IMDRF International Medical Device Regulators Forum

FINAL DOCUMENT

Title: Data Exchange Guidelines - Common Data Elements for Medical Device Identification

Authoring Group: IMDRF RPS Working Group

Date: 16 March 2017

Kimby Barton, IMDRF Chair

Contents

Preface

The document herein was produced by the International Medical Device Regulators Forum (IMDRF), a voluntary group of medical device regulators from around the world. The document has been subject to consultation throughout its development.

1 Introduction

The International Medical Device Regulators Forum (IMDRF) was conceived in February 2011 as a forum to discuss future directions in medical device regulatory convergence. It is a voluntary group of medical device regulators from around the world who have come together to build on the strong foundational work of the Global Harmonization Task Force (GHTF). The Forum will accelerate international medical device regulatory harmonization and convergence.

Regulators require submission of device identification information at different points in the regulatory life cycle of a medical device. Structured device identification information in standard electronic format is expected (now or in the future) to be included as part of pre-market submission, post-marketing distribution and use (disposal and discard), adverse event/vigilance reporting, and corrective field actions (e.g., recall, advisory notices).

Once the medical device is commercially available, a Unique Device Identification (UDI) system is expected to capture the device identification data elements at the level of a particular medical device. However, at the point of initial regulatory submission, specific medical device identification data elements are not always assigned. Therefore it would be useful to establish common data elements which can be defined throughout the life cycle. These data elements are not currently identified resulting in the lack of a consistent nomenclature, definitions and structure for submission of this identifying information. Each type of submission may reference the product differently. For example, a regulatory submission may refer to the medical device's trade name, the data attributes associated with UDI may contain brand name and a recall may refer to proprietary name – all referring to the same medical device. The identification information is also often submitted in an unstructured way; through regulatory submission forms and other unstructured documents. The combination of different ways to identify a medical device and the unstructured way medical device information is submitted make it difficult over time to reconcile references to the same medical device.

Work was completed to define the common data elements to address the inconsistencies and lack of harmonized definitions used for the submission of medical device information to regulatory authorities (see IMDRF/RPS WG/N19 FINAL:2016, Common Data Element for Medical Device Identification). With the harmonization of terms and their definitions, there is a future possibility of electronic regulatory submission of device identification information and potential for reuse of the common data elements for use in postmarket initiatives such as capture of device identification information in adverse events, recalls and as part of patient registry design. This document will provide data exchange guidelines to be used when other IMDRF working groups are assigned to develop technical implementation guides for specific uses (e.g., premarket regulatory submissions or reporting of device identification information in postmarket). These guidelines provide a common framework that will allow effective, technically consistent exchange of medical device identification information across the device lifecycle.

2 Scope

This document outlines the data exchange guidelines for the common data elements identified in the *Common data elements for medical device identification (IMDRF/RPS WG/N19)* document. The guidelines in this document may be used through regulatory activities or processes,

including any implementation specifications for electronic exchange of regulatory submission. This document will provide guidelines to other IMDRF Working groups to consider when developing implementation specifications.

The scope of this document is to set forth a set of options for the IMDRF implementation working groups to consult when developing implementation guides/specifications for a specific regulatory activity. This document is not meant to be prescriptive in nature – only to provide guidance that may assist the implementation working groups to achieve consistent representations of the common data elements when exchanged between parties.

Note: This document includes the current state of exchange standards at the time of publication. Exchange standards are constantly evolving, therefore the IMDRF working groups will need to consult the current exchange standards when developing the implementation guides.

3 References

The following references were used in the development of this document:

- IMDRF/RPS WG/N19 FINAL:2016, Common Data Element for Medical Device Identification
- IMDRF/UDI WG/N7 FINAL:2013, UDI Guidance - Unique Device Identification (UDI) of Medical Devices.
- HL7 Version 3 Normative Standards
- GHTF/SG2/N87:2012, XML Schema for Electronic Transfer of Adverse Event Data

4 Definitions

- Common Data Elements - See Appendix A for the Common Data Elements for Medical Device Identification.

- Data Exchange – the electronic exchange of information between two (or more) parties in a structured format.
- Data Exchange Guidelines – a set of instructions for exchange standards that provides suggestions to the implementation groups developing implementation specifications.
- Implementation Specification – the technical guidance issued in a specific exchange format for a particular regulatory activity – e.g., regulated product submissions or reporting device identification information.

