

**ONC HEALTH IT CERTIFICATION PROGRAM**

**Program Policy Resource #18-01:**

**Post-certification Assessment of Program Requirements**

(Last updated: October 5, 2018)

**Table of Contents**

I. INTRODUCTION ..... 2

    A. Background and Purpose ..... 2

    B. Terminology ..... 2

II. PURPOSE AND SCOPE OF POST-CERTIFICATION ASSESSMENTS ..... 4

    A. Overview..... 4

    B. Limitations of Testing..... 4

    C. Post-certification Conformity Assessments..... 4

    D. Responsibility of ONC-ACBs for Administering Post-certification Assessments —  
    Exercising Professional Judgment..... 6

III. ASSESSING PERFORMANCE OF REQUIRED CAPABILITIES IN THE FIELD ..... 6

    A. Basic Principles..... 6

    B. Post-Certification Assessment Process..... 7

    C. Review the Scope of Required Capabilities to Be Assessed ..... 8

        1. Identifying Required Capabilities and Outcomes..... 8

        2. Confirming the Scope of a Product’s Required Capabilities in the Field ..... 12

    D. Identifying Facts and Circumstances That May Impact Performance ..... 14

    E. Does the Product Perform as Required in the Field? ..... 15

        1. Does the Product Support the Required Capabilities?..... 16

        2. Has the Developer Impermissibly Interfered with the Use of Certified Capabilities? ..... 17

        3. Do Required Capabilities Perform in an Accurate, Reliable, and Successful Manner? .... 20

        4. Developer’s Ability to Reasonably Influence or Control..... 21

IV. OTHER POST-CERTIFICATION REQUIREMENTS ..... 25

    A. Disclosure of Known Material Information ..... 25

    B. Cooperation with Testing, Certification, and Surveillance ..... 26

    C. Providing Information to ONC-ACBs..... 27

## I. INTRODUCTION

---

### A. Background and Purpose

This resource describes the approach taken by ONC-Authorized Certification Bodies (ONC-ACBs) to assess whether health information technology (health IT) certified under the ONC Health IT Certification Program (Program) conforms to the requirements of its certification when it is implemented and used in the field. In particular, this resource clarifies the responsibilities of ONC-ACBs for evaluating how certified health IT performs in real-world environments, such as hospitals and health care practices. It also explains how Program requirements are interpreted and applied in these post-certification settings.

An exhaustive treatment of Program requirements or of any particular requirement is beyond the scope of this resource, which should be reviewed in conjunction with other applicable resources and regulations, including the following, which contain detailed information and additional analysis concerning many of the requirements discussed herein—

- Program Policy Resource #18–03: Surveillance Resource (**Surveillance Resource**)
- Program Policy Resource #18–02: Disclosure of Material Information (**Disclosure of Material Information Resource**)
- 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule, [80 FR 62601](#) (Oct 16, 2015) (**2015 Edition final rule**)
  - ↳ [Section IV.D.1](#) — *“In-the-field” Surveillance and Maintenance of Certification*
  - ↳ [Section IV.D.2](#) — *Transparency and Disclosure Requirements*
- ONC Health IT Certification Program: Enhanced Oversight and Accountability final rule, [81 FR 72404](#) (Oct 19, 2016) (**EOA final rule**)
  - ↳ [Section II.A.1.a\(1\)](#) — *Requirements of the Program*

### B. Terminology

To make this resource more accessible, plain language terms are used as a short-hand for certain regulatory concepts. The use of these terms is strictly for convenience and does not create any new requirements or alter the interpretation of existing requirements under the Program. When encountering any of these terms, the reader should substitute the definitions in Table 1 below.

**Table 1: Terms Used in this Resource**

Term	Definition
<b>compliance</b>	With respect to a requirement of the Program, conformity with such requirement.
<b>developer</b>	A person or entity that submits health IT for certification under the Program and/or is responsible for maintaining a certification issued to health IT under the Program.
<b>in the field</b>	With respect to certified health IT, as implemented and used in a production environment (as defined below).
<b>non-conformity</b>	The failure of certified health IT or of a certified health IT developer to conform to a requirement of the Program.

Term	Definition
<b>pre-certification and post-certification</b>	At or concerning the period of time <i>before</i> (“pre-certification”) or <i>after</i> (“post-certification”) health IT is certified under the Program.
<b>product</b>	A Complete EHR or Health IT Module that has been issued a certification or has been submitted for certification under the Program (as the context requires).
<b>production environment</b>	Any real-world setting (such as a hospital or doctor’s office) in which the capabilities of certified health IT are implemented or used.
<b>Program</b>	The ONC Health IT Certification Program.
<b>required capability or certified capability</b>	A capability or other aspect of health IT that is required by one or more certification criteria to which the technology is certified, typically comprising one or more required outcomes (as defined below).
<b>required outcome</b>	Any characteristic that a product must possess or any outcome it must enable to support a required capability (as defined below).
<b>technology</b>	A “product” (as defined above).
<b>testing</b>	The process of evaluating a product’s performance under simulated and/or controlled conditions, including but not limited to pre-certification testing conducted under the supervision of an ONC-Authorized Testing Lab (ONC-ATL) in accordance with approved test procedures, testing tools, and, where applicable, test data.

## II. PURPOSE AND SCOPE OF POST-CERTIFICATION ASSESSMENTS

---

### A. Overview

A health IT product's certification is conditioned on conformity with all applicable Program requirements ([80 FR 62709–10](#)). However, due to practical constraints—including the limitations of testing a product's capabilities in a controlled environment—many Program requirements cannot be evaluated on the basis of test results and other information available when a product is presented to an ONC-ACB for certification. Consequently, conformity determinations made at the time of certification must be augmented with assessments following certification that are carried out during an ONC-ACB's surveillance of the products they have certified (*see* 45 CFR 170.556). Performing comprehensive assessments following certification in accordance with the principles described in this resource is vital to the effective administration of the Program's requirements and is therefore one of an ONC-ACB's core responsibilities.

### B. Limitations of Testing

When an ONC-ACB certifies a health IT product, its initial determination of conformity is based primarily on test results and declarations provided by the health IT developer. While pre-certification test results are an important part of an ONC-ACB's overall analysis, such results have limits:

- Testing focuses on discrete and narrowly-defined outcomes that can be readily demonstrated in the controlled environment managed by a testing laboratory while certification criteria govern how products perform in actual production environments.
- The test procedures used in pre-certification testing are designed to reflect basic scenarios that health IT will be subjected to in the field. During testing, a product's performance is evaluated under carefully-controlled conditions and includes only a limited range of fixed "test cases" or "scenarios," pre-determined data and inputs, and well-defined sequences of steps, user actions, and events—all of which are described in test procedures and available to developers prior to testing. By contrast, certified products deployed in the field are exposed to a much greater depth and breadth of use cases, workflows, data, and other circumstances, which are often complex and difficult to limit or control.
- How a product performs in the field after certification is affected both by the actions its developer takes and decisions customers make with respect to implementation and customization due to their needs. For example, developers may impose contractual restrictions or other limitations that substantially interfere with the use of a product's certified capabilities. And customization or integration with another health IT product may result in the certified capability to function in unexpected ways. These considerations are beyond the scope of pre-certification testing but are fundamental to a product's conformity with certification requirements.

For these reasons, pre-certification test results provide only an initial indication that a product will be able to support the capabilities and outcomes required by its certification ([80 FR 62709](#)). That preliminary determination of conformity is always subject to an ONC-ACB's ongoing surveillance of certified products, including its post-certification assessment of the product's certified capabilities as implemented and used in the field ([80 FR 62709–10](#)).

