Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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I. Introduction

When finalized, this draft document will clarify for industry, FDA-accredited issuing agencies, and FDA staff the requirements under 21 CFR 801.40. Specifically, this draft guidance defines the expected content and forms of the Unique Device Identifier (UDI), to assist both labelers, as defined under 21 CFR 801.3, and FDA-accredited issuing agencies, as defined under 21 CFR 830.3, to better ensure the UDIs developed under systems for the issuance of UDIs are in compliance with the Unique Device Identification System Rule, 78 FR 58786 (September 24, 2013) (UDI Rule).

Throughout this draft guidance document, the terms "we," "us" and "our" refer to FDA staff from Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER).

FDA's guidance documents, including this draft guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The UDI Rule, establishing the unique device identification system, was published on September 24, 2013.

The main objective of the UDI system is to adequately identify devices through distribution and use. The UDI Rule requires the label and device packages of every medical device distributed in the United States to bear a UDI, unless an exception or alternative applies (21 CFR 801.20). The UDI must be issued by an FDA-accredited issuing agency that operates a system that conforms to the international standards listed under 21 CFR 830.20. The UDI must be presented in two forms on the label and device packages: easily readable plain-text and automatic identification and data capture (AIDC) technology (21 CFR 801.40(a)). When a device must bear a UDI as a direct marking, the UDI may be provided through either or both easily readable plain-text and AIDC technology forms, or any alternative technology that will provide the UDI of the device on demand (21 CFR 801.45(c)).

In addition to the UDI label requirements under 21 CFR 801 Subpart B, labelers must submit product information concerning devices to FDA's Global Unique Device Identification Database (GUDID), unless subject to an exception or alternative (21 CFR 830 Subpart E). Most of the information submitted to GUDID is available to the public through AccessGUDID.

The UDI Rule is intended to create a standardized identification system for medical devices used in the United States. As stated in the preamble, this system makes it possible to rapidly and definitively identify a device and some key attributes that affect its safe and effective use (78 FR 58786). The UDI Rule specifies that the labeler, as defined under 21 CFR 801.3, is responsible for complying with the UDI labeling (21 CFR 801 Subpart B) and GUDID submission (21 CFR 830 Subpart E) requirements. The UDI Rule also requires UDIs to be issued under a system operated by an FDA-accredited issuing agency (21 CFR 830.20(a)). Each labeler, therefore, must work with one or more FDA-accredited issuing agencies to develop UDIs for devices that are required to bear a UDI. In order for there to be an effective identification system, it is essential that the FDA-accredited issuing agencies develop and operate systems for the assignment of UDIs that allow labelers using these systems to be in compliance with UDI labeling requirements.

In this guidance, we will describe the two forms of a UDI and clarify the content of the UDI, including the data delimiters that identify specific data elements within the UDI. The order of the data in a UDI and UDI carrier will be discussed as well.

III. Definitions

For purposes of this guidance, we define the following terms:

Automatic identification and data capture (AIDC)
Any technology that conveys the unique device identifier (UDI) or the device identifier (DI) portion of a UDI of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. 21 CFR 801.3. See section IV.A.2.

Data delimiter
Within an encoded data string, a defined character or set of characters that identifies specific data elements. See section IV.D.

Device identifier (DI)
A mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device. 21 CFR 801.3.

Easily readable plain-text
The legible interpretation of the data characters encoded in the AIDC form of the UDI, including the data delimiters. See section IV.A.1.

Production identifier (PI)
A conditional, variable portion of a UDI that identifies one or more of the following when included on the label of the device:

(a) The lot or batch within which a device was manufactured;
(b) The serial number of a specific device;
(c) The expiration date of a specific device;
(d) The date a specific device was manufactured;
(e) For an HCT/P regulated as a device, the distinct identification code required by 21 CFR 1271.290(c) of this chapter. 21 CFR 801.3.

Unique device identifier (UDI)
An identifier that adequately identifies a device through its distribution and use by meeting the requirements of 21 CFR 830.20. A unique device identifier is composed of a device identifier (DI), any applicable production identifiers (PIs), and the data delimiters for the DI and PIs included in the UDI. See section IV.

UDI carrier
The means to convey the UDI and any non-UDI elements by using easily readable plain-text and AIDC forms. See section IV.E.

IV. Unique Device Identifier (UDI)

The UDI, as defined under 21 CFR 801.3, is an identifier that adequately identifies a device through its distribution and use. Under the UDI Rule, the UDI must meet the requirements of 21 CFR 830.20- Requirements for a unique device identifier, and 21 CFR 801.40- Form of a unique device identifier. A UDI is composed of (1) a device identifier (DI), (2) typically one or more production identifiers (PIs) when included on the device label, and (3) the data delimiters for the

DI and PIs included in the UDI. Under 21 CFR 801.20, a UDI is required on the label and package of every device in commercial distribution in the United States as of the applicable compliance date, unless an exception or alternative applies.

