GUDID Global Unique Device Identification Database

DI Record

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Learning Objectives

- Obtain an overview of GUDID
- Understand the DI record and the data elements
- Understand how to manage your DI record so the information is current
- Learn about best practices for better GUDID data

UDI = DI + PI

Device Identifier(DI) = mandatory, fixed portion of a UDI that identifies the specific version or model of a device and the labeler of that device

Production Identifier(PI) = a conditional, variable portion of a UDI that identifies one or more of the following when included in the UDI:

Lot or batch number, Serial number, Expiration date, Manufacturing date, and, for an HCT/P regulated as a device, the distinct identification code

GUDID Global Unique Device Identification Database

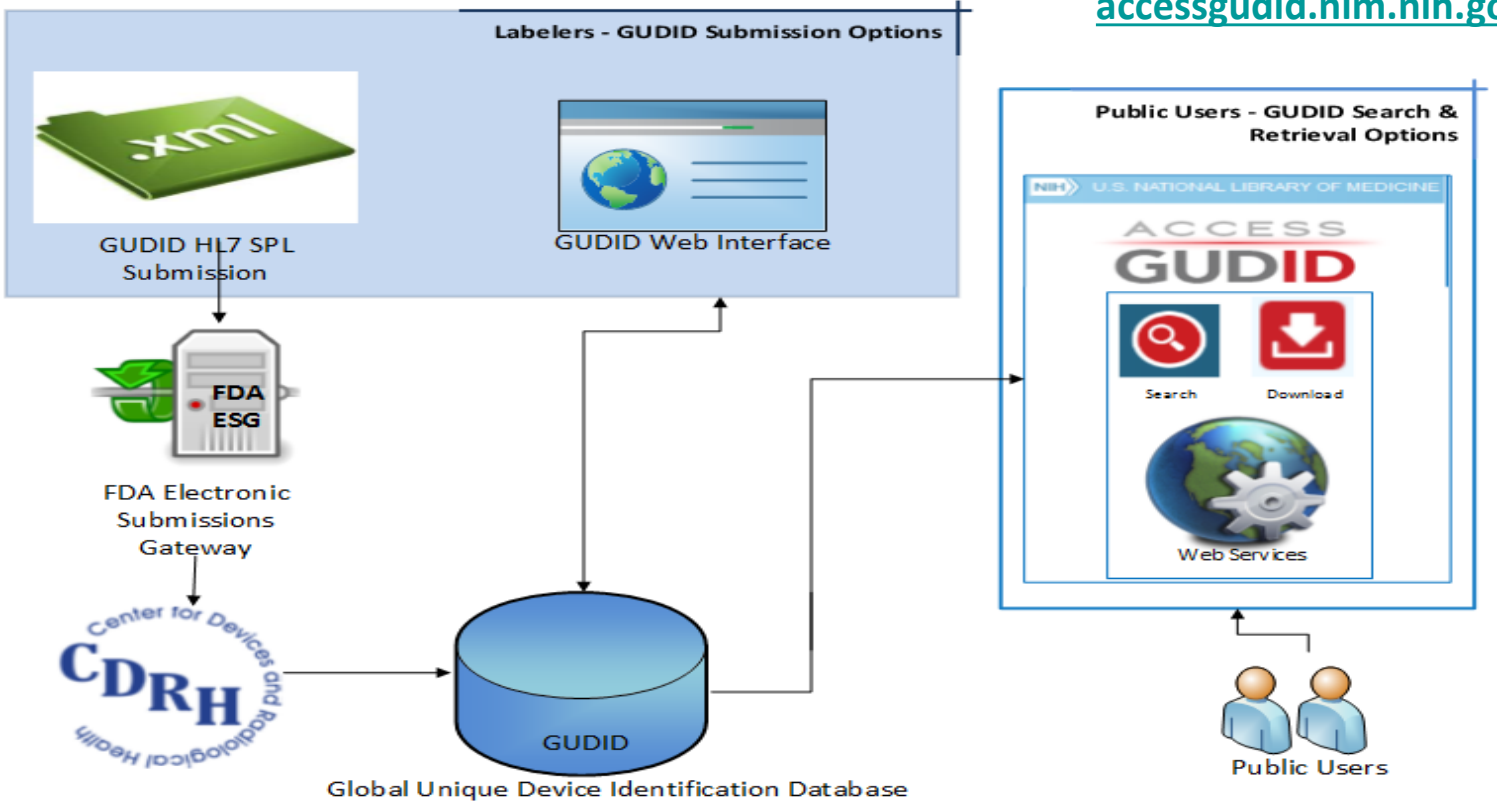
Repository of key device identification information

Contains ONLY the DI; PIs are not submitted to nor stored in the GUDID

Contains only PI flags to indicate which PIs are on the device UDI

GUDID Overview

accessgudid.nlm.nih.gov



GUDID Web Interface


GUDID Web Interface

- Secure Web Application
- Submission of device information one record at a time by Labelers
- Suitable for those with small submission volumes