5 Data Exchange Guidelines Used for Common Data Elements

This document identifies preferred data exchange guidelines for the IMDRF defined common data elements that may be used to identify a medical device through its life cycle. The data exchange guidelines for the common data elements are a result of consensus discussions and are subject to specific regional considerations that are not included in this work item.

5.1 Roadmap for Exchanging Data

The RPS Common Data Elements Working Group has developed this document to describe data exchange guidelines (Step 2 outlined below) to facilitate the interchange of information and minimize re-work when operating across jurisdictions.

The following roadmap identifies the steps that need to be taken to prepare for the electronic submission of any regulatory data that may include the common data elements.

Step 1: The RPS Working group – CDE Work stream developed definitions for common data elements for medical device identification. See the Appendix A for the Common Data Elements for Medical Device Identification.

Step 2: The CDE Work stream developed this document of recommended data exchange guidelines for the IMDRF Working Groups to consider in their future implementation work.

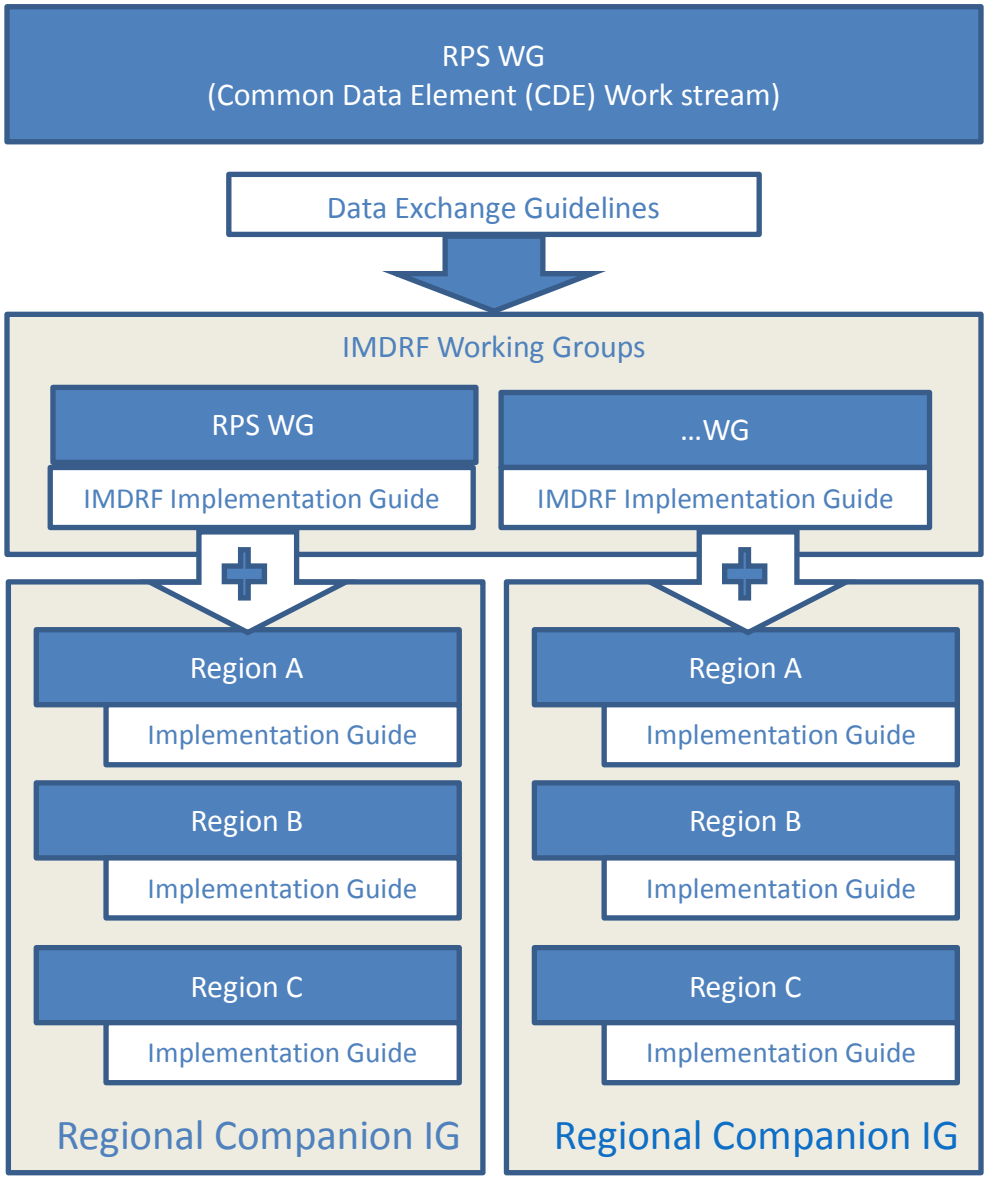
Step 3: Each IMDRF Working Group will consult the definitions of common data elements and consider the data exchange guidelines when developing a harmonized Implementation Specifications for a particular regulatory purpose (e.g. pre-market submission, adverse event, or registry). The IMDRF Working Groups will be focused on the implementation details of any specific regulatory submission.

