§170.315(a)(14) Implantable device list

2015 Edition Test Procedure

Version 1.3 Updated on 09-21-2017

Revision History

Version #	Description of Change	Version Date
1.0	Final Test Procedure	01-08-2016
1.1	Removed active UDI from step in paragraph (a)(14)(iv).	03-08-2016
1.2	Updated paragraph (a)(14)(ii)(A), paragraph (a)(14)(ii)(B), and paragraph (a)(14)(iii)(A) to clarify in all formats established by the 3 UDI issuing Agencies. Updated paragraph (a)(14)(iv)(A) to UDIs, plural.	04-08-2016
1.3	As of September 21, 2017, Test Procedure has been moved to Attestation/Developer self-declaration only.	09-21-2017

Regulation Text

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§170.315 (a)(14) *Implantable device list*—

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

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

(A) Device Identifier; and

(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).

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

(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 in paragraph (a)(14)(iii)(A)(*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)."

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

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

(B) For each active Unique Device Identifier recorded for a patient, the description of the implantable device specified by paragraph (a)(14)(iii)(A) of this section; and

(C) A method to access all Unique Device Identifiers recorded for a patient.

(v) For each Unique Device Identifier recorded 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; and

(D) The attributes associated with the Unique Device Identifier, as specified by paragraph (a)(14)(iii)(B) of this section.

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

Standard(s) Referenced

None

Additional Resources:

AccessGUDID

Global Medical Device Nomenclature (GMDN)

§ 170.207(a)(3) International Health Terminology Standards Development Organisation (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®) International Release July 2012 and US Extension to SNOMED CT® March 2012 Release

Testing components

Self-Declaration: As of September 21, 2017, the testing approach for this criterion is satisfied by self-declaration.

The archived version of the Test Procedure is attached below for reference.

System Under Test	Test Lab Verification
The health IT developer submits their self-declaration to the ONC-ATL.	The Tester verifies the self-declaration document contains all of the required data elements.

Archived Version:

§170.315(a)(14) Test Procedure

Content last reviewed on September 24, 2018