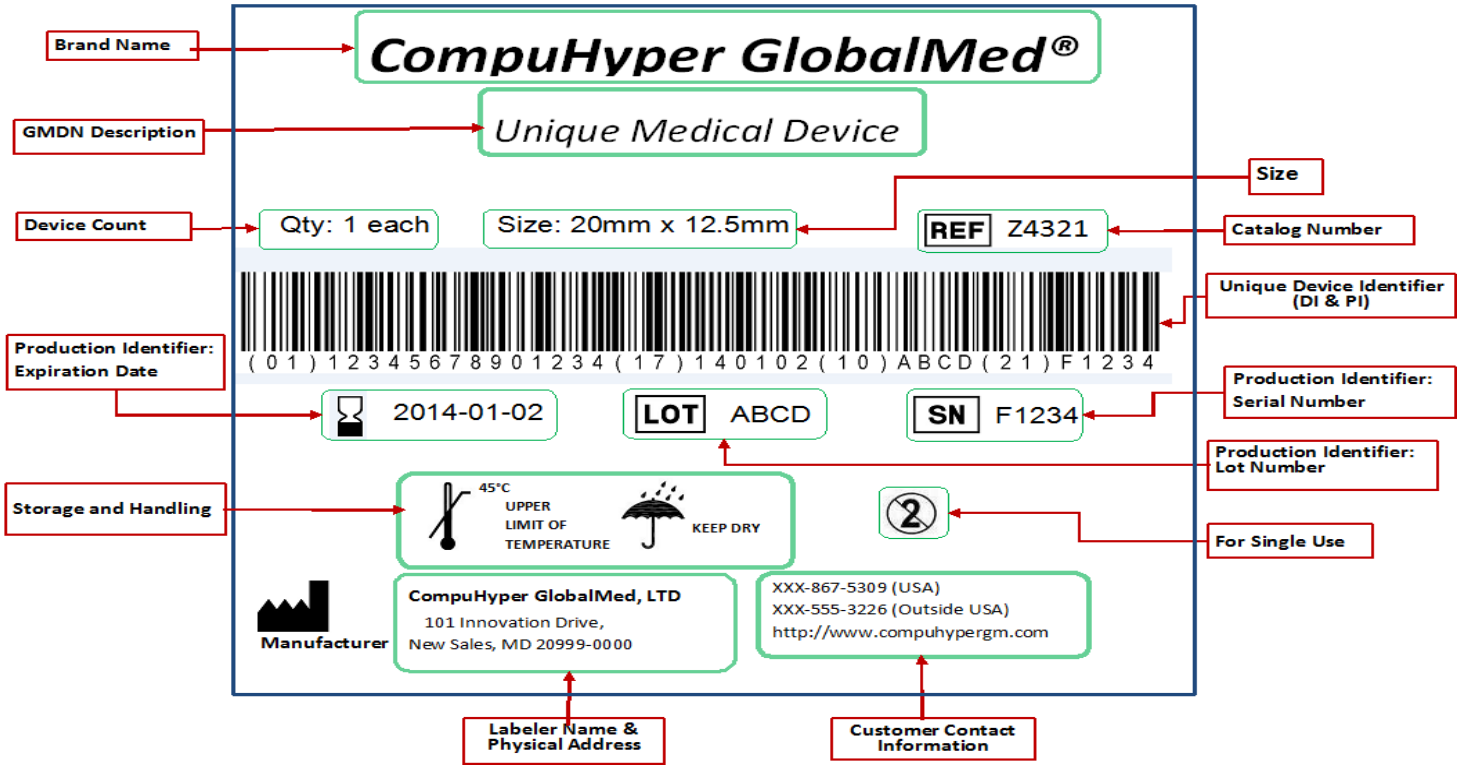
DI Record and Data Elements

Device Identifier Record

- A Device Identifier(DI) identifies –
  - A given version or model of a device AND
  - The Labeler of the device

- DI Record in GUDID
  - Device Identifier + GUDID Data Element values

The majority of the DI record information is on the device label



GUDID DI Record

- Web Interface – created by LDE users
- HL7 SPL Submission option – submitted as xml files

Device Information

Primary DI = DI on the base package. Base Package is the lowest package level containing a full UDI

Device Identifier (DI) Information

Issuing Agency: *	Primary DI Number: *	Device Count: *	Unit of Use DI Number:
HIBCC	WSDIOVERVIEW	1	

Labeler DUNS Number: *	Company Name:	Company Physical Address:
362507753	US TEST COMPANY 911	899 EATON AVE, BETHLEHEM, PA

Brand Name: *	Version or Model Number: *	Catalog Number:
DIOverview	123456	123456

Device Description (max 2000 characters):

DIOverviewRecord

Commercial Distribution

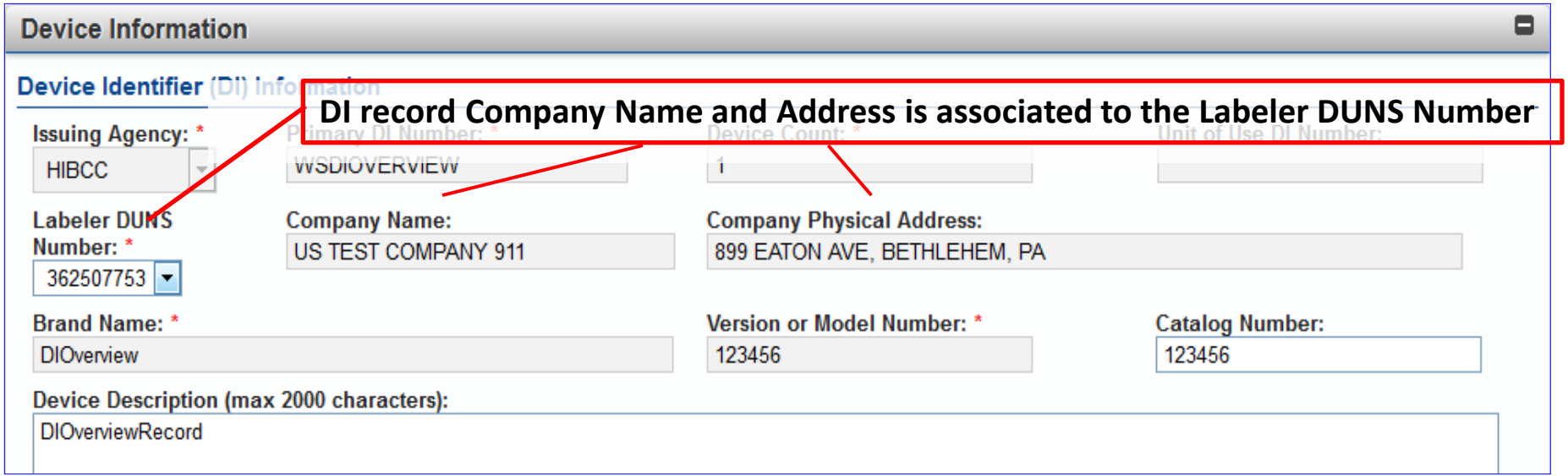
DI Record Publish Date (yyyy-mm-dd): *	Commercial Distribution End Date (yyyy-mm-dd):	Commercial Distribution Status:
2014-05-09		In Commercial Distribution