Under 21 CFR 830.20, a UDI must be issued under a system operated by an FDA-accredited issuing agency and conform to the following international standards incorporated by reference in the UDI Rule under 21 CFR 830.10: ISO/IEC 15459-2; ISO/IEC 15459-4; and ISO/IEC 15459-6. Additionally, the UDI may only use characters and numbers from the invariant character set of ISO/IEC 646. It is critical that each FDA-accredited issuing agency develop and operate a system for the assignment of UDIs that allows labelers to confidently use the FDA-accredited issuing agency's system to develop UDIs that are in compliance with the UDI labeling requirements under 21 CFR 801 Subpart B. Therefore, the FDA-accredited issuing agencies' systems for issuing UDIs should align with the UDI labeling requirements.

A. Forms of UDI

21 CFR 801.40(a) specifies that the UDI must be presented in both easily readable plain-text and AIDC technology forms on the label of the device and on each device package. For those devices required to be directly marked with a UDI under 21 CFR 801.45, the UDI may be provided through either or both forms, or any alternative technology that will provide the UDI of the device on demand (21 CFR 801.45(c)).

The AIDC form of UDIs should be scanned or otherwise used for the identification of the device whenever possible to minimize errors in records resulting from manual transcriptions. UDIs, particularly when provided through AIDC technology, will allow rapid and accurate data acquisition, recording, and retrieval. The availability of the easily readable plain-text form allows patients, health care professionals, FDA, and other users of the UDI system to still read and enter the UDI into patient records, reports to FDA, and data systems without any technological assistance. Additionally, the easily readable plain-text form may be used as a failsafe to capture the UDI if the AIDC form cannot be scanned or used.

1. Easily readable plain-text

"Easily readable plain-text" means the legible interpretation of the data characters encoded in the AIDC form of the full UDI, including the data delimiters. The easily readable plain-text form of the UDI should include the device identifier (DI), production identifiers (PIs), and data delimiters contained in the UDI, and be limited to those characters specified under ISO/IEC 646. The easily readable plain-text form of the UDI may be presented as a single line or multiple lines of text and should be displayed below or near the AIDC technology form of the UDI.

2. AIDC

AIDC is defined under 21 CFR 801.3 as any technology that conveys the UDI or the DI portion of a UDI of a device in a form that can be entered into an electronic patient record or other computer system via an automated process. While the UDI Rule does not require the use of specific forms of AIDC or specific AIDC technologies to present the UDI, the AIDC form of the UDI should be in a format that can be read by a bar code scanner or some other AIDC technology. The labeler should also test that the AIDC form of the UDI is generated in such a way that the UDI can be reliably read at the point of scanning by the applicable type of technology.

Due to space limitations or other reasons, the AIDC form of the UDI may be split into multiple segments. For example, one UDI may be presented in two linear bar codes: one bar code for the DI and another bar code for the PIs. These two bar codes should be proximally located to each other on the device label, device packages, and when required, on the device itself. Additionally, the DI bar code should precede the PI bar code.

The labeler may choose to use more than one type of AIDC technology form to assist users who may be employing different methods of UDI capture technology. For example, a labeler may include a linear bar code and data matrix code (2-D) on the device label, both representing the same UDI. In this instance, only one easily readable plain-text form of the UDI should be on the label and should be in near proximity to one of the AIDC forms of the UDI.

If a labeler choses a bar code form of AIDC, the bar code form of the UDI should be tested for print quality. Please refer to the most recent version of the following standards for more information on how to determine the print quality: ISO/IEC 15416 Information technology -- Automatic identification and data capture techniques -- Bar code print quality test specification -- Linear symbols; ISO/IEC 15415 Information technology -- Automatic identification and data capture techniques -- Bar code symbol print quality test specification – Two-dimensional symbols; and ISO/IEC TR 29158 Information technology -- Automatic identification and data capture techniques – Direct Part Mark (DPM) Quality Guideline. For linear and 2-D bar codes, labelers should consult the most recent version of the standards listed above, and the guidelines of their FDA-accredited issuing agency, to determine the minimum overall symbol grade based upon ISO/IEC verification processes. For purposes of this draft guidance, we define "overall symbol grade" as the arithmetic mean of the grades of multiple scans of the symbol. The minimum acceptable grade should be satisfied under the expected handling and use life of the device. Labelers should discuss print quality requirements with their FDA-accredited issuing agency.