### C. Post-certification Conformity Assessments

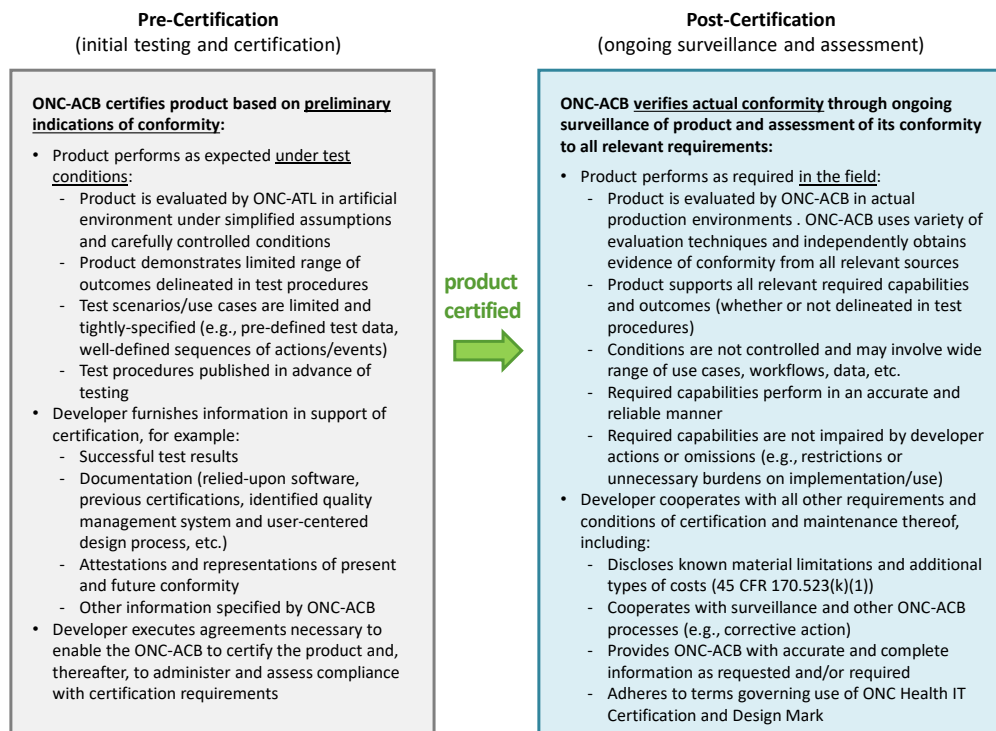
The post-certification assessments carried out by ONC-ACBs address the limitations of pre-certification testing and provide customers and users with greater confidence that their certified

health IT will perform in an acceptable manner when it is implemented and used in the field (45 CFR 170.556). Importantly, post-certification assessments:

- are not limited to evaluating the specific capabilities and outcomes that a product was required to demonstrate as part of pre-certification testing;
- are not limited to evaluating a product’s performance under the specific test scenarios, use cases, and other assumptions described in test procedures;
- provide the opportunity to evaluate whether a product supports *all* certified capabilities and outcomes within the scope of its certification;
- provide the opportunity to evaluate whether a product performs in a manner conforming with its certification under real-world conditions, including under scenarios, use cases, workflows, and other circumstances that were not tested prior to certification; and
- provide the opportunity to evaluate whether developers have fulfilled their related responsibilities for making required capabilities available to customers and users in a manner that is transparent, free from undisclosed costs and limitations, and consistent with other Program requirements.

Figure 1 below illustrates the phases of conformity assessment under the Program, as discussed above.

**Figure 1: Phases of Conformity Assessment**



## D. Responsibility of ONC-ACBs for Administering Post-certification Assessments — Exercising Professional Judgment

Due to their expertise and ability to directly observe the use and performance of certified health IT in the field, ONC-ACBs are well positioned to assess whether required capabilities perform in accordance with a product's certification. We expect ONC-ACB's to use their independent professional judgment to correctly apply Program requirements in an informed, objective, and well-reasoned manner that produces consistent and fair results across varied factual situations.<sup>1</sup> An ONC-ACB's professional judgment should be based on the ONC-ACB's knowledge, skills, and experience and may be informed by considerations including but not limited to:

- The ONC-ACB's expertise in understanding and applying certification criteria and other Program requirements described in applicable rules, regulations, and resources.
- The ONC-ACB's familiarity with the product or capabilities at issue and with other comparable products and capabilities.
- The ONC-ACB's knowledge of how required capabilities are made available, including:
  - ↳ the manner in which products containing required capabilities are marketed or made available;
  - ↳ the types of customers and users to whom such products are marketed;
  - ↳ the types of real-world uses and outcomes that customers and users seek to realize when implementing and using required capabilities; and
  - ↳ the reasonable expectations of customers and users as to the use and performance of certified products and capabilities, in light of the apparent purposes for which they are marketed or made available.
- The ONC-ACB's experience in conducting conformity assessments under the Program, including the collective experience of ONC-ACBs when administering corrective action in response to findings of non-conformity.
- The ONC-ACB's general knowledge of the health IT industry and marketplace.

While ONC-ACBs are expected to exercise their independent professional judgment and are well placed to address most issues they encounter when conducting surveillance of certified health IT, ONC-ACBs may request additional policy advice or technical assistance from ONC as needed.

## III. ASSESSING PERFORMANCE OF REQUIRED CAPABILITIES IN THE FIELD

---

### A. Basic Principles

To provide confidence that certified health IT performs in a manner consistent with its certification, ONC-ACBs are required to conduct ongoing surveillance of the health IT products they certify.<sup>2</sup>

---

<sup>1</sup> We recognized the need for ONC-ACBs to exercise their professional judgment in the 2015 Edition final rule. There, we explained that in-the-field surveillance necessarily requires “the exercise of some discretion” by ONC-ACBs ([80 FR 62722](#)). We observed that ONC-ACBs have become increasingly adept at analyzing the performance of certified health IT in the field, including working with developers and end-users to identify the causes of reported problems and to distinguish certification issues from other factors that may affect the performance of certified health IT ([80 FR 62708–09](#)).

<sup>2</sup> 45 CFR 170.556; 170.523(i). We clarify that an ONC-ACB is deemed to “have certified” health IT if: (1) it has issued and has not withdrawn a certification to the health IT; or (2) it has assumed responsibility for a certification issued by another ONC-ACB and has not withdrawn the certification.

Central to this responsibility is an assessment of the product's conformity with all applicable Program requirements once the product is deployed and used in the field.

We have previously articulated the basic principles by which ONC-ACBs assess whether products conform to the requirements of their certifications under the Program, including that:

- Products must be able to perform all required capabilities and enable users to achieve all required outcomes within the scope of the certification criteria to which products are certified (45 CFR 170.545; 170.550; [80 FR 62710–12](#); [81 FR 72412](#)).
- Developers must make required capabilities available to customers and users in a manner that allows them to be used for their intended purposes, including any uses reasonably within the scope of applicable certification criteria ([80 FR 62710–11](#); [81 FR 72413](#)).
- Products must be able to perform all required capabilities in an accurate, reliable, and successful manner ([81 FR 72412](#); [81 FR 72420](#)).
- A product does not conform to the requirements of its certification if it is subject to technical, contractual, or other limitations that have substantially interfered with—or are likely to substantially interfere with—any current or future user's ability to access or use certified capabilities for their intended purposes ([80 FR 62711](#); [81 FR 72413](#)).
- More generally, developers may not engage in any action or omission that is likely to substantially interfere with a user's ability to access or use certified capabilities for their intended purposes ([80 FR 62711](#); [81 FR 72413](#)).<sup>3</sup>
- A product does not fail to conform to the requirements of its certification if it fails to perform in an acceptable manner solely as a result of factors far removed from the control or responsibility of the developer ([80 FR 62710](#)).

The remainder of this Part III elaborates on these principles and provides additional information and examples to assist ONC-ACBs as part of their ongoing surveillance and post-certification conformity assessments. We caution, however, that it is impossible to anticipate and provide a bright-line rule for every situation that may present itself during an ONC-ACB's surveillance. As we explained in the 2015 Edition final rule, the surveillance of required capabilities focuses on real-world outcomes, which must be evaluated in light of the many different circumstances and contexts in which such capabilities may be implemented and used ([80 FR 62709](#)).

## B. Post-Certification Assessment Process

To assess a product's post-certification conformity to the requirements of the Program, an ONC-ACB should carry out the following activities, which are discussed in more detail below:

- First, **review the scope of required capabilities to be assessed**, including all capabilities and associated outcomes that are within the scope of the certification criteria to which the product is certified and that are relevant to the aspects of the product that are the focus of the surveillance (*see* Part III.C).
- Second, **identify any facts and circumstances** that may impact the performance of the required capabilities in the production environment(s) in which they will be assessed (*see* Part III.D).

---

<sup>3</sup> For example, as discussed in Part III.E.2.a below, if a developer fails to disclose required information about a product's limitations or types of costs (as required by 45 CFR 170.523(k)(1)), a prospective customer may encounter unanticipated challenges that substantially impair its implementation or use of required capabilities. Under these circumstances, the developer's omission is an impermissible interference with the use of a required capability and as such is a non-conformity to the corresponding certification criterion ([80 FR 62711](#); [81 FR 72413](#)).



- Third, **determine whether the product supports the required capabilities and conforms to all other requirements in the production environment(s)** (*see* Part III.E).