Labeler DUNS Number

The company name and address associated to the Labeler DUNS Number should match the company name and address on the device label. A Doing Business As (DBA) name is also acceptable

Labeler DUNS and the GUDID DI Record

Device Identifier (DI) Record Details



Labeler DUNS and the AccessGUDID DI Record

Device Information

Direct Marking (DM)

☐ **Device Subject to Direct Marking (DM), but Exempt**

☐ **DM DI Different from Primary DI**

DM DI Number:

Secondary DI

Add Secondary DI

Issuing Agency	Secondary DI Number	Action
GS1	00909090909090	

Package DI

Add Package DI

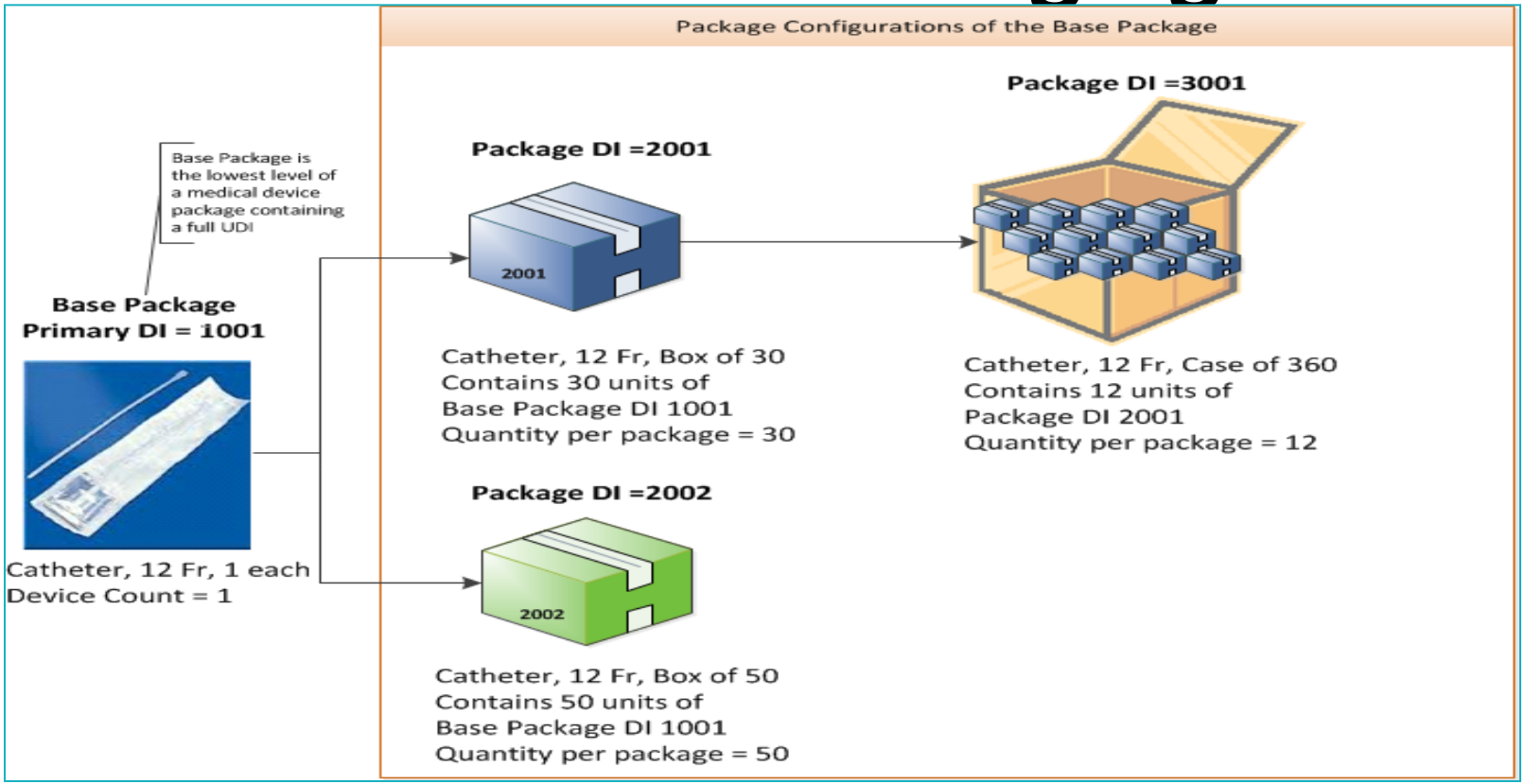
Package DI Number	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status	Action
wsPkg2	10	wsPkg1	Carton		In Commercial Distribution	
wsPkg1	5	wsDIOverview	Box		In Commercial Distribution	