Step 4: Each IMDRF Region will need to develop a companion Implementation specification to provide any region-specific instructions for the regulatory submission.

Step 5: Each IMDRF Region will implement the IMDRF Implementation Guide and Regional Implementation Guides concurrently for any specific regulatory submission.

Figure 1 depicts the working groups and the work items that will result during the course of developing the regulatory submission implementation guides. Note that the scope of this document is to define the device identification elements that would be included in data exchange guidelines to be used by the IMDRF implementation working groups.

Figure 1: Relationship of Working Groups and Work Items



This document serves as a reference guideline so that, where possible, stakeholders can work towards consistent exchange guidelines when issuing implementation guides for IMDRF work items. The common data elements are specified in the data exchange guidelines, but regions may add region-specific data elements that will need to be identified and specified when developing a full data exchange message for a particular regulatory purpose.

Note: Regional regulatory requirements will supersede the guidelines set forth in this document.

5.2 Stakeholders

The stakeholders involved in the exchange and/or use of data elements to identify a medical device include, but are not limited to the following:

- Primary Stakeholders – audience for the use of the data exchange standards in implementation guides
    - Regulatory Authorities;
    - Regulated Entities (e.g., Sponsors, Applicants, Manufacturers, Labelers, Suppliers and Distributors, Maintenance/Service Providers);
    - Implementers (e.g., Software Developers or Vendors)
- Secondary Stakeholders – affected by the use of the data exchange standards in implementation guides
    - Users of medical devices (e.g., Healthcare providers, Health ministries, Patients, Consumers)
    - Reimbursement or payer organizations (e.g., Health Insurance Agencies)
    - Medical device registry sponsors
    - Clinical Researchers and data analysts

Note: It is important to note that there are various uses of medical device identification information and each stakeholder will have a different use of it based on their interaction with the device.

5.3 Exchanging data across the Medical Device Lifecycle

The exchange of data takes place across the medical device lifecycle to aid in the identification of the medical device and its identifying characteristics.

5.4 Data Exchange Standards

5.4.1 HL7 Regulated Product Submission (RPS) R2

The HL7 RPS R2 Normative standard defines the message for exchanging product approval information electronically between Regulators and Regulated Industry, or between sets of regulators. The standard foci of the regulatory product submissions – e.g., premarket marketing applications or notifications – describe the submission contents with structured data. In addition to the messaging standard, the submission package includes the accompanying files described in the message as attachments with submission contents.

5.4.2 HL7 Structured Product Labeling (SPL) R5 or greater

Structured Product Labeling (SPL) is a document/message standard that specifies the structure and semantics of the regulated products (e.g., medical devices). Example uses of the SPL standard include "product label," "package insert," "prescribing information," and "product information". The precise definition and content of product information usually varies depending on the regional authority.

5.4.3 HL7 Individual Case Safety Report (ICSR)

The Individual Case Safety Report (ICSR) is a messaging standard that specifies a common format for adverse events, product problems and consumer complaints that can occur with the use of one or more medical device products. The focus of this message is on the event more so than the medical device, but the information about the medical device may be provided in a structured format.

