and not the parsing of the data which can require more look ups than is necessary to obtain this information.    4. While not a part of the certification criterion per se, the issue of what to do about historic data about device information that is still current but may be maintained in unstructured forms is not addressed by ONC’s or CMS’s proposals yet compounds the availability of data for inclusion in the CCDA in the form that is anticipated.    5. We believe that the purpose would be better served for ONC to focus on supporting reference implementations and pilots for proving out the use cases for enabling application to application interoperability for providing UDI information from source system to CEHRT and/or for its capture natively in CEHRT before including it in the Base EHR definition. 3. We support the inclusion of application access to the Common Clinical Data Set as being a part of the Base EHR for the provider to provider use case. We do not believe that ONC should define any prescriptive requirements for the architecture or deployment of the application access for support of provider access to the CCDS. We do encourage ONC to support assurance that strong privacy and security features are included in the access requirements to assure that the identity of the individual or entity requesting the data is adequately authenticated and trusted.    1. We have concerns with the inclusion of the application access to the CCDS in the consumer use case for the purpose of View, Download and Transmit as a Base EHR requirement. It should at most be an optional capability. We are concerned that despite ONC’s intent to enable consumer abilities to have access to their data for purpose of consolidation to something they would manage and control agnostic to or beyond the provider setting, providers still will be in the mode of behavior of presuming they all need to enable consumers to use the provider’s consumer portal or PHR as the point of consolidation which only pushes the current state of the market from one of everyone offering a consumer portal to everyone offering APIs to receive data. The result may be that providers place far more emphasis on enabling requesting of data than making it available to consumers beyond the borders of any given provider’s own consumer access. It is likely that patients would look to their provider’s office staff for any issues related to APIs running on the patient portal leading to disruption of workflow, increased calls, complaints, and dissatisfaction.    2. We recommend that some of the data elements proposed for the Common Clinical Data Set not be required as they are not collected by all manners of providers depending on their practice specialty. These include       1. O2 Saturation measured by pulse oximetry       2. ABGs       3. The UDI 4. We recommend that 170.315(a)(4) – Drug-Drug/Drug-Allergy interaction checking for CPOE be included in the Base EHR definition as it is specifically for CPOE which is already a part of base EHR. 5. We support the proposal of having 170.315(h)(2) as an equivalent alternative means to 170.315(h)(1) as it enables HISP portability or modularity for pairing with any given source EHR without mandating a coupling of the two, but we are concerned there will be several effects    1. There will be more HISPs required to adopt all the protocols    2. HISP portability will only work if       1. The HISP is aware of the transport capabilities of sending and receiving EHRs       2. The HISP acts to accommodate those capabilities       3. Sender or receiver EHRs act to support transport protocols beyond what they certify to if they only certify to one 6. Otherwise we support the Base EHR concept as proposed. | |
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| [**Retesting and Certification**](http://www.federalregister.gov/a/2015-06612/p-919) **p. 197** |
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| We believe that ONC-ACB determinations related to the ongoing applicability of the SED certification criterion to certified health IT for the purposes of inherited certified status (§ 170.550(h)), adaptations and other updates would be based on the extent of changes to user-interface aspects of one or more capabilities to which UCD had previously been applied. We believe that ONC-ACBs should be notified when applicable changes to user-interface aspects occur. Therefore, we include these types of changes in our proposal to address adaptations and updates under the ONC-ACB Principles of Proper Conduct (§ 170.523). Please see section IV.D.6 of this preamble for further discussion of this proposal. |
| **Public Comment Field:**  We offer the following comments:   1. We support the proposal that vendors should be required to update the ONC-ACBs of changes to the user interface aspects of CEHRT that have been previously subject to SED testing however    1. Only one workflow per MU certification requirement should be subject to SED testing. Alternative workflows present in the product should not all have to be subject to SED testing. This is consistent to what is expected under live observed testing of the functionality being presented for certification under any of the criteria where SED testing was done for 2014 certification.       1. Additional workflows added after certification to the original workflow subjected to SED testing that are alternate means of meeting the same criterion should not be subjected to SED testing as long as the original certified workflow remains unchanged    2. We suggest that much of what ONC may be proposing for separate application under SED testing be folded into surveillance activities instead of specifying other potential retesting scenarios or requirements. Surveillance should be the assurance activity to hold vendors accountable for abiding by disclosure requirements and SED testing requirements relative to introduction of new workflows or material changes to their user interfaces. 2. We recommend that ONC not fix a monthly update cycle requiring vendors to notify ONC-ACBs of product updates but instead gear this requirement to match to a given vendor’s typical release cycle for major and minor updates.    1. We suggest that ONC take steps to assure a normalized requirement is in place for how major and minor updates are characterized and what due diligence is required by ONC-ACBs of vendors relative to both    2. We suggest ONC normalize how versions are referenced on the ONC CHPL so that all vendors are consistent in how their versions are represented on the CHPL for what vendors represent to be major and minor updates. There is significant inconsistency in vendor and ONC-ACB practice in this regard. Some vendors have version updates of a certified product granted new CHPL listings unto themselves and other vendors do not. There is little way to designate a major update from a minor one, and there is no consistency of when a new product listing is required and when it is not.       1. We do not suggest ONC dictate version numbering conventions to vendors but ONC should provide consistent guidance to ONC-ACBs for how major and minor version updates are represented on the ONC-CHPL, and we suggest that best accomplished by a disclosure statement or reference within the certification details for a certified product or within its test report as maintained over time for what versions inherit certified status from the original certification. ONC could accomplish this through a table or version control section indicating the version number and date of grant of certified status. |