Customer Contact

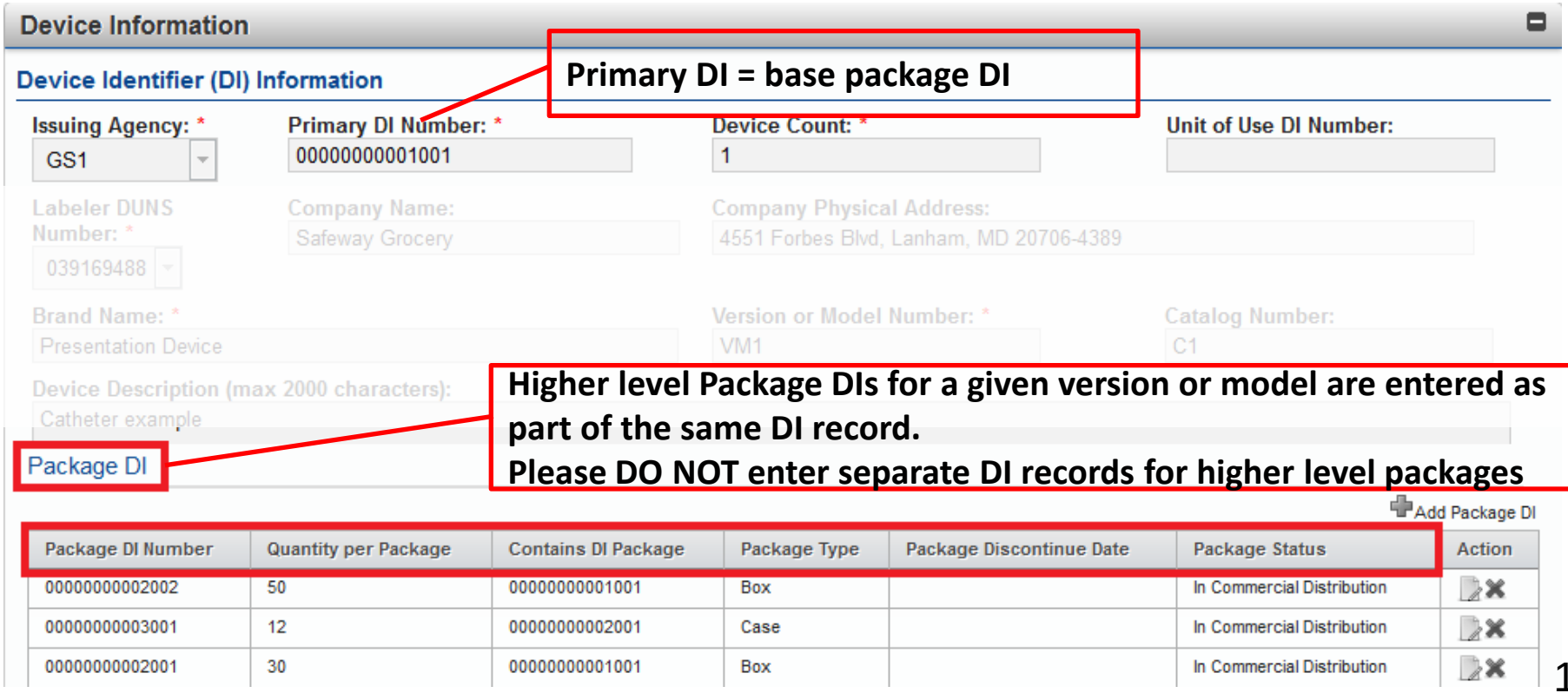
Add Customer Contact

Customer Contact Phone	Customer Contact Email	Action
8005551234	xxx@xx.xx	
9999999999	none@none.net	

Levels of Packaging



Packages in GUDID



Package DI Number	Quantity per Package	Contains DI Package	Package Type	Package Discontinue Date	Package Status	Action
00000000002002	50	00000000001001	Box		In Commercial Distribution	
00000000003001	12	00000000002001	Case		In Commercial Distribution	
00000000002001	30	00000000001001	Box		In Commercial Distribution	

Device Status

☐ Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P) ☐ Kit ☐ Combination Product

Premarket *

☐ Device Exempt from Premarket Submission

Add Premarket Submission Number

FDA Premarket Submission Number	Supplement Number	Action
P100001	000	
BK000030	0	

FDA Product Code *

Add Product Code

Product Code	Product Code Name	Action
IJZ	Oil, Clearing	

Global Medical Device Nomenclature

FDA Listing *

Add FDA Listing

FDA Listing Number	Action
D202923	

GMDN *

Add GMDN

Code	Name	Definition	Action
99999	FOR TESTING PURPOSES ONLY		

GMDN

- GMDN = Global Medical Device Nomenclature
- Provides a way to group or categorize devices
- Consists of:
  - GMDN Code
  - GMDN Preferred Term
  - GMDN Preferred Term Definition
- Required element in GUDID

Device Characteristics

For Single-Use: * Yes

Production Identifier(s) on Label

Lot or Batch Number: * Yes
Serial Number: * No
Expiration Date: * Yes
Manufacturing Date: * No
Donation Identification Number: * No

Latex Information

Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437): *
No

☐ Device labeled as "Not made with natural rubber latex"

Prescription Status

☑ Prescription Use (Rx)

☑ Over the Counter (OTC)

MRI Safety

What MRI safety information does the labeling contain?: *
Labeling does not contain MRI Safety Information

MR Safe
MR Unsafe
MR Conditional
Labeling does not contain MRI Safety Information

Device Characteristics

Clinically Relevant Size

Add Size

Size Type Text	Action
Depth: 2.5 Centimeter	
Length: 3.5678999000 Femtometer	

Storage and Handling

Add Storage and Handling

Storage and Handling	Action
Handling Environment Temperature: greater than 56 Degrees Celsius	
Handling Environment Temperature: greater than 45 Degrees Fahrenheit	
Handling Environment Temperature: exactly 45 Degrees Celsius	
Storage Environment Humidity: between 45 and 78 Percent (%) Relative Humidity	