### C. Review the Scope of Required Capabilities to Be Assessed

The starting point for an ONC-ACB's post-certification assessment is to carefully review the scope of the relevant capabilities that must be assessed. As discussed in Part II, once a product is certified under the Program, it must support *all* of the capabilities and associated outcomes required by the certification criteria to which it is certified, not just the narrowly-defined functionalities and outcomes that the product demonstrated during pre-certification testing (45 CFR 170.545; 170.550; [80 FR 62710–12](#); [81 FR 72412](#)). At the outset, therefore, an ONC-ACB should review the certification criteria to which a product has been certified to confirm the full range and scope of applicable capabilities that the ONC-ACB should evaluate as part of its surveillance and assessment of the product's performance in the field. In particular, ONC-ACBs should identify:

- The relevant certification criteria to which the product is certified;
- For each certification criterion, the relevant capabilities that the product must support (each a “required capability”); and
- For each required capability, the associated outcomes that the capability must support (each a “required outcomes”).

Although a product may be certified to numerous certification criteria and required to support a broad range of capabilities, an ONC-ACB's post-certification assessments will typically focus on a narrower range of capabilities that are relevant to a particular concern or complaint or that are otherwise the subject of the ONC-ACB's surveillance. Moreover, because surveillance episodes frequently involve similar issues and tend to implicate some capabilities more than others, an ONC-ACB will often be able to draw on its past experience analyzing and interpreting relevant certification criteria. Nevertheless, ONC-ACBs should be sufficiently familiar with the requirements of each certification criterion to be able to identify any potential non-conformity that may arise, as required by 45 CFR 170.556(b), whether or not the non-conformity involves issues that an ONC-ACB has previously encountered.<sup>4</sup>

#### 1. Identifying Required Capabilities and Outcomes

Identifying the certification criteria to which a product is certified is a straightforward task. This information is readily available to an ONC-ACB and can be verified from a product's entry on the Certified Health IT Product List (CHPL). However, this is only the first step in determining the scope of the product's required capabilities. As noted above, each certification criterion establishes a range of required capabilities. These may be described with varying specificity and granularity and may govern a range of different aspects of a product's functionality, design, operation, and use. ONC-ACBs must be able to identify and correctly interpret the scope of any of these capabilities that are relevant to its surveillance and post-certification assessment ([80 FR 62709](#)).

This will be easier for some required capabilities than others. The scope of some required capabilities, for example, will be plain from the text of the certification criterion and will require minimal interpretation. This is more likely true when a capability implements a specific technical outcome that is defined with a high degree of specificity and granularity, such as an outcome that is fully described and tightly constrained by an adopted technical standard. As an

---

<sup>4</sup> An ONC-ACB must initiate surveillance (including, as necessary, in-the-field surveillance) whenever it becomes aware of facts or circumstances that would cause a reasonable person to question a certified product's continued conformity to the requirements of its certification (45 CFR 170.556(b); *see also* [80 FR 62713](#)).



illustration, the certification criterion at 45 CFR 170.315(a)(5) requires, among other capabilities, that a user be able to record a patient's sex in accordance with the standard at 45 CFR 170.207(n)(1). This capability presents little interpretive difficulty because of the narrowness with which it is defined and the close correlation between its required outcomes and the aforementioned technical standard.<sup>5</sup>

In contrast, many required capabilities present more difficult interpretive issues that call for a more detailed analysis. Certain capabilities in particular are likely to require greater interpretive effort. These typically include capabilities:

- that support a broad range of associated outcomes;
- that can be implemented or used in a variety of ways;
- whose required outcomes depend on how the capability is made available or how it is implemented and used in the field; or
- that involve outcomes that are more general or qualitative in nature and, for this reason, cannot be evaluated solely on the basis of conformity with one or more technical standards.

Some examples of capabilities that possess some or all of these characteristics include:

- 45 CFR 170.315(b)(1)(ii)(B) requires that information be displayed in a “human-readable format”;
- 45 CFR 170.315(e)(2) requires that messages be sent “in a secure manner”;
- 45 CFR 170.315(b)(1)(ii)(C) requires that the technology enable a user to configure what data is displayed in section views and how it will be presented; and
- 45 CFR 170.315(b)(6)(i)(A) requires that a user be able to execute a data export “without subsequent developer assistance.”

To determine the scope of capabilities such as these, ONC-ACBs should look at a certification criterion's purpose and objectives, including the required capabilities and associated outcomes that products certified to the criterion are intended to support. While regulation text is always the starting point for an ONC-ACB's analysis, ONC-ACBs should also pay close regard to regulatory materials that explain the scope of the capabilities and outcomes established by a particular certification criterion. These details are memorialized in the preamble sections of the relevant proposed and final rules in which certification criteria were adopted, revised, or updated and may be supplemented by subsequent interpretive resources issued by ONC. To this end, ONC-ACBs should carefully consider the following materials when determining the scope of a product's required capabilities:

- The text of the certification criterion, including its structure and context, and of any related definitions, referenced standards and implementation specifications, or other relevant regulatory provisions;
- Provisions of any rules (including proposed and final rules) that set forth:
  - ↳ the purposes and objectives of the certification criterion, including the types of potential uses and other outcomes that products certified to the criterion are intended to support in the field;

---

<sup>5</sup> We note that not all aspects of the capability or its required outcomes are dictated by the standard alone. As with all required capabilities, the capability to record a patient's sex must be understood and assessed in light of the overarching requirements of the Program, including the requirement that capabilities perform in an accurate and reliable manner and be unencumbered by impermissible interference ([80 FR 62708](#); [80 FR 62711](#); [81 FR 72413](#)). These and other requirements are included within the scope of a product's required capabilities.

- ↳ other rationale for the criterion; and
- ↳ policy choices that were made during the process of adopting the criterion; and
- Other interpretive resources issued by ONC, noting that test procedures and other materials prepared by ONC to support pre-certification testing should be read and understood on the basis that they have been prepared with the express purpose of evaluating a limited subset of required capabilities in a controlled environment.<sup>6</sup> As such, this type of resource is not determinative of the full scope of a product’s required capabilities.

As an example, consider the clinical quality measure (CQM) export capability described at 45 CFR 170.315(c)(1)(ii). The following table illustrates how the text of the certification criterion, combined with key provisions of the 2015 Edition final rule, provide important context for understanding the scope of the capability and its required outcomes.

45 CFR 170.315(c)(1)(ii) – Clinical quality measures – record and export – Export	
Source	Description
Regulation text	<p>“A user must be able to export a data file at any time the user chooses and without subsequent developer assistance to operate:</p> <p>(A) Formatted in accordance with the standard specified in 170.205(h)(2);</p> <p>(B) Ranging from one to multiple patients; and</p> <p>(C) That includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section.”</p>
2015 Edition final rule ( <a href="#">80 FR 62650</a> )	<p>“[T]he ability to export CQM data serve[s] two purposes.” CQM data export functionality:</p> <ul style="list-style-type: none"> <li>• “will allow a provider or health system to view and verify their CQM results for quality improvement on a near real-time basis.”</li> <li>• “gives providers the ability to export their results to multiple programs, such as those run by CMS, states, and private payers.”</li> </ul> <p>“[O]ur intent is for users . . . to be able to export CQM data . . . without needing to request support from a developer.” Providers must not be required to “submit requests for the health IT developer to assist or perform the export function on their behalf.”</p> <p>“[P]roviders and health systems should determine the protocols around when and how providers export CQM data . . . .”</p>
Other interpretive resources	<p><i>2015 Edition Certification Companion Guide—Clinical Quality Measures – Record and Export - 45 CFR 170.315(c)(1)</i></p>

In some instances, a certification criterion or its corresponding regulatory materials may require further interpretation. For example, a user and a developer may have contrary views as to whether a product is required to support a specific capability or outcome in the user’s production environment. In general, ONC-ACBs should rely on their professional judgment, consistent with the following interpretive principles:

---

<sup>6</sup> See discussion in Part II.B above concerning the limitations of pre-certification testing and of testing in general.

- A capability or outcome is required by (that is, within the scope of) a certification criterion if it can reasonably be inferred from the criterion’s text, purposes and objectives, and rationale, as described above.
- At a minimum, a product must support all capabilities and associated outcomes—including all design elements and specifications, standards, functionalities, features, characteristics, and services—that may be necessary to enable the full use of the product in a user’s production environment.
- The full use of a product requires that a user be able to realize any and all uses, use cases, workflows, and other production outcomes that are consistent with the intended purposes and objectives of the certification criteria to which the product is certified, and that:
  - ↳ may be of significant importance to any class of intended user; and
  - ↳ are of a kind that should have been anticipated by an experienced health IT developer or implementer.

However, if an ONC-ACB believes that it has encountered a novel issue and no additional interpretative resource can be found, the ONC-ACB should contact ONC for additional analysis.