5.4.4 HL7 Fast Healthcare Interoperability Resources (FHIR)

The HL7 Fast Healthcare Interoperability Resources (FHIR) is a framework to exchange information using a set of resources that can be assembled to meet various data exchange requirements – including those in the regulatory domain. The medical device specific resources can be used to convey medical device identification information that is linked to other aspects of a patient's clinical care.

5.4.5 GHTF/SG2/N87, XML Schema for the electronic transfer of adverse event data

IMDRF messaging standard for adverse events of medical devices is GHTF/SG2/N87:2012. The terminology and coding of adverse events of medical devices are in the process of discussion at IMDRF Adverse Events working group. The common data elements will be mapped to the elements of the XML Schema found in the N87 guidance.

Note: The N87 schema was not available to complete mapping of the data elements. This will need to be done in a future version of the document.

5.4.6 HL7 Consolidated – Clinical Document Architecture and EHR related messages

The HL7 Consolidated – Clinical Document Architecture and EHR related messages convey the clinical information about patients – including the use or implantation of medical devices. The representation of the medical device in these messages will be important as there is a shift to relying more heavily on Real World Data[1] to inform regulatory decision making and supplement data submitted directly to regulatory authorities.

5.5 Controlled Vocabularies

The following controlled vocabularies may be used by IMDRF working groups to bind to certain common data elements in their implementation guides. The following section outlines the recommendations and options for controlled vocabularies for structured data elements (i.e., elements with code datatypes).

5.5.1 IMDRF Vocabularies

The common set of vocabularies that are shared across regions should be considered candidates for IMDRF controlled vocabularies. The IMDRF Working Groups authoring the implementation guides will determine if the candidate vocabularies will be implemented as harmonized or managed by each region. The following vocabularies may be considered in the future:

- **Type of Medical Device name**
    - The type of medical device names included in the definition were:
        - Brand name/Proprietary/Trade name

[1] Use of Real World Evidence to Support Regulatory Decision Making, FDA Draft Guidance, Issued July 27, 2016 see http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM513027.pdf?source=govdelivery&utm_medium=email&utm_source=govdelivery

        - Common name
- **Type of Regulated Entity**
    - The type of regulated entities may include[2]:
        - Manufacturer,
        - Applicant,
        - Marketing Authorization Holder (MAH),
        - Fabricator,
        - Original Equipment Manufacturer (OEM),
        - Reprocessor,
        - Importer,
        - Distributor,
        - Supplier,
        - Contract Manufacturer,
        - Authorized Agent/Representative/Correspondent,
        - Labeler,
        - Service Agent,
        - Maintenance Agent**,**
        - Sterilizer**,**
        - Specification Developer**.**
- **Medical Device Classification** (note – also see regional vocabularies)
    - The GHTF Risk Classification values

Note: that these controlled vocabularies should be considered regional if future harmonization is not obtained.

5.5.2 Regional Vocabularies

There are a set of controlled vocabularies that need to be specified by regions due to the nature of the information that needs to be conveyed. These vocabularies most often are dictated by regulatory requirements and/or regulations, e.g., type of regulatory authorization or marketing numbers and status.

The following controlled vocabularies should be considered regional by IMDRF working groups:

- **Medical Device Type** (note – also see external vocabularies)
    - Regions may have additional or alternative vocabularies to further categorize or group medical devices (e.g., JMDN, USFDA Product Codes, China product codes, ANVISA device technical nomenclature).

- **Medical Device Classification** (note – also see IMDRF vocabularies)
    - Regions may have alternative vocabularies to classify the risk level of the medical device.
- **Type of Regulatory Authorization or Marketing number**

[2] The following regulated entity types are examples of potential vocabulary. These terms will be regionally defined as they are defined in legislation and regulations.

    - Regions should have a valid set of values to describe the type of regulatory activity that was completed before placing the medical device on the market.
- **Type of Regulatory Authorization or Marketing status**
    - Regions should have a valid set of values to describe the authorization or marketing status assigned to a medical device. This may or may not be publically available, but it may be exchanged between regulator and regulated industry.

5.5.3 HL7 Vocabularies

There are a set of controlled vocabularies that must be used in HL7 messages as required terms – and these are more implementation specific vocabularies used to describe datatypes and/or the type of structured data provided by the data element.