Sterilization

Device Packaged as Sterile: * No

Requires Sterilization Prior to Use: * Yes

Add Sterilization Method

Sterilization Method	Action
Sound Waves	

DI Record Management

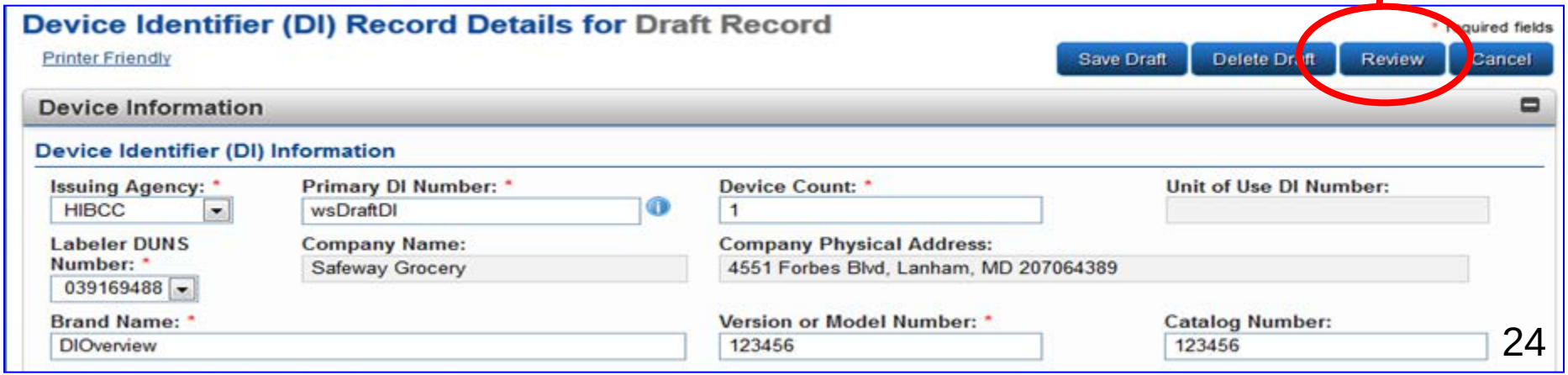
DI Record Life Cycle

- Managing entry and edits to device identification information throughout the life of the device
- 3 DI record states –
  - Draft
  - Unpublished
  - Published

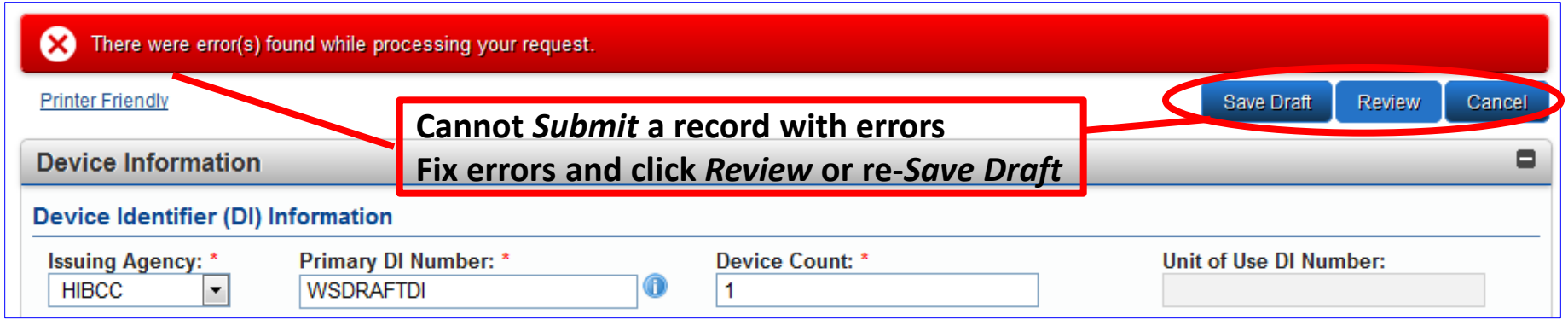
Draft DI Record

- Use to “test/learn” GUDID
- Saved in the system, but not “submitted”
- Unlimited editing
- Purged after 180 days of inactivity
- Allows for Review prior to submitting

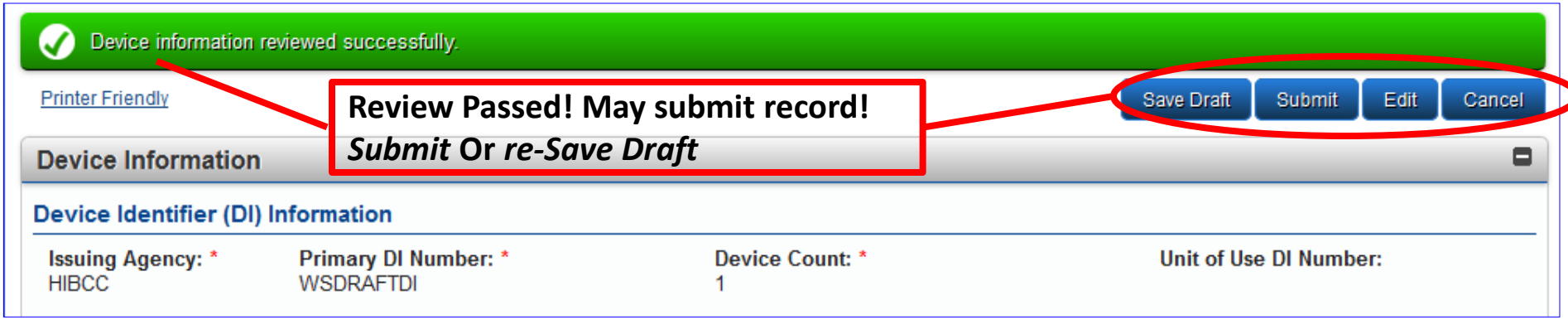
Review **checks record against business rules**