Continuing with the CQM export example, the following scenario illustrates how an ONC-ACB would, as an initial matter, use the materials and interpretive principles outlined above to confirm the scope of that capability.

***Scenario 1-A – CQM Export***

An ONC-ACB receives a complaint from an ambulatory practice using a product certified to 45 CFR 170.315(c)(1) (Clinical quality measures — record and export). The practice manager alleges that authorized users are experiencing up to a 96-hour delay from the time they execute a command to export CQM data to the time the resulting data file is created. The practice manager explains that the delay is impacting the practice’s quality improvement activities.

Based on this initial information, the ONC-ACB initiates reactive surveillance of the product to assess whether it continues to conform to the requirements of 45 CFR 170.315(c)(1)(ii). Before it can perform this assessment, however, the ONC-ACB must identify the nature and scope of those requirements as they relate to the export of CQM results (the “CQM export requirements”).

A careful consideration of the criterion’s text and other materials outlined above reveals several relevant observations about the purposes and objectives of the CQM export requirements, including—

- The regulation text provides that “A user must be able to export a data file at any time the user chooses and without subsequent developer assistance . . . .” (45 CFR 170.315(c)(1)(ii))
- The 2015 Edition final rule explains that the CQM export capability “will allow a provider or health system to view and verify their CQM results *for quality improvement on a near real-time basis*” (emphasis added) ([80 FR 62650](#)).

These purposes and objectives directly inform the ONC-ACB's understanding of the scope of the CQM export requirements, including the outcomes that must be supported in the field.

As noted above, this inquiry into the scope of a product's required capabilities need not extend beyond those aspects that are relevant to an ONC-ACB's evaluation of the issues before it, such as those presented in a complaint or encountered during the ONC-ACB's surveillance of the product in the field. Here, the allegations in the complaint relate to whether the CQM export capability is providing results in a sufficiently timely manner. Therefore, with regard to the scope of the CQM export capability, the central issue appears to be the meaning of the requirement "to export a data file at any time the user chooses," and the related expectation that such data will be provided "on a near real-time basis," that allows a provider or health system to view and verify their CQM results for quality improvement.

Focusing on the issue of timeliness, having considered the purposes and objectives of the CQM export capability outlined above, and based on the initial information provided in the complaint, the ONC-ACB determines that the following requirements are within the scope of the CQM export requirements and will be relevant to evaluating its performance:

- (1) "Near real-time" export does not require that a user receive CQM data instantaneously upon entering a command to generate the export.
- (2) However, CQM export must be accomplished quickly enough that any delay does not substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement purposes.

Having identified the scope of the relevant requirements to be assessed, the ONC-ACB can proceed with its observation of the product in the field and other fact-finding necessary to complete its post-certification assessment of the product's conformity. *(This scenario is continued in Part III.C.2 below.)*

## **2. Confirming the Scope of a Product's Required Capabilities in the Field**

As outlined above, ONC-ACBs will initially rely on their experience and professional judgment to identify the required capabilities that are relevant to a particular surveillance episode and to determine the scope of such capabilities. This preliminary determination may be based on information in a complaint, observations in the field, or any other information that comes to the attention of the ONC-ACB. It will also reflect the ONC-ACB's experience from prior surveillance, such as the typical use cases, workflows, and other production conditions that have been observed in similar or related contexts.

However, a surveillance episode will often reveal additional issues or insights that were not apparent from complaints and other information available to an ONC-ACB at the outset of its surveillance. In some instances, these issues or insights will require the ONC-ACB to consider additional aspects of the capability under examination and whether these also are within the scope of the relevant certification criteria. For example, the ONC-ACB may encounter additional uses, use cases, or workflows for a required capability that are consistent with the purposes and objectives of the relevant certification criterion and that would therefore require additional scrutiny. Conversely, an ONC-ACB may initially conclude that a certification criterion must support a particular outcome, but upon closer inspection it may find that the outcome is inconsistent with the purposes and objectives of the criterion and is therefore beyond the scope of the product's required capabilities.

ities. Given these and other possibilities, an ONC-ACB must be prepared, if necessary, to revisit its initial interpretation of the scope of a product’s required capabilities and the requirements that the product must conform to in the field.

The following scenario illustrates how new facts and circumstances encountered during surveillance may require an ONC-ACB to revisit its initial inquiry into the scope of a product’s required capabilities.

***Scenario 1-B – CQM Export (continued from Part III.C.1)***

In this scenario, continued from above, an ONC-ACB is conducting surveillance on the basis of a complaint received from an ambulatory practice using a product certified to 45 CFR 170.315(c)(1) (Clinical quality measures — record and export). The practice manager alleges that users are experiencing up to a 96-hour delay from the time they execute a command to export CQM data to the time the resulting data file is created. The practice manager explains that the delay is impacting the practice’s quality improvement activities.

As discussed above, the ONC-ACB initially believes, based on the information provided in the complaint, that the key issue for surveillance is whether the CQM export is accomplished “quickly enough” that any delay does not substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement purposes. However, during its surveillance, the ONC-ACB obtains additional information about the product’s functionality that compels the ONC-ACB to engage in a more nuanced analysis of this certification requirement. Conversations with the developer indicate that the product takes on average 24 hours to process a batch CQM data export but in some cases may take up to 96 hours. This is because the product has been designed to “initiate” the CQM export upon a user’s command but not to actually begin *processing* the request until the developer’s remote servers have adequate processing and network resources available. Thus, depending on the volume of requests the developer receives at a particular time, users experience variable delays of 8 – 96 hours between initiating and receiving the results of the CQM export.

These facts and circumstances lead the ONC-ACB to reframe the key issue for surveillance to include not only whether CQM results are delivered “quickly enough” but also whether the results are delivered consistently enough so as to be accurate for use (based on when they were requested).

Incorporating the new insights gleaned from its initial surveillance, the ONC-ACB reframes its inquiry to focus on the following requirements relevant to evaluating the performance of the CQM export capability in the field:

- (1) “Near real-time” export does not require that a user receive CQM data instantaneously upon entering a command to generate the export.
- (2) However, CQM export must be accomplished:
  - (i) quickly enough, and
  - (ii) consistently enough so as to be accurate for use

such that any delay does not substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement purposes.

Having reframed the relevant requirements to be assessed, the ONC-ACB continues to observe the performance of the product in the field and to engage in other relevant fact-finding necessary to complete its post-certification assessment of the product's conformity. *(This scenario is continued in Part III.E.1 below.)*

#### D. Identifying Facts and Circumstances That May Impact Performance

Once an ONC-ACB determines that a particular capability is required and relevant to the ONC-ACB's post-certification assessment, the ONC-ACB should identify all relevant facts and circumstances that may impact the performance of the capability and its associated outcomes in the field. The facts and circumstances will differ in each case because certified products may be integrated with a wide range of systems, processes, and people, and may be customized and used in many different ways. At the same time, there are many ways that developers go about selling or licensing their certified products that impact how those products are deployed and used. An ONC-ACB's assessment of the performance of a certified product must be informed by these unique circumstances and the context in which a particular product is implemented and used ([80 FR 62709](#)).

An ONC-ACB's overall assessment of a product's performance should be informed by all relevant facts and circumstances, including but not limited to:

- The extent of the product's use by health care providers. If a certified product is widely used by health care providers, an assessment by an ONC-ACB about the performance of a certified product in one setting might be usefully informed by how that same product has performed in other locations.
- The characteristics of a product's intended customers and users. The types of customers and users to whom the developer markets or makes available any of its certified products and capabilities will often be relevant to an ONC-ACB's assessment of performance. This is because the size, technical sophistication, resources, and other characteristics of customers and users may affect their ability to use required capabilities or to achieve required outcomes.
- The manner in which a developer makes a certified product available to customers and users. ONC-ACBs should pay special attention to developer choices such as implementation options, contractual terms, and other factors that could affect the performance of the capabilities in the field. ONC-ACBs may need to obtain documentation from a developer to properly understand that basis on which a product is made available so that this information can inform the ONC-ACB's assessment of the product's performance.
- The roles and responsibilities held by the developer, the customer or user, and any third party in connection with the implementation and use of the product in the field. Identifying the involvement of third party technology or services, and understanding the roles and responsibilities of all parties, is essential to an ONC-ACB's ability to assess whether any alleged non-conformity is within a developer's reasonable influence or control (*see* Part III.E.4 below).
- Any customer-specific implementations, use cases, workflows, configurations, or other variations that might affect the performance of a required capability. This might include, for example, understanding whether the developer encourages, allows, or supports such variations and whether a customer or user is following the developer's recommendations as to proper implementation and use of customer-specific implementations, use cases, workflows, configurations, or other variations (*see* Part III.E.4 below).