B. Disclosure of presence of AIDC technology

21 CFR 801.40(c) specifies that if the UDI presented in the AIDC technology format is not visible to the human eye upon visual examination of the label or device package (e.g., RFID technology), the label or device package must disclose the presence of AIDC technology. It is

up to the discretion of the labeler to determine how best to disclose the presence of AIDC technology that is not evident upon visual examination. The FDA does not require a specific type of marking or a symbol, providing the labelers greater flexibility and reduced burdens.

C. Content of UDI

We interpret 21 CFR 801.3 and 801.40 as specifying that a UDI is composed solely of a single DI and one or more of the five PIs listed in 21 CFR 801.3 and 801.40(b), along with the data delimiters for the DI and PIs. While some of the FDA-accredited issuing agencies may allow for non-UDI elements, such as quantity, in the UDI carrier, we do not recognize any such additional non-UDI elements as being part of the UDI.

The UDI Rule does not include any additional requirement to place any of the five elements that would be considered a PI on the label. There are some situations where a UDI may comprise a DI only. The UDI of a class I device, for instance, is not required to include a PI. However, it is important to note that for other than class I devices, if one or more of the five PIs defined under 21 CFR 801.3 are included on a device label, the UDI must include each of the PIs that appears on the label (21 CFR 801.40(b)).

D. Data delimiters

For the purposes of this draft guidance, "data delimiter" means a defined character or set of characters that identifies specific data elements within an encoded data string. The data delimiters are key to UDI comprehensibility and utility. The data delimiters indicate the DI value or the PI values that follow each data delimiter within the UDI, and may also indicate other non-UDI elements that may be included within the UDI carrier. Data delimiters for the DI and PIs should be included in the UDI. If non-UDI elements are included in the UDI carrier, separate data delimiters for these non-UDI elements outside the scope of a UDI should be included in the UDI carrier. Data delimiters should be included in both the easily readable plain-text and AIDC technology forms of the UDI.

The UDI elements should be able to be readily distinguishable and captured separately from any non-UDI elements that may be represented in the UDI carrier. The data delimiters allow users to parse the DI and PIs from the easily-readable plain text UDI, as well as to verify that the information encoded in the AIDC form of the UDI matches the easily-readable plain text form of the UDI. Additionally, the data delimiters enable the UDI to be parsed into electronic systems once scanned.

The data delimiters vary based on the FDA-accredited issuing agencies, and consist of a specific set of characters used to identify the information immediately following the data delimiter. FDA-accredited issuing agencies should submit their proposed data delimiters to FDA as part of their issuing agency accreditation application under 21 CFR 830.110(a)(3)(iii). The approved data delimiters can be found in the UDI Formats by FDA-Accredited Issuing Agency document on the UDI webpage (www.fda.gov/udi).

E. Order of the data represented in the UDI carrier

For purposes of this draft guidance we define "UDI carrier" as the means to convey the UDI and any non-UDI elements by using easily readable plain-text and AIDC forms. In the UDI carrier, the UDI should precede any non-UDI elements. The easily readable plain-text form of the UDI should be ordered to specify the DI first, followed by the PIs. If there are any non-UDI elements in the UDI carrier, the non-UDI elements should follow the PIs that are part of the UDI. For example, if the label of a particular device bears the expiration date PI and quantity, and the labeler wishes to include the quantity in the UDI carrier, the easily readable plain-text of the UDI carrier should display the data delimiter for the DI, followed by the DI; the data delimiter for expiration date, followed by the expiration date PI; and lastly, the data delimiter for quantity, followed by the quantity. In this example, FDA does not prohibit the inclusion of quantity in the UDI carrier; however, quantity is not considered part of the UDI and the data delimiter for quantity should be separate from the DI and PI data delimiters in the UDI. For more information on non-UDI elements capable of being included in the UDI carrier, labelers should contact their FDA-accredited issuing agency.

V. List of References

ISO/IEC 15459-2, Information technology — Automatic identification and data capture techniques — Unique identification — Part 2: Registration procedures

ISO/IEC 15459-4, Information technology — Automatic identification and data capture techniques — Unique identification — Part 4: Individual products and product packages

ISO/IEC 15459-6, Information technology — Automatic identification and data capture techniques — Unique identification — Part 6: Groupings

ISO/IEC 646, Information technology - ISO 7-bit coded character set for information interchange

ISO/IEC15415, Information technology — Automatic identification and data capture techniques — Bar code symbol print quality test specification — Two-dimensional symbols

ISO/IEC 15416, Automatic identification and data capture techniques — Bar code print quality test specification — Linear symbols

ISO/IEC TR 29158, Information technology — Automatic identification and data capture techniques — Direct Part Mark (DPM) Quality Guideline