Draft DI Record- Review Failed



Draft DI Record- Review Passed



Submitted DI Record

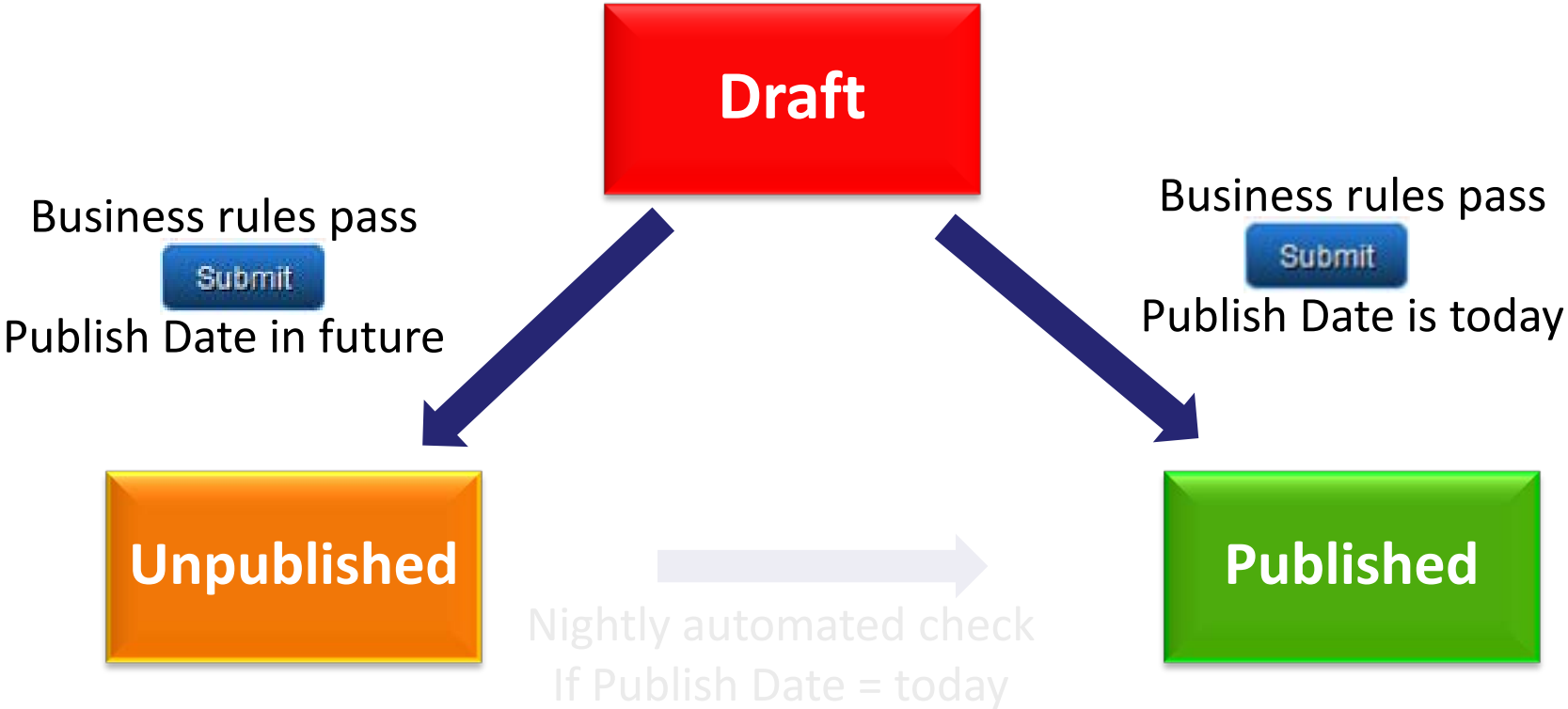
- No longer in DRAFT state – time to pay attention to GUDID business rules!

- **Publish Date** determines DI record state -- Unpublished OR Published

DI Record Publish Date

- Determines when a DI record is saved in the “published” state
- GUDID requires Publish Date to be today or in the future.
- GUDID submission requirements are met the date the DI record is saved in the “published” state