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| [**§ 170.315(g)(3) Safety-enhanced design**](http://www.federalregister.gov/a/2015-06612/p-860) **p.190** | |
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| **Included in 2015 Edition Base EHR Definition?**  No, but a conditional certification requirement | |
| **Stage 3 MU Objective**  N/A | |
| **2015 Edition Health IT Certification Criterion**  (3) Safety-enhanced design.  (i) User-centered design processes must be applied to each capability technology includes that is specified in the following certification criteria: paragraphs (a)(1) through (10) and (18), (20), (22), (23), and (b)(2) through (4) of this section.  (ii) The following information must be submitted on the user-centered design processed used:  (A) Name, description and citation (URL and/or publication citation) for an industry or federal government standard; or  (B) Name the process(es), provide an outline of the process(es), a short description of the process(es), and an explanation of the reason(s) why use of any of the existing user-centered design standards was impractical.  (iii) The following information/sections from NISTIR 7742 must be submitted for each capability to which user-centered design processes were applied:  (A) Name and version of the product; date and location of the test; test environment; description of the intended users; and total number of participants;  (B) Description of participants, including: sex; age; education; occupation/role; professional experience; computer experience; and product experience;  (C) Description of the user tasks that were tested and association of each task to corresponding certification criteria;  (D) List of the specific metrics captured during the testing, including; task success (%); task failures (%); task standard deviations (%); task performance time; and user satisfaction rating (based on a scale with 1 as very difficult and 5 as very easy);  (E) Test results for each task using metrics listed above in paragraphs (g)(3)(ii)(A) through (D) of this section;  (F) Results and data analysis narrative, including: major test finding; effectiveness; efficiency; satisfaction; and areas for improvement.  (iv) Submit test scenarios used in summative usability testing. | |
| **Preamble FR Citation:** 80 FR 16856 | **Specific questions in preamble?** *Yes* |
| **Public Comment Field:**  We offer the following comments:   1. Some of the criteria proposed to be subject to Safety Enhanced Design testing are more administrative in nature such as for configuring drug-drug alert settings or for configuring CDS rules. The recruitment of clinician end users for testing of these criteria is not required as they are not part of the workflow typically covered by clinical end users. We recommend either that the minimum requirement of 15 participants be significantly reduced for these criteria or their inclusion in the SED criterion requirement be removed. 2. The minimum of 15 participants for each category would prove burdensome for smaller EHR vendors with smaller client installation bases from which to draw, and particularly for vendors focused on ambulatory settings comprised of smaller practices, would require engaging with many clients to meet whereas a larger vendor may be able to conduct testing with fewer larger clients. We recommend a smaller number such as 10 participants for clinical tasks and 4 for non-clinical administrative tasks (if administrative criteria are to be retained in the testing requirement).    1. We also recommend that the minimum for clinical roles be a total number across all clinical roles involved in any given criterion testing and not by category of clinical role. Again particularly for vendors focused on smaller ambulatory practice venues, there can be practical difficulty in identifying participant panels of 15 per clinical role. 3. Some of the descriptive factors for identifying participants including sex, age and education do not represent information that provides evidence of correct use and application of User Centered Design procedures. They are insignificant in discriminating user behavior patterns. We recommend focusing on summary descriptor information that demonstrates the participants are representative of clinical users that are of significance such as occupation/role and professional experience. 4. Task Standard Deviations (%) does not make sense in the context provided in the rule as a metric by which to measure User Centered Design. The reference standard of NISTIR 772 uses Task Deviations as a metric for effectiveness, which is not a reported as a percentage. We request clarification on whether this portion of the rule is defining the statistical procedure to use for measuring effectiveness (which would not make sense in the context of Successes or Failures) or the Effectiveness metric (which is not standard deviations, but simply task deviations). 5. The rule guidance to use a User Satisfaction Rating with a scale of 1 to 5 as a task-based measure suggested as an example is not representative of an industry standard questionnaire for analyzing software usability. The primary scientifically recognized single task-based satisfaction rating is the Single Ease-of-use Question which uses a 7-point scale. We recommend supporting the ability to use literature recognized satisfaction measures such as the Single Ease-of-use Question, System Usability Scale, or Software Usability Measurement Inventory, which all use different measurement scales and not specify which satisfaction measure is used or the specification of task-based satisfaction measures versus a post-session satisfaction measures. 6. We urge that all the ACBs include the full complete usability test report in the public test report. This is a discrepancy with current reporting by the ACBs and we urge ONC to enforce common practice on this point. | |