5.5.4 External Vocabularies

There are a set of controlled vocabularies that are specified by external organizations. The following provides an example of these vocabularies that may be considered by IMDRF working groups during the development of implementation guides and should remain as recommendations.

The following controlled vocabularies are governed by external organizations:

- **Medical Device Type** (note – also see regional vocabularies)
    - The Global Medical Device Nomenclature (GMDN) is a controlled vocabulary used by regulators, hospitals and manufacturers to identify types of medical devices using generic terms. These terms can be used to search and group like medical devices.
    - The Systematized Nomenclature of Medicine (SNOMED) is a controlled vocabulary that provides a comprehensive set of clinical health terms maintained by the International Health Terminology Standards Development Organisation (IHTSDO). The terms are used to describe clinical care interactions, including some medical device terms.

5.5.5 Other Code Systems

There are requirements to identify the source (i.e., code system) of a particular value in an exchange message. In the context of exchange standards, the attribute that allows the receiver to identify the code system is essential to correctly assigning the values in the receiving system. For example, if a regulator assigns a particular identifier for an application and/or establishment, that identifier is linked to the regulator's system and cannot be understood outside of that context. There may also be external assignments of identifiers and the code system then links to that external repository for its associated data (e.g., Dun and Bradstreet numbers are an example of identifiers for regulated entities).

The following common data elements include a code system that will need to be used to convey the complete context of a value in the exchange message.

- **Catalog/Reference (REF)** – the assigning entity will be identified when providing the value for the catalog/reference.
- **UDI** – the jurisdiction that the medical device is regulated will be identified when providing the value for the UDI. Note: the unique device identifiers are assigned based

on the issuing agency rules and therefore an identifier for the jurisdiction is necessary when providing the full UDI value.

- **DI** – the issuing agency that is used to generate the device identifier will be identified when providing the value for the DI.
- **Regulated Entity Identifier** – the assigning entity will be identified when providing the identifier value for the regulated entity.

5.6 Overview of Common Data Elements in Regulatory Submissions

The common data elements may be represented in one or more regulatory submissions based on the available data to identify the medical device. Each of the requirements for exchange may or may not be met by each of the identified exchange standards.

The assessment of the exchange standards was done at a point in time and was made from a purely technical perspective, and does not necessarily reflect any regulatory requirements and/or business process. There is an indicator, Met, Partially Met or Unmet for each of the data elements. The status of "Met" indicates that the requirements for that common data element values are fully represented in existing exchange standards. The status of "Partially Met" indicates that the requirements for the common data element values are not fully represented – i.e., it is missing some of the value representation. The status of "Unmet" indicates that the requirements for the common data element values are not met at all in current data exchange standards.

Refer to the IMDRF/RPS WG/N19, Common Data Elements for Medical Device Identification document, which includes the definitions for each of the common data elements presented in this section. Also see Appendix A.

5.6.1 Premarket Submission

During the premarket submission activities, there is a limited set of the common data elements available for exchange. The two exchange standards that are most relevant during the premarket submission are RPS, SPL and FHIR; and one of the three may be used to implement any exchange during the premarket phase of the medical device lifecycle. Note that the SPL message may be one of the documents submitted via the RPS message. The following table outlines the common data elements that are relevant to regulated medical device premarket submissions.

Table 1: Data Exchange in Premarket Submissions

Data Element	**Considerations**	**RPS**	**SPL**	**FHIR**
Medical Device Name (Brand/Trade/Proprietary or Common name)	Brand Name may not be available until late in the submission process. Common Name may be the only name available.	Partially Met	Met	Unmet
Model		Met	Met	Met
Catalog/Reference (REF)		Unmet	Met	Unmet
Catalog/Reference (REF) Description	This is a new term that is currently not consistently collected, but would provide value when identifying the medical device by a catalog/reference number.	Unmet	Unmet	Unmet
Version (Software or Firmware)	During premarket, a particular version may be approved.	Unmet	Met	Met
Regulated Entity - Name		Met	Met	Met
Regulated Entity - Address		Met	Met	Met
Regulated Entity - Identifier		Met	Met	Unmet
Regulated Entity - Type	There are various types of regulated entities that may be exchanged during premarket submissions.	Met	Met	Met
Kit		Unmet	Met	Unmet
Medical Device System	Need vocabulary for SPL to be implemented.	Unmet	Partially Met	Unmet
Contains Biological Materials	There are additional attributes that will need to be added to meet the requirements.	Unmet	Partially Met	Unmet
Single Use Device		Unmet	Met	Unmet
Reusable - Single Patient Use Device	Need vocabulary for SPL to be implemented.	Unmet	Partially Met	Unmet
Reusable - Multi-Patient Use Device	Need vocabulary for SPL to be implemented.	Unmet	Partially Met	Unmet
Supplied Sterile		Unmet	Met	Unmet
Needs Sterilization before use		Unmet	Met	Unmet
Method of Sterilization		Unmet	Met	Unmet