Moving between DI Record States

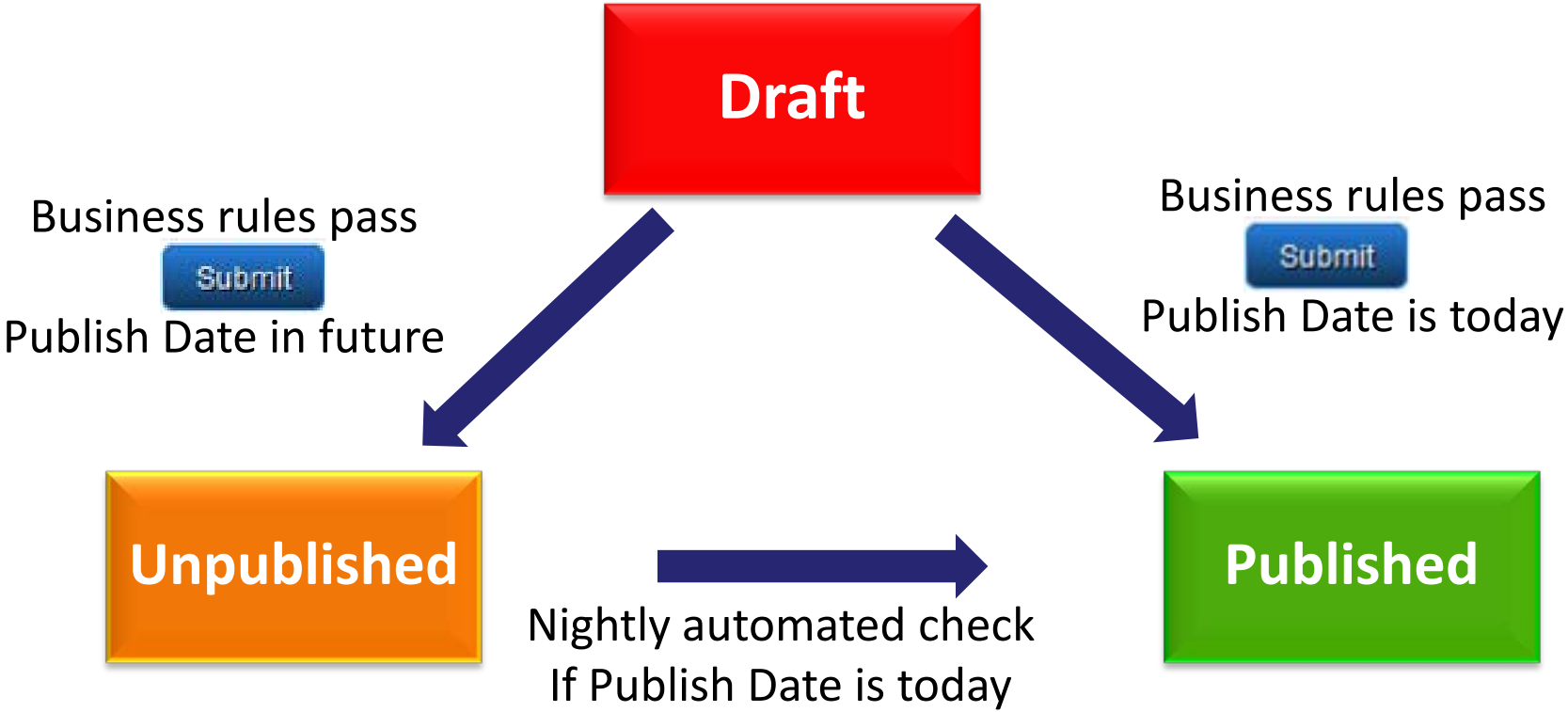


Unpublished DI Record

- DI record has passed review
- DI record was submitted
- Publish Date in the future
- Unlimited editing
- Records are NOT released to AccessGUDID
- Can be copied to create new DI records

Unpublished DI Record

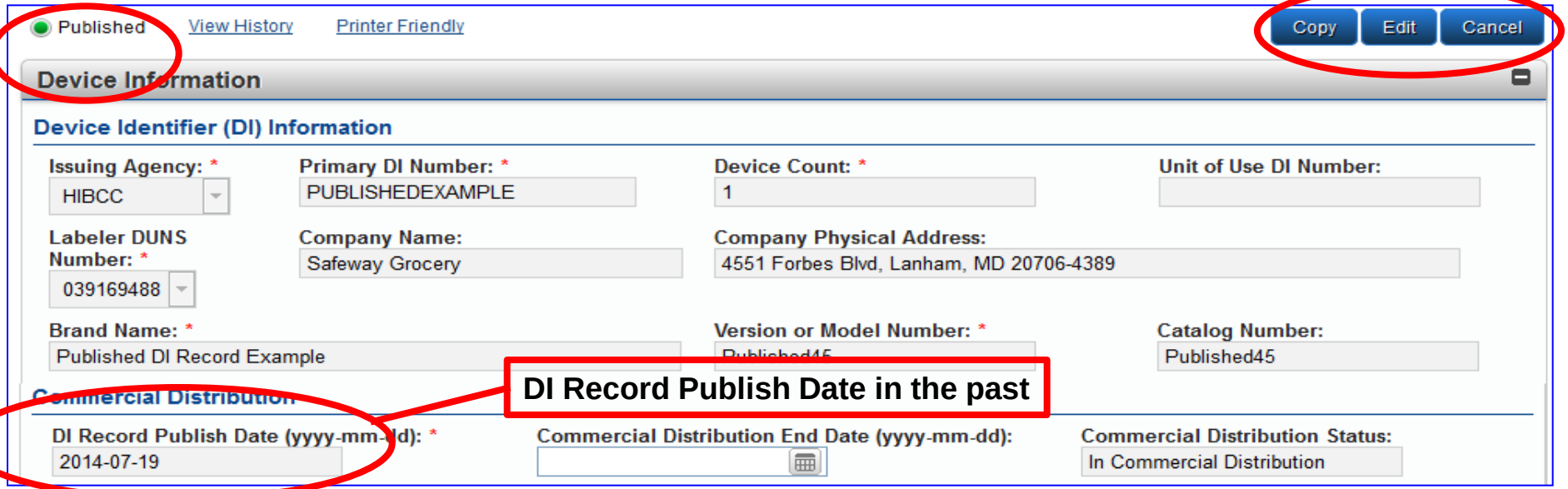
Moving between DI Record States



Published DI Record

- DI record has passed review
- DI record was submitted
- Publish Date is today OR in the past
- Limited editing
- Records are released to AccessGUDID
- Can be copied to create new DI records
- GUDID submission requirements are met the date the DI record is saved in the “published” state

Published DI Record



DI Record Life Cycle

- DI Record Life Cycle = DI record states + business rules
- DI record state determines applicable business rule

Draft DI Record

- Business rules N/A
- Publish Date N/A
- Unlimited Editing
- Not released to AccessGUDID
- Not available via HL7 SPL