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| [**Web Content Accessibility Guidelines (WCAG)**](http://www.federalregister.gov/a/2015-06612/p-716)  **p. 164** |
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| We reaffirm for stakeholders that the proposed 2015 Edition VDT criterion includes the WCAG 2.0 Level A (Level A) conformance requirements for the “view” capability. This is the same requirement we include in the 2014 Edition VDT criterion. We do, however, propose to modify the regulatory text hierarchy at § 170.204(a) to designate this standard at § 170.204(a)(1) instead of § 170.204(a). This would also require the 2014 Edition VDT certification criterion to be revised to correctly reference § 170.204(a)(1). We also seek comment on whether we should adopt WCAG 2.0 Level AA (Level AA) conformance requirements for the “view” capability included in the 2015 Edition VDT criterion (instead of Level A). |
| We would recommend ONC hold off on raising the WCAG level to 2.0 Level AA. As noted, there is a lack of quality compliance test tools. Also as mentioned, clearer guidance on mobile accessibility is a concern, and with more systems using mobile for viewing of health data, such guidance would be of great value. We would recommend ONC support efforts to improve the tools, or at least better consolidate those which are viable, and help in developing the necessary guidance for mobile accessibility. Once these two areas are better strengthen, the decision on moving to Level AA can be revisited. |

| [**Design and Performance (§ 170.315(g))**](http://www.federalregister.gov/a/2015-06612/p-1229) **p. 261** | |
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| **Preamble FR Citation:** 80 FR 16876 | **Specific questions in preamble?** *No* |
| **Public Comment Field:**  The proposed requirement in this section calls for a vendor to certify to the 170.315(g) criteria for safety enhanced design or accessibility anytime they are seeking to certify to 170.315(a), 170.315(b) or 170.315(e) criteria where there is also a requirement to certify to safety enhanced design or accessibility. It also proposes vendors certify to the quality management system as a part of any given modular certification. Finally, it also requires certification to the CCDA creation performance criterion when other criteria are part of certification that involve creation of the CCDA. We are generally supportive of this proposal but have a few specific comments.   1. Paragraph (g) also includes a requirement for ONCACBs to certify all Health IT Modules presented for certification to the 2015 Edition to §170.315(g)(4) (quality system management) and (g)(8) (accessibility-centered design)” -> Most EHR vendors have legacy systems which were developed when the standards for accessibility-centered design were not as mature as they are today. Applying these standards on all Health IT modules would imply rewriting the whole User Interface which is not feasible for most EHRs. Therefore we welcome the proposal to pattern it after the 2014 Edition “Quality System Management” which permits a response that “no health IT accessibility centered design standard or law was applied to all applicable capabilities” as an acceptable means of satisfy this proposed certification criterion. 2. On page 210 of the display copy of the NPRM, it specifies “This criterion would require the identification of user-centered design standard(s) or laws for accessibility that were applied, or complied with, in the development of specific capabilities included in a Health IT Module or, alternatively, the lack of such application or compliance.” We recommend this requirement be limited to only the 17 criteria proposed for “user-centric design” in the 170.315 (g)(3) Safety-enhanced Design.      |  | | --- | | . | | |

| [**Request for Comment on Summative Testing**](http://www.federalregister.gov/a/2015-06612/p-918)  **p. 196** |
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| We understand that some health IT developers are concerned that the summative testing report may not adequately reflect the design research that has been performed throughout a product's lifecycle. We request public comment regarding options that we might consider in addition to—or as alternatives to—summative testing. For example, if formative testing reflects a thorough process that has tested and improved the usability of a product, could a standardized report of the formative testing be submitted for one or more of the 17 certification criteria for which summative testing is now required? What would be the requirements for this formative testing report, and how would purchasers evaluate these reports? |
| **Public Comment Field:**  We recommend that formative testing not be a required form of testing but that at most it may be alternative and optional to summative testing. There are certain issues which may make it difficult for it to fit in the certification framework:   1. It takes place during the product development lifecycle and hence may not correctly represent the product which is being certified. 2. Formative testing approaches vary widely and are context-specific. The results depend on how it was deployed within the development cycle. Achieving standardization in formative testing process is a challenge. 3. The purpose of formative testing is to reveal issues with the system to improve the design. Since the current regulations require that these test results be posted publically on the ONC Certified Health Product List, there are concerns about including formative test results in the EHR certification criteria that are fundamentally interim in nature and internal to the development process and may not be reflective of the state of the final product. These results of an interim nature do not add value to what is informative to the buyer for issues addressed and not present in the final certified product. As such, the results published in the publicly available test report may not be correctly interpreted by the reader and may only be noise causing issue for the vendor even if the process of its discovery and resolution has rather helped to improve the design.    1. If formative testing was allowed, additional guidance would be needed to properly constraint and direct it. Also, the public report findings should still focus on users’ final feedback on version of software being released. 4. As a negative, formative testing would require vendor to have users evaluate the product at multiple stages which could impact smaller vendors due to cost considerations. |