## E. Does the Product Perform as Required in the Field?

To complete its post-certification conformity assessment, an ONC-ACB must evaluate whether the product under surveillance performs in a manner that is consistent with the requirements of its certification (*see* 45 CFR 170.556(a)). At this point, the ONC-ACB will have narrowed the focus of its assessment to one or more capabilities required by the product’s certification and will have carefully considered the scope of those required capabilities, including the associated outcomes that the product must be able to support (*see* Part III.C). In addition, the ONC-ACB will have identified any facts and circumstances that it may need to examine as part of its evaluation of the required capabilities and associated outcomes in the field (*see* Part III.D). Having completed these steps, the ONC-ACB must now observe the product in use in one or more production environments to determine whether and to what extent it actually supports the required capabilities and outcomes (45 CFR 170.556(c)(4)(i)).<sup>7</sup>

Because real-world conditions are varied and complex, it is not possible to anticipate every factual scenario that an ONC-ACB may encounter when assessing products “in the field” or to provide a comprehensive “checklist” of issues that the ONC-ACB should evaluate (80 FR 62709).<sup>8</sup> Nevertheless, there are several established principles that provide ONC-ACBs with a consistent and objective framework for assessing, within the limits of their authorizations and accreditations, whether a product performs in a manner consistent with its certification:

- The product must be able to perform all required capabilities and enable a user to achieve all required outcomes within the scope of the applicable certification criteria (45 CFR 170.545; 170.550; [80 FR 62710–12](#); [81 FR 72412](#)) (*see* Part III.E.1).
- The developer must make the required capabilities available in a manner that allows them to be used for their intended purposes, including any uses reasonably within the scope of applicable certification criteria ([80 FR 62710–11](#); [81 FR 72413](#)) (*see* Part III.E.1).
- Conversely, the developer must not engage in action or omission that substantially interferes with—or is likely to substantially interfere with—any current or future user’s ability to successfully implement or use the required capabilities or to achieve the associated required outcomes ([80 FR 62711](#); [81 FR 72413](#)) (*see* Part III.E.2).
- The product must be made available in a manner that enables it to be implemented and used in an accurate, reliable, and successful manner ([80 FR 62708](#); [81 FR 72420](#)) (*see* Part III.E.3).
- A product’s failure to perform in an acceptable manner does not constitute a non-conformity if it is solely the result of factors that are far removed from the control or responsibility of the developer ([80 FR 62710](#)) (*see* Part III.E.4).

---

<sup>7</sup> In addition to observing how capabilities function in the field, an ONC-ACB might supplement its field observations with information gleaned from other sources of surveillance, such as, for example, interviewing and reviewing information provided by actual users of the product; reviewing the developer’s complaint logs and its root-cause analyses and resolutions of issues; and attempting to replicate suspected problems or deficiencies under controlled conditions (80 FR 62709). To the extent that ONC-ACBs perform additional testing as part of their surveillance, they may use any test methods that are appropriate and are not confined to the test procedures or data approved by ONC. We reiterate, however, that testing by itself is not an adequate means of evaluating the performance of required capabilities and outcomes in the field. Thus, while ONC-ACBs may use testing as a starting point for their in-the-field assessments, they may not rely exclusively on test results and must utilize other methodologies and approaches to obtain adequate assurances that certified products conform to the full range of relevant requirements.

<sup>8</sup> As explained in Part II, developers design and offer their products in many different ways, and products in turn may be integrated with a wide range of other systems, processes, and people and may be customized to accommodate local implementation considerations, customer preferences, and countless other individual circumstances. As a practical matter, these circumstances are too numerous and diverse to catalog, and too contextual to analyze completely in the abstract.



## 1. Does the Product Support the Required Capabilities?

During its surveillance of a certified product, an ONC-ACB must verify that the product is made available to customers and users in a manner that allows them to access and use required capabilities in their production environments and that enables them to reasonably achieve the required outcomes associated with those capabilities (80 FR 62710).

The parameters of this inquiry are established by the scope of the relevant required capabilities and outcomes. As explained in Part III.C, a product must support all capabilities and outcomes—including design elements and specifications, standards, functionalities, features, characteristics, and services—that may be necessary to enable the full use of the product in a user’s production environment, including the ability to realize any and all uses, use cases, workflows, and other production outcomes that are consistent with the intended purposes and objectives of the certification criteria to which the product is certified, and that:

- may be of significant importance to any class of intended user; and
- are of a kind that should be anticipated by a health IT developer or implementer.

If an ONC-ACB identifies that a certified product does not support any required capability or outcome, the ONC-ACB will make a finding of non-conformity, as illustrated in the following scenario.

### ***Scenario 1-C – CQM Export (continued from Part III.C.2)***

In this scenario, continued from above, an ONC-ACB is conducting surveillance on the basis of a complaint received from an ambulatory practice using a product certified to 45 CFR 170.315(c)(1) (Clinical quality measures — record and export). As discussed above, the ONC-ACB has identified and carefully considered the scope of the product’s required capabilities, focusing on the timeliness of the CQM export capability. This is the central issue presented by the complaint and the ONC-ACB’s subsequent surveillance of the product in the field. On this basis, the ONC-ACB has determined that the following requirements are within the scope of the criterion and are relevant to evaluating the performance of the CQM export capability:

- (1) “Near real-time” export does not require that a user receive CQM data instantaneously upon entering a command to generate the export.
- (2) However, CQM export must be accomplished:
  - (i) quickly enough, and
  - (ii) consistently enough so as to be accurate for use

such that any delay does not substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement purposes.

The ONC-ACB has now completed its in-the-field surveillance, including interviewing users and the developer and observing the performance of the product’s CQM export capability in the ambulatory practice’s production environment. During its observation of the product’s performance, the ONC-ACB witnesses results being delivered within the 8-96hr timeframe the product’s developer noted could exist. However, the ONC-ACB also observes that when the results are returned with extended delays the data returned is inconsistent with the practice’s data and as such not accurate enough for their use. Based on these first-hand observations, the ONC-ACB concludes that the CQM export capabil-

ity, as made available to users in the field, does not conform to the requirements of 45 CFR 170.315(c)(1)(ii).<sup>9</sup>

In reaching this conclusion, the ONC-ACB determines that while not requiring instantaneous delivery, the certification criterion requires that CQM data be available quickly enough and consistently enough such that any delay does not substantially interfere with the ability of a provider or health system to view and verify their CQM results for quality improvement purposes.

Here, the manner in which the CQM export capability has been designed and made available to users in the field falls short of the criterion's required outcomes. Even assuming *arguendo* that a delay of up to 96 hours before CQM results are delivered would not itself be a non-conformity, the combination of the delay and inconsistent delivery of results, which gives the practice inaccurate information at times, prevents the practice from effectively using this certified capability for quality improvement purposes as intended.

The foregoing findings and analysis indicate that the product, due to its design limitations and the manner in which it has been made available, does not support the full use of the CQM export capability in the ambulatory practice's production environment, including the ability to realize all uses, use cases, workflows, and other production outcomes that are consistent with the intended purposes and objectives of the certification criterion at 45 CFR 170.315(c)(1). As such, the product does not conform to the requirements of its certification.

## 2. Has the Developer Impermissibly Interfered with the Use of Certified Capabilities?

When making required capabilities available to users, developers may not engage in any actions or omissions that substantially interfere with—or would be likely to substantially interfere with—the ability of any current or future user to successfully implement or use required capabilities or to realize required outcomes ([80 FR 62711](#)). If an ONC-ACB determines that a developer has engaged in such actions or omissions, the ONC-ACB must make a finding of non-conformity. In addition, the ONC-ACB must require the developer to take corrective action to cure the interference and restore the full use of the affected capabilities for all users who have been, or who may be, affected (45 CFR 170.556(d)).

ONC-ACBs should keep in mind several points when determining whether a particular action or omission constitutes an impermissible interference:

- The term *interference* is to be construed broadly. It includes, for example, the imposition of limitations, restrictions, fees, contractual terms, technical limitations, or other circumstances that could in any way prevent a user from successfully implementing or using a required capability or achieving a required outcome ([80 FR 62711](#)).
- An *interference* need not involve an affirmative act, but may also result from a developer's omissions or failure to fulfill its responsibilities under the Program. For example:

---

<sup>9</sup> A separate non-conformity might also arise to the extent that the limitations described in this scenario are not disclosed by the developer to its customers in accordance with the requirements of 45 CFR 170.523(k)(1). While a developer is required to disclose, to all current and prospective customers and users, all material limitations related to a product's certification, the act of making a disclosure about a limitation does not necessarily mean that the product will escape a finding of non-conformity, particularly in the event that an undisclosed limitation prevents a required capability from conforming to the requirements of its certification, or is otherwise impermissible. See Disclosure of Material Information Resource.