Data Element	**Considerations**	**RPS**	**SPL**	**FHIR**
Medical Device Type		Unmet	Met	Met
Medical Device Risk Classification		Unmet	Met	Unmet
Submission Number		Met	Met	Unmet
Regulatory Authorization or Marketing Number		Unmet	Met	Unmet
Regulatory Authorization or Marketing Status		Met	Unmet	Unmet

5.6.2 Adverse Events

During adverse event submission activities, there is a limited set of the common data elements available for exchange. The three exchange standards that are most relevant for adverse event submissions are GHTF/SG2/N87, HL7 ICSR and FHIR; and one of the three may be used to implement any exchange during the postmarket phase of the medical device lifecycle. The following table outlines the common data elements that are relevant to regulated medical device adverse events submissions.

Table 2: Data Exchange in Adverse Events Submissions

Data Element	**Considerations**	**N87**	**ICSR**	**FHIR**
Medical Device Name (Brand/Trade/Proprietary or Common name)	Brand Name may not be available until late in the submission process. Common Name may be the only name available.	Met	Met	Unmet
Model		Met	Met	Met
Catalog/Reference (REF)		Met	Unmet	Unmet
Catalog/Reference (REF) Description	This is a new term that is currently not consistently collected, but would provide value when identifying the medical device by a catalog/reference number.	Unmet	Unmet	Unmet
Version (Software or Firmware)		Met	Unmet	Met
Unique Device Identifier (UDI)		Unmet	Met	Met
Device Identifier (DI)		Met	Met	Met

Data Element	**Considerations**	**N87**	**ICSR**	**FHIR**
Production Identifier - Serial Number	Represented as a value.	Met	Met	Met
Production Identifier - Lot or Batch Number	Represented as a value.	Met	Met	Met
Production Identifier - Manufacturing Date	Represented as a value.	Met	Met	Met
Production Identifier - Expiration Date	Represented as a value.	Met	Met	Met
Regulated Entity - Name	For the Manufacturer and/or Reporter of the adverse event	Met	Met	Met
Regulated Entity - Address		Met	Met	Met
Regulated Entity - Identifier		Unmet	Unmet	Unmet
Regulated Entity - Type		Partially Met	Met	Unmet
Kit		Unmet	Unmet	Unmet
Medical Device System		Unmet	Unmet	Unmet
Contains Biological Materials		Unmet	Unmet	Unmet
Single Use Device	N87 includes its own controlled vocabulary for device usage.	Met	Unmet	Unmet
Reusable - Single Patient Use Device	N87 includes its own controlled vocabulary for device usage.	Met	Unmet	Unmet
Reusable - Multi-Patient Use Device	N87 includes its own controlled vocabulary for device usage.	Met	Unmet	Unmet
Supplied Sterile		Unmet	Unmet	Unmet
Needs Sterilization before use		Unmet	Unmet	Unmet
Method of Sterilization		Unmet	Unmet	Unmet
Medical Device Type		Met	Met	Met
Medical Device Risk Classification		Met	Unmet	Unmet
Regulatory Authorization or Marketing Number		Unmet	Met	Unmet
Regulatory Authorization or Marketing Status		Unmet	Unmet	Unmet

5.6.3 Unique Device Identification

During the unique device identification submission activities, there is a limited set of the common data elements available for exchange. The two exchange standards that are most

relevant during the unique device identification submission are SPL and FHIR; and one of the two may be used to implement any exchange during the unique device identification reporting phase of the medical device lifecycle. The following table outlines the common data elements that are relevant to regulated medical device unique device identification submissions.