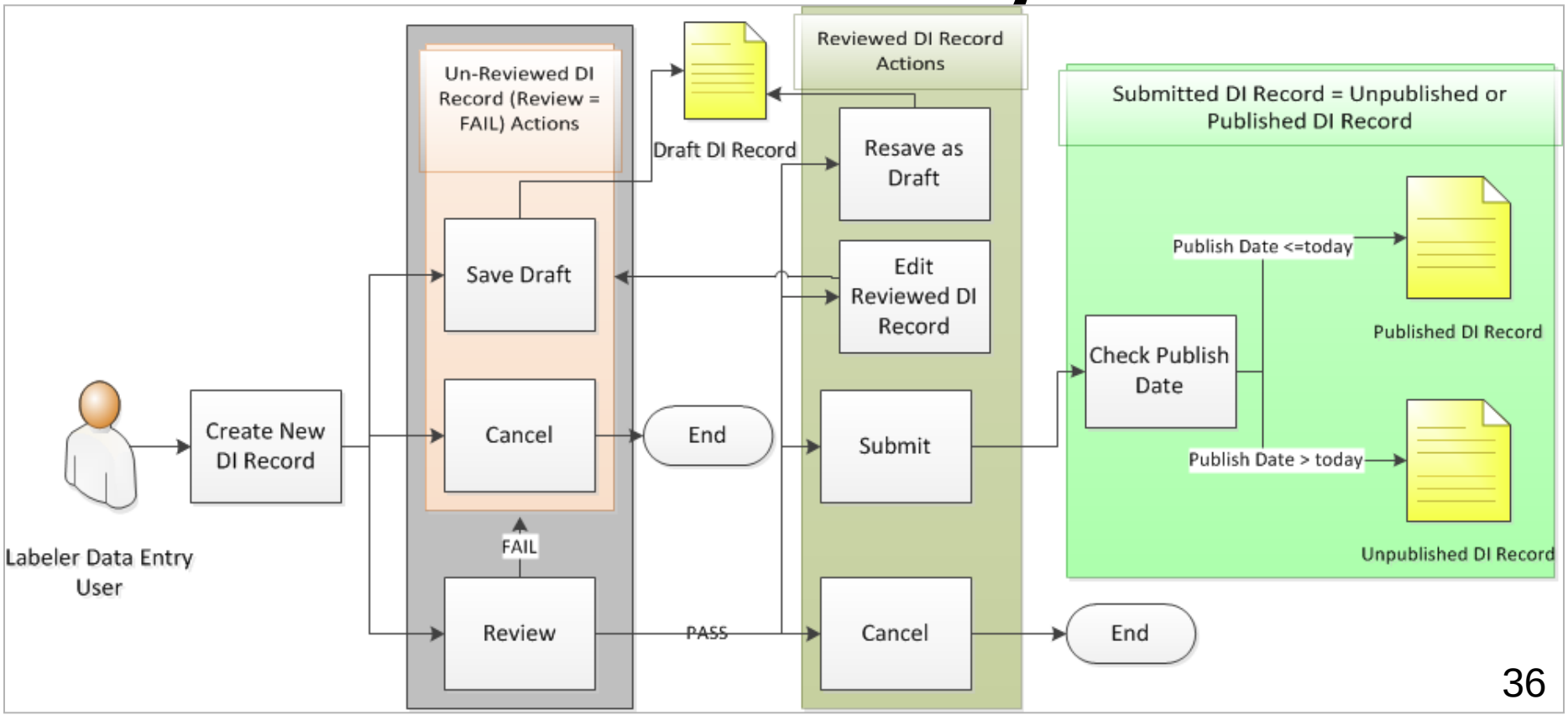
Unpublished DI Record

- Business rules passed
- Publish Date in future
- Unlimited Editing
- May be copied
- Not released to AccessGUDID

Published DI Record

- Business rules passed
- Publish Date is today or in future
- Limited Editing
- May be copied
- **Released** to AccessGUDID

DI Record Life Cycle



DI Record Management

Editing Published DI records

New DI Trigger Element – when changed, requires a new DI and new DI record in GUDID.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
For Single-Use	Indicates that the device is intended for one use or on a single patient during a single procedure.	Choose Yes/No from the drop down list.	None	Required	Type: Boolean	Yes/No	YES
Device Packaged as Sterile	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device as it enters Commercial Distribution. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler.	None	Required	Type: Boolean	Yes/No	YES

Grace Period Applies to Published DI Records

Publish Date	Grace Period Start Date	Grace Period End Date
Friday, January 15, 2016	Saturday, January 16, 2016	Monday, February 15, 2016

Grace Period = 30 calendar days*

During Grace Period

- Unlimited Editing, except for Publish Date
- **Please review your data in GUDID!**

After Grace Period

- **Record released to AccessGUDID**
- New DI Trigger Data Elements – no edits
- Limited Editing

*Grace period subject to change

GUDID and Data Quality

- Start with GOOD Data
- Review your data in GUDID During-the-Grace-Period
  - Export your records from GUDID and review/validate
- Do not wait to do your review after records show up on AccessGUDID, which is AFTER the grace period when editing is limited

Best Practices for Better Data

Data Element	Data Quality Issue
Device Identifier	Ensure your DI is correct – validate your check digits
Version or Model	Do not include the word “Model” or “Version” If no Version or Model available, enter Catalog Number
Device Description	Do not leave blank; recommend approved/cleared indications for use
Clinically Relevant Size	Do not include size under ‘Device Description’ or ‘Brand Name’ Use List of Values vs. “Device Size Text, Specify”
GMDN Code	One code sufficient for most medical devices
Donation Identification Number (DIN)	Applicable to ICCBBA Device Identifiers ONLY

Steps for Success!

1) Review resources on the UDI Website
2) Select Issuing Agency and label your devices with UDI
3) Determine primary submission option
4) Gather your data
5) Understand the GUDID Account Structure
6) Identify/Obtain DUNS numbers
7) Obtain a GUDID Account
8) Submit DI records
9) Subscribe to get notified about GUDID System Status

GUDID System Status

- Subscribe to GUDID Email Alerts by visiting our website
- Scheduled downtimes -- email alerts sent and posted on www.fda.gov/udi
- Unscheduled downtimes
  - Visit www.fda.gov/udi for information
  - If no information, report issue via FDA UDI Help Desk

Your Call to Action

- It is time to get started!
- Utilize the resources available on our website
- Do not forget data quality
- Be sure to understand the DI record edit rules
- Use the grace period effectively to ensure your device information is accurate
- Subscribe to the GUDID System Status notification

Providing Industry Education

1. CDRH Learn – Multi-Media Industry Education

- over 80 modules - videos, audio recordings, power point presentations, software-based "how to" modules
- accessible on your portable devices: http://www.fda.gov/Training/CDRHLearn

2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance

3. Division of Industry and Consumer Education (DICE)

- If you have a question - Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Live Agents 9am – 12:30 pm; 1-4:30 pm EST)
- **Web Homepage:** http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ContactUs--DivisionofIndustryandConsumerEducation/default.htm