- ↳ The failure to supply users with necessary training materials or other information could interfere with the successful implementation or use of required capabilities ([80 FR 62711](#); [81 FR 72413](#)).
- ↳ The failure to disclose material limitations or types of costs may, in certain circumstances, interfere with the use of a required capability or the achievement of a required outcome for one or more users ([80 FR 62711](#); [81 FR 72413](#)).
- Only interferences that are *substantial*—that is, likely to substantially interfere with the implementation or use of a required capability—will give rise to a non-conformity.
- To determine whether an interference is substantial, an ONC-ACB must exercise its professional judgment and should consider, among other relevant considerations:
  - ↳ The likely impact of the interference on the ability of a customer or user to successfully implement and use the required capability and to realize its associated outcomes (*see* Part III.C).
  - ↳ The reasonable expectations and abilities of customers and users to whom the product is marketed and made available, and to other relevant facts or circumstances (*see* Part III.D) that could limit or frustrate the ability of customers and users to successfully implement and use the required capability for its intended purposes and objectives.
- An interference is substantial if, without limitation—
  - ↳ The interference has or could have the effect of preventing a user from utilizing the required capability or realizing any of its associated outcomes<sup>10</sup> ([80 FR 62711](#)); or
  - ↳ The interference has or could have the effect of impeding or frustrating a user from fully utilizing the capability or fully realizing any associated required outcome. For example:
    - the use of a required capability disrupts the clinical workflows used by a health care professional to deliver care in connection with the certified product;
    - it takes an unreasonable amount of time or effort to achieve a required outcome, such that the capability cannot be used effectively for the delivery of care; or
    - the use of a required capability requires the performance of additional processes or steps that are not necessary or that could reasonably be achieved through less burdensome means.
- Finally, an ONC-ACB need not find that substantial interference with a required capability *has* occurred, but only that such interference is likely to occur—whether for one or more existing users or future users to whom the developer may market its certified product ([80 FR 62719](#)).

To further illustrate these principles and their application, the following are examples of actions or omissions that would constitute a substantial, and thus impermissible, interference with the successful implementation or use of required capabilities. We note that this is not an

---

<sup>10</sup> For the sake of completeness, we note that a user does not need to attempt to utilize the capability or attempt to realize the outcome before an impermissible interference will be considered a non-conformity. For example, a latent limitation that would be likely to substantially interfere with the successful use of a required capability would constitute a non-conformity even if it has not yet affected any user.

exhaustive list, and that in all cases an ONC-ACB must exercise its professional judgment, in light of relevant facts and circumstances, as explained in Part II.D.

- A developer disables functionalities, workflows, or other aspects that are within the scope of the product’s required capabilities.
- A developer discourages customers or users from implementing or using certain aspects of a required capability, or achieving certain associated outcomes, such as by limiting warranties, technical support, or other services provided to customers or users, or by requiring customers or users to specifically request that required capabilities be “enabled.”
- A developer imposes substantial additional costs for the use of a required capability that were not disclosed at the time the certified product was purchased or licensed (*see* Part III.E.2.a).
- A developer changes or insists on new contract or license terms that substantially interfere with the continued use of required capabilities by existing customers or users (*see* Part III.E.2.a).
- A developer makes required capabilities available but does so in a manner that imposes a substantial burden on their use, such as by—
  - ↳ requiring customers or users to expressly request that a particular aspect be enabled, complete unnecessary documentation, or satisfy other conditions that are unnecessary (or, if necessary, for which less burdensome approaches are available); or
  - ↳ designing or making such aspects available in a manner that requires unnecessary involvement by, or dependence on, the developer (e.g., requiring the developer’s intervention each time the user wishes to perform a batch export or send a Direct message to a new recipient).
- A developer refuses to work in good faith with a customer’s employees or contractors or will do so only on terms that are so onerous as to amount to a refusal.

**a. Impermissible Interference Arising from a Developer’s Failure to Disclose Known Limitations or Additional Types of Costs**

The Mandatory Disclosure Requirement (45 CFR 170.523(k)(1)) requires developers to disclose known material limitations and additional types of costs that a user may encounter to implement or use certified products. This requirement seeks to protect customers and users from encountering unanticipated implementation issues and costs after they have already purchased or licensed a particular certified product.

In some cases, the nature of a material limitation or additional type of cost may be such that the failure to disclose it causes a customer or user to experience unanticipated implementation or other challenges that substantially interfere with their ability to successfully implement or use a required capability or to realize a required outcome. As to these affected customers or users, the disclosure violation is secondary to the developer’s failure, as a result of its omission, to make the product available in a manner that supports the use of all required capabilities (*see* Part III.E.1). Accordingly, the ONC-ACB must require the developer to take corrective action not only to cure the disclosure violation but to restore the full use of the required capabilities for those customers and users to whom the material information was not disclosed ([80 FR 62717](#)). For information on corrective actions that a developer may need to take to correct a disclosure violation and/or

an impermissible limitation or additional type of cost, see Part IV of the Disclosure of Material Information Resource.

### 3. Do Required Capabilities Perform in an Accurate, Reliable, and Successful Manner?

The mere inclusion of required capabilities in a product's design is not, in and of itself, sufficient. Rather, to conform to the requirements of its certification, a product must enable the *successful* use of all required capabilities and associated outcomes in the field ([80 FR 62708](#); [81 FR 72420](#)). This is essential to providing customers and users who rely on certifications issued under the Program with confidence that their certified products will perform as expected and in an acceptable manner in users' production environments.

Certified products must be made available by developers such that, when deployed in the field, the product:

- Will function in a manner that is consistent with the purposes and objectives of the certification criteria to which the product is certified, including all potential uses, use cases, workflows, and other production outcomes that products certified to those criteria are intended to enable or support (45 CFR 170.545; 170.550; [80 FR 62710–12](#); [81 FR 72412](#)); and
- Enables users to implement the product in an accurate, reliable, and successful manner ([80 FR 62708](#); [81 FR 72412](#); [81 FR 72420](#)).

For example, a product will not conform to the requirements of its certification if:

- The product is made available for use in the field in such a way that it does not respond promptly to commands entered by a user, thereby rendering a required capability ineffective or unusable for a reasonable user in the circumstances. This scenario could arise, for example, if the response time for commands entered into an EHR was too slow to meet the requirements of a health care provider's clinical workflow;
- A developer fails to provide adequate technical or other support to a customer or user (which it is required to provide under the terms under which the product is supplied) such that a reasonable user cannot avail themselves of required capabilities or cannot achieve required outcomes without special effort; and
- A product performs in a manner that is unpredictable or unreliable, or that is otherwise likely to prevent a reasonable user, in the circumstances, from consistently and successfully achieving a required outcome. This scenario could arise, for example, if a medication list was presented differently to a health care professional depending on the EHR screen visited by the health care professional immediately prior to viewing the medication list.

To illustrate this aspect of post-certification assessment, we reiterate an example included in the EOA final rule ([81 FR 72421](#)):

#### ***Scenario – Clinical Decision Support Interventions***

In the course of treating a patient in a hospital's emergency department (ED), an attending physician accessed the patient's record in the EHR and, observing that no blood tests had been ordered, proceeded to order relevant lab tests from a standard order set. Contemporaneously, a nurse was in the process of entering the same lab tests from the same order set. The nurse completed her order a few seconds before the physician completed hers. Neither the nurse nor physician recall any duplicate order alerts, although hospital IT staff state that clinical decision support (CDS) was active in the EHR system and had been configured to intercept and display alerts when duplicate orders are entered.

The duplicate orders were noticed later when the physician was reviewing the patient's record in the EHR. At that time, the physician cancelled the nurse's order, which thereafter was no longer displayed in the EHR. The EHR continued to display the physician's order with a status of "pending collection." The lab system assumed that the identical lab requests for the same patient were duplicates and cancelled the physician's request because the nurse's request had arrived first. The lab system, however, did not create an outgoing interface message to the ordering EHR indicating that the physician's "duplicate" request had been cancelled. As a result, the physician's order continued to be displayed in the EHR with a status of "pending collection."

The hospital's clinical staff and leadership believe the EHR is not performing appropriately and lodge a complaint with the EHR developer's ONC-ACB. The complaint states that in a large and busy ED it is not uncommon for health care professionals to enter contemporaneous orders.

