

2015 Edition §170.315(a)(14) Implantable Device List					
Testing Components:					
Test Procedure Version 1.1 – Last Updated 10//15					

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification criterion with which these testing steps are associated. We also encourage developers to consult the Certification Companion Guide in tandem with the test procedure as they provide clarifications that may be useful for product development and testing.

Note: The order in which the test steps are listed reflects the sequence of the certification criterion and does not necessarily prescribe the order in which the test should take place.

Required Tests

(a)(14) Implantable device list

(i) Record Unique Device Identifiers associated with a patient’s Implantable Devices.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(i)	The user records the unique device identifiers for a patient’s implantable device.	The tester verifies the unique device identifiers are recorded for a patient’s implantable device.

(ii) Parse the following identifiers from a Unique Device Identifier (UDI):

(A) Device Identifier;

(B) The following identifiers that compose the Production Identifier:

- (1) The lot or batch within which a device was manufactured;
- (2) The serial number of a specific device;
- (3) The expiration date of a specific device;
- (4) The date a specific device was manufactured; and
- (5) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR § 1271.290(c).

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(ii)(A)	The Health IT module parses the Device Identifier from a UDI.	The tester verifies the Health IT module parses the Device Identifier from a UDI and able to parse the UDI in human readable format.

Criteria ¶	System Under Test	Test Lab Verification
(ii)(B)	<p>The Health IT module parses the following identifiers from a UDI:</p> <ol style="list-style-type: none"> (1) The lot or batch within which a device was manufactured; (2) The serial number of a specific device; (3) The expiration date of a specific device; (4) The date a specific device was manufactured; and (5) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR § 1271.290(c). 	<p>The tester verifies the health IT module parses the identifiers from an UDI that includes the items listed in 1-5.</p>

(iii) Obtain and associate with each Unique Device Identifier (UDI):

(A) A description of the implantable device referenced by at least one of the following:

- (1) The “GMDN PT Name” attribute associated with the Device Identifier in the Global Unique Device Identification Database.
- (2) The “SNOMED CT Description” mapped to the attribute referenced in paragraph (a)(14)(iii)(1) of this section.

(B) The following Global Unique Device Identification Database attributes:

- (1) “Brand Name”;
- (2) “Version or Model”;
- (3) “Company Name”
- (4) “What MRI safety information does the labeling contain?”; and
- (5) “Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).”

Standard(s): Global Medical Device Nomenclature (GMDN) – www.gmdnagency.org

[International Health Terminology Standards Development Organisation \(IHTSDO\) SNOMED CT® International Release July 2012 and US Extension to SNOMED CT® March 2012 Release](#)

Criteria ¶	System Under Test	Test Lab Verification
(iii)(A)	<p>The Health IT module obtains and associates with each UDI the description of the implantable device as one of the following:</p> <ol style="list-style-type: none"> (1) The “GMDN PT Name” attribute associated with the Device Identifier in the Global Unique Device Identification Database; or (2) The “SNOMED CT Description” code mapped to the attribute in step (a)(14)(iii)(1). 	<p>The tester verifies the description is obtained and associated with each UDI either “GMDN PT Name” attribute associated with the Device Identifier in the Global Unique Device Identification Database; or “SNOMED CT Description” code mapped to the attribute in step (a)(14)(iii)(1).</p> <p>Optionally the testers can use the Implant API at http://accessgudid.nlm.nih.gov/docs</p>
(iii)(B)	<p>The Health IT module is able to obtain and associate the following Global Unique Device Identification Database attributes:</p> <ol style="list-style-type: none"> (1) “Brand Name”; (2) “Version or Model Number”; (3) “Company Name”; (4) “What MRI safety information does the labeling contain?”; and (5) “Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).” 	<p>The tester verifies the Health IT module obtains and associates the Global Unique Device Identification Database attributes 1-5.</p>

(iv) Display to a user an implantable device list consisting of:

(A) The active Unique Device Identifiers recorded for a patient; and

(B) For each active Unique Device Identifier, the description of the implantable device specified by subparagraph (iii)(A) of this paragraph.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(iv)	The user is provided an implantable device list that consists of the following: (A) The active UDI recorded for a patient. (B) For each active UDI, the description of the implantable device specified by step (a)(14)(iii)(A).	The tester verifies the user is provided an implantable device list consisting of the active UDI recorded for a patient and the description of the implantable device specified by step (a)(14)(iii)(A) for each active UDI.

(v) For each Unique Device Identifier for a patient, enable a user to access:

- (A) The Unique Device Identifier;
- (B) The description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section;
- (C) The identifiers associated with the Unique Device Identifier, as specified by paragraph (a)(14)(ii) of this section ;
- (D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)(B) of this section.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(v)	The user has access to : (A) The Unique Device Identifier; (B) The description of the implantable device specified by step (a)(14)(iii)(A); (C) The identifiers associated with the Unique Device Identifier specified by step (a)(14)(ii). (D) The attributes associated with the Unique Device Identifier specified in step (a)(14)(iii)(B).	The tester verifies the user has access to the all items listed in A-D.

(vi) Enable a user to change the status of Unique Device Identifier recorded for a patient.

Standard(s): None

Criteria ¶	System Under Test	Test Lab Verification
(vi)	The user is able to change the status of a Unique Device Identifier recorded for a patient.	The tester verifies the status of the Unique Device Identifier for a patient is changed.

Document History

Version Number	Description of Change	Date
1.0	Released for Comment - NPRM	March 20, 2015
1.1	Released for Comment - FR	October , 2015

Dependencies: For all related and required criteria, please refer to the [Master Table of Related and Required Criteria](#).