An ONC-ACB conducting in-the-field surveillance in response to the complaint would assess the performance of, among other required capabilities, the CDS capabilities set forth at 45 CFR 170.315(a)(9). This certification criterion provides in part that "interventions provided to a user must occur when a user is interacting with the technology" (*see* 45 CFR 170.315(a)(9)(i)). The criterion also specifically references interventions based on lab results (*see* 45 CFR 170(a)(9)(ii)(B)(1)(v)). Understood in light of the purposes and objectives of the certification criterion, as set forth in the corresponding preamble provisions of the 2015 Edition final rule,<sup>11</sup> it is evident that while the criterion allows flexibility as to which interventions a developer supports, once a particular intervention is configured it must consistently trigger in a timely manner that supports clinical decision-making.

Accordingly, if the ONC-ACB identified that the certified CDS capability was in fact configured to trigger an intervention for duplicate orders but failed to consistently trigger such interventions, and assuming that such failure was within the developer's ability to reasonably influence or control, the ONC-ACB would make a non-conformity finding on the basis of the product's failure to perform in an accurate and reliable manner.

#### 4. Developer's Ability to Reasonably Influence or Control

If a certified product fails to perform in an acceptable manner, an ONC-ACB should determine (to the best of its ability) the reasons for the failure before it can conclude that the product fails to conform to the requirements of its certification. This determination should always take into account the role of the technology as well as the roles played by the health IT developer, users, and other relevant parties.

There may be instances in which certified health IT cannot successfully perform required capabilities or outcomes for reasons that the developer cannot reasonably influence or control ([80 FR 62710](#)). We have explained that the requirements of the Program that apply to developers focus only on aspects of health IT that they can reasonably influence or control. Where an ONC-ACB determines that a certified product is not performing in an acceptable manner due to factors that are far removed from the ability of the developer to reasonably influence or control, the ONC-ACB will not find a non-conformity ([80 FR 6710](#)). For example, an ONC-ACB will not find a non-conformity if the failure of a product to satisfy a requirement is attributable solely to:

---

<sup>11</sup> *See* 80 FR 16820 ("CDS is a primary means of supporting the implementation of best evidence and new knowledge at the point of care and in real time . . . . When effective decision support is presented in a useful manner, it enhances usability and helps providers and patients avoid medical errors.")

- matters that are reasonably committed to the responsibility of users or other persons;
- aspects of third party technology or relied-upon software that are far removed from the developer’s reasonable influence or control; or
- clear and unavoidable user error.

We emphasize that the concept of “control” does not mean that an ONC-ACB must find that a developer or its certified product were the sole—or even a predominant—cause of the product’s failure to satisfy a requirement. If the developer or its product were one substantial cause of the failure, even if there were other contributing factors, then the product does not conform to the requirements of its certification.

**a. Matters Reasonably Committed to the Responsibility of Users or Others Persons**

Certified health IT is provided to users under a range of commercial terms. Under some arrangements, a certified product is provided in an application services provider model where a developer delivers and maintains the software and provides ongoing services to assure conformity with all Program requirements. Under other arrangements, a developer’s role is more confined and may not involve, for example, routine maintenance between software releases. ONC-ACBs are usually very familiar with the various types of arrangements that exist in the market for certified health IT products and will consider the scope of a developer’s reasonable responsibilities when assessing the reasons why a certified product is not performing in an acceptable manner.

The following contrasting scenarios illustrate how a performance issue may or may not be reasonably committed to the responsibility of users or other persons and thus fall beyond a developer’s ability to reasonably influence or control ([80 FR 62710](#)):

***Scenario – Linked Referential Clinical Decision Support***

An ONC-ACB initiates in-the-field surveillance of a product certified to the clinical decision support (CDS) certification criterion at 45 CFR 170.315(a)(9). The ONC-ACB observes the use of the capability at a location at which it has been implemented. The ONC-ACB observes as a user unsuccessfully attempts to access user diagnostic or therapeutic reference information for a patient as required by the criterion. The ONC-ACB then performs a series of troubleshooting and diagnostic exercises with the provider and the developer of the certified product. After additional fact-finding and analysis, the ONC-ACB concludes that the failure of the technology to perform as expected was caused by the failure to implement a routine update of the linked referential clinical decision support component of the product. Under the terms of the provider's agreement with the developer, the developer was solely responsible for implementing routine updates in return for an annual maintenance fee, which the provider had paid in full.

Based on these facts, the ONC-ACB would find a non-conformity because the failure of the certified health IT to function as expected was due solely to the actions of the developer that prevented the user from accessing capabilities to which the health IT was certified.

***Scenario – Minimum Hardware and Network Requirements***



An ONC-ACB determines as part of its post-certification assessment that a hospital has chosen not to install and maintain the minimum specified hardware and network requirements published by the developer of the certified health IT. As a direct result of the substandard hardware and network connectivity, the certified health IT is suffering system timeouts, losing network packets, and not operating correctly.

Based on these findings, the ONC-ACB would find that while the certified capability is not performing in an acceptable manner, the reason for the substandard performance is that the hospital has chosen not to follow the developer's minimum hardware and network recommendations. The hospital's decision to intentionally disregard the developer's clear instructions regarding certified health IT is a factor that is beyond the ability of the developer to reasonably influence or control. Therefore, the ONC-ACB would not find a non-conformity.

**b. Aspects of Third-party Technology Outside of Developer's Reasonable Influence or Control**

A developer may not necessarily control whether a customer deploys third-party products in conjunction with the developer's certified health IT, or the manner in which those third-party products perform or interact with the developer's certified health IT. Developers are required to take reasonable steps to ensure that third-party products that the developer anticipates will be used with its certified product perform in accordance with the requirements of the product's certification. However, to the extent that a developer cannot reasonably anticipate the use of a third-party technology or cannot reasonably influence or control some failure of a third-party technology, the failure of the technology or software would not by itself give rise to a non-conformity ([80 FR 62710](#)).

We note that the foregoing does not apply to relied-upon technology. Developers who use relied-upon technology to meet certification requirements are deemed in control of and responsible for ensuring that their products and any relied-upon technology conform to the requirements of the product's certification.

***Scenario – Clinical Decision Support Reference Information***

An ONC-ACB initiates in-the-field surveillance of a Health IT Module certified to the clinical decision support certification criterion (CDS) 45 CFR 170.315(a)(9). The ONC-ACB observes the use of the capability at a location at which it has been implemented. The ONC-ACB observes as a user unsuccessfully attempts to view user diagnostic or therapeutic reference information for a patient as required by the criterion. Upon further evaluation, the ONC-ACB learns that the provider had notified the developer that it did not wish to purchase or sublicense the standard clinical reference information bundled with the developer's clinical decision support technology and requested instead that the developer integrate its technology with the provider's preferred third-party database of clinical reference information. The developer agreed to integrate the third-party database information as requested, but in writing advised the provider that, because the developer did not have a sublicensing agreement in place with the third-party vendor, the provider would be responsible for obtaining and maintaining the necessary licenses for access to the third-party vendor's database. The developer successfully integrated the third-party database information as requested, and the required capabilities performed as expected using the third-party database information for several months prior to the ONC-ACB's surveillance. However, at the time of the surveillance, access to the third-party database information had been temporarily suspended because of the provider's failure to pay sev-

eral outstanding invoices from the third-party vendor—the result of an oversight in the provider's accounting department. Because of the suspension in service, the technology, which was otherwise performing as required by its certification, was unable to retrieve and display user diagnostic and therapeutic reference information.

Based on these facts, the ONC-ACB would not find a non-conformity because, while the technology was unable to perform required capabilities in the field, the failure was caused by factors far removed from the control or responsibility of the developer. Indeed, the developer took care to warn the provider that, while the technology could be customized to support third-party database information, the provider would be responsible for maintaining any necessary licenses for access to the third party database information.

If an ONC-ACB suspects that a product's performance may be affected by third party technology or relied upon software that interacts with one or more required capabilities of a certified product, it may be necessary for the ONC-ACB to inquire into some or all of the following matters as part of its surveillance:

- Is the third party technology outside of the developer's reasonable influence or control?
- Was the developer aware of the third party product, or should they have been?
- Could the developer have reasonably anticipated that its customer might implement, configure, or customize the product in the manner it has?
- What instructions, if any, did the developer provide its customer about the proper implementation and configuration of its certified product?
- What representations, if any, did the developer make to its customer about the impact that the third party product (or any third party product) might have on the performance of any required capabilities?
- What is the developer's role, if any, to support the third party technology, and has that role been fulfilled?

**c. Clear and Unavoidable User Error**

In rare instances, performance issues impacting a product's conformity with its certification can be attributed exclusively to clear and unavoidable user error. Such performance issues, to the extent that they implicate the requirements of the product's certification, are beyond the control of a developer and should not be grounds for a finding of non-conformity.

ONC-ACBs should be careful in attributing performance issues to user error. It is reasonable to assume that health IT developers are experts on their own products and services and possess sophisticated technical and market knowledge related to the implementation and use of health IT in a variety of settings in which their products are used ([80 FR 62721](#)). It is also reasonable to expect developers to take reasonable steps to educate users on the proper use of their products, to design their products to be fault-tolerant and user-centered, and to implement safeguards against reasonably foreseeable user errors and other human factors.

Accordingly, an ONC-ACB may not discount a non-conformity on the basis of user error unless:

- the product's failure was caused exclusively by the actions of a user;

- the user’s actions constituted a clear deviation from the product’s design and supported operations;
- a reasonable user would have known that the actions constituted such a deviation; and
- the developer could not reasonably have anticipated or taken steps to accommodate or prevent the deviation.

To illustrate this distinction, we provide the following examples:

- An ONC-ACB finds that certified health IT was not performing appropriately because a user failed to populate several required data fields. The ONC-ACB would not hold the developer responsible if it found, for example, that the user routinely bypassed structured data fields and instead entered data in a free-form “notes” field and this was contrary to the user’s training and the clear instructions presented to the user on the data-entry screen.
- In contrast, the ONC-ACB *would* hold the developer responsible if the user did not populate required data fields due in part to usability or design deficiencies of the product (e.g., a user takes advantage of a shortcut to access a data entry field, but that field behaves differently depending on the page accessed immediately prior to entering the data). In this case, the failure was not exclusively caused by the actions of the user; the user’s actions were not a clear and unreasonable deviation from the product’s design and supported operations; and the developer should have anticipated and taken steps to accommodate or prevent the “error.”
- A health care professional ignores warning prompts served up by certified health IT. The developer’s product would not ordinarily be held responsible for errors that flow from the health care professional’s actions in this case. However, if the product has been designed so that warning prompts are not conspicuous or do not have appropriate particularity, the product will be a contributing factor to the performance failure and would be non-conforming.

#### **IV. OTHER POST-CERTIFICATION REQUIREMENTS**

---

While ONC-ACB’s post-certification assessments will focus primarily on evaluating the performance of certified products in the field, there are a number of other Program requirements that must also be administered after products are certified. This Part outlines some of these post-certification requirements that merit special attention by ONC-ACBs. The following is not an exhaustive list of requirements and should be reviewed in conjunction with other applicable resources and regulations (*see* Part I.A).

##### **A. Disclosure of Known Material Information**

The 2015 Edition final rule requires health IT developers to conspicuously disclose—in plain language on their websites and in all marketing materials, communications statements, and other assertions related to their certified products—a detailed description of all known material information concerning limitations and additional types of costs that a person may encounter or incur to implement or use certified health IT capabilities (45 CFR 170.523(k)(1)).

The effective surveillance and enforcement of this Mandatory Disclosure Requirement is critical to users of certified health IT and to the overall effectiveness of the ONC Health IT Certification Program. The disclosures developers must make to comply with this requirement help customers

and users of certified products better understand the capabilities, limitations, and trade-offs of competing health IT products and services, allowing them to more effectively compare and select health IT solutions that meet their needs. In the absence of these disclosures, customers and users are less likely to be able to select appropriate technologies and are more likely to encounter unanticipated costs, limitations, and problems when attempting to implement and use certified health IT.

ONC-ACBs are expected to exercise the same degree of professional judgment in their assessment of developers' disclosures as they would when assessing other types of post-certification requirements, such as the performance requirements described in Part IV above ([80 FR 62722](#)). In this context the exercise of professional judgment will include assessing whether, in light of the objectively reasonable expectations of customers and users and other relevant circumstances, a developer's disclosures conform to requirements relating to:

- The **manner of the disclosure made**, including that:
  - ↳ Disclosures are made in all required forms;
  - ↳ Disclosures are sufficiently conspicuous; and
  - ↳ Disclosures are accessible.
- The **substance of the disclosures made**, including that:
  - ↳ Disclosures are complete;
  - ↳ Disclosures have the requisite particularity; and
  - ↳ Disclosures are in plain language.

ONC's **Disclosure of Material Information Resource** provides ONC-ACBs with detailed information on the evaluation factors and other considerations that ONC-ACBs must apply to this assessment.

## **B. Cooperation with Testing, Certification, and Surveillance**

As a condition of certification, developers must cooperate in good faith with processes for the testing, certification, and surveillance of their certified products and must not take actions that could undermine or circumvent those processes ([81 FR 72412–13, 72420](#); *see also* [80 FR 62716–18](#)). A developer's involvement in the surveillance of certified health IT can improve the work of ONC-ACBs in a variety of ways, and ONC encourages developer involvement where appropriate. Developers can, for instance, provide technical assistance to ONC-ACBs in understanding and analyzing variations not seen during the testing and certification process and other complexities. Developers can also assist in analyzing and determining the causes of issues, provided such assistance does not compromise the ONC-ACB's independence or the requirements of its accreditation ([80 FR 62709](#)).

This requirement of good faith cooperation includes but is not limited to:

- Responding in a timely manner to inquiries from an ONC-ACB.
- Furnishing information and assistance that an ONC-ACB determines is necessary to inform its surveillance or any other determination under the Program.
- Proactively reporting and encouraging customers and users to report potential non-conformities and other problems or issues involving certified health IT or the health IT developer.

An ONC-ACB must find a non-conformity and take other remedial actions, consistent with its accreditation and the Principles of Proper Conduct (45 CFR 170.523), if it determines that a developer has engaged in any action that is likely to undermine the testing, certification, or surveillance of health IT under the Program, including but not limited to the following actions:

- Falsifying test results or attempting to manipulate, circumvent, or “game” the testing procedures and processes administered by ONC-ATLs or the certification and surveillance processes administered by ONC-ACBs.
- Concealing or withholding—or causing to be concealed or withheld—any information that may be relevant to any determination by an ONC-ATL or ONC-ACB, such as information related to a potential non-conformity with Program requirements.
- Submitting or causing to be submitted information that the developer knows or should know to be false, inaccurate, or misleading.
- Misrepresenting or making false or misleading statements to customers or users about the certification or required capabilities of the developer’s health IT.
- Engaging in reprisal, retaliation, or any other action that could discourage or prevent a person from reporting problems or issues with certified health IT or with a health IT developer, or from cooperating with the authorized surveillance or oversight of the developer’s certified health IT.

If an ONC-ACB suspects that a developer has taken these or other actions that may undermine the testing, certification, or surveillance of certified health IT, the ONC-ACB must immediately notify ONC in addition to taking other appropriate remedial actions consistent with its accreditation and responsibilities under the Program ([81 FR 72420](#)).

### **C. Providing Information to ONC-ACBs**

Upon request, a developer must provide its ONC-ACB with any information relevant to the ONC-ACB’s certification and surveillance of the developer’s products (80 FR 62716).<sup>12</sup> Such information includes but is not limited to the following:

- Information about the developer’s customers and users, including customer lists and contact information.
- User complaints and complaint logs, service tickets, and other records related to customers’ and users’ experience with the performance of certified health IT.
- Information about the developer’s quality management systems, user-centered design processes, and other internal processes that may bear on the accuracy or reliability of required capabilities.
- Marketing materials, communications, and other assertions about the developer’s certified products, whether made publicly or to prospective customers, users, or other persons.
- Contracts, service agreements, policies, fee schedules, and other materials containing information relevant to any Program requirement, including information about types of costs or limitations associated with a developer’s certified products or capabilities.
- Any other information that the ONC-ACB determines is necessary to enable it to carry out its testing, certification, or surveillance responsibilities with respect to the developer or the developer’s certified products.

Developers are responsible for ensuring the accuracy and completeness of all information provided to an ONC-ACB and for proactively disclosing all information that may be material to the testing, certification, or surveillance of the developer or its products. If at any time a developer has reason to believe that the information it has provided is inaccurate, misleading, incomplete, or in any other

---

<sup>12</sup> As described in the 2015 Edition final rule, we expect ONC-ACBs to provide for appropriate safeguards against disclosure of proprietary and confidential information ([80 FR 62718](#)).

way deficient, it must immediately notify the ONC-ACB and provide all information necessary to correct the deficiency.

If an ONC-ACB suspects that a developer has made false or misleading statements or representations or engaged in other actions that may call into question the validity of a certification or the integrity of the Program, the ONC-ACB should immediately notify ONC, in addition to taking other appropriate action consistent with its accreditation and responsibilities under the Program.