Table 3: Data Exchange in Unique Device Identification Submissions

Data Element	**Considerations**	**SPL**	**FHIR**
Medical Device Name (Brand/Trade/Proprietary or Common name)	Common Name may be the only name available.	Met	Unmet
Model		Met	Met
Catalog/Reference (REF)		Met	Unmet
Catalog/Reference (REF) Description	This is a new term that is currently not consistently collected, but would provide value when identifying the medical device by a catalog/reference number.	Unmet	Unmet
Version (Software or Firmware)		Met	Met
Unique Device Identifier (UDI)	Is reported at this level for specific regulatory submissions.	Unmet	Met
Device Identifier (DI)		Met	Met
Production Identifier - Serial Number	Value is a Boolean flag to indicate if the production identifier is provided on the label.	Met	Met
Production Identifier - Lot or Batch Number	Value is a Boolean flag to indicate if the production identifier is provided on the label.	Met	Met
Production Identifier - Manufacturing Date	Value is a Boolean flag to indicate if the production identifier is provided on the label.	Met	Met
Production Identifier - Expiration Date	Value is a Boolean flag to indicate if the production identifier is provided on the label.	Met	Met
Regulated Entity - Name		Met	Met
Regulated Entity - Address		Met	Met
Regulated Entity - Identifier		Met	Unmet
Regulated Entity - Type		Met	Unmet
Kit		Met	Unmet
Medical Device System		Met	Unmet
Contains Biological Materials		Met	Unmet

Data Element	Considerations	SPL	FHIR
Single Use Device		Met	Unmet
Reusable - Single Patient Use Device		Met	Unmet
Reusable - Multi-Patient Use Device		Met	Unmet
Supplied Sterile		Met	Unmet
Needs Sterilization before use		Met	Unmet
Method of Sterilization	The coded values may not be the same for all jurisdictions.	Met	Unmet
Medical Device Type		Met	Met
Medical Device Risk Classification	A code is needed to represent this concept, in addition to the values of risk classification.	Met	Unmet
Regulatory Authorization or Marketing Number		Met	Unmet
Regulatory Authorization or Marketing Status		Unmet	Unmet

5.6.4 Establishment Registration

During the establishment registration submission activities, there is a limited set of the common data elements available for exchange. The two exchange standards that are most relevant during the establishment registration submission are SPL and FHIR; and one of the two may be used to implement any exchange during the establishment registration phase of the medical device lifecycle. The following table outlines the common data elements that are relevant to establishment registration submissions.

Table 4: Data Exchange in Registration Submissions

Data Element	Considerations	SPL	FHIR
Regulated Entity - Name		Met	Met
Regulated Entity - Address		Met	Met
Regulated Entity - Identifier		Met	Unmet
Regulated Entity - Type		Met	Unmet
Medical Device Type		Met	Met
Medical Device Risk Classification		Met	Unmet

Data Element	**Considerations**	**SPL**	**FHIR**
Regulatory Authorization or Marketing Number		Met	Unmet
Regulatory Authorization or Marketing Status		Unmet	Unmet

5.6.5 Recalls

The CDE Working group has identified a regulatory submission area that is not currently covered by the existing exchange standards, but may be an area for consideration in the future. The core data elements within the recalls and advisory notice regulatory activities would be expected to be consistent with the other common data elements presented in this document.

6 Appendix A: Common Data Elements

The following table includes the common data element for medical device identification.

Name, Term, Concept (Required)	Definition (Required)	Format (data type)	Name of Value Set used	Optional Value Sets
Medical Device Identity				
Medical Device Name (Brand/Trade/Proprietary or Common name)	A name used to assist in the identification of the regulated medical device.	Text	N/A	N/A
Medical Device Name (Brand/Trade/Proprietary or Common name) Type	The type of name that identifies the regulated medical device.	Code	Brand Commercial/Trade/Proprietary Common/Generic	
Model	The value used to represent one medical device or a family of medical devices to group many variations that have shared characteristics.	Text	N/A	N/A
Catalog/Reference (REF)	The value given by the Regulated Entity to identify the specific medical device as it relates to its form/fit, function and process (i.e., manufacturing processes requiring differentiation for distribution control (e.g., sterilization, component material, reprocessing, etc.).	Text	N/A	N/A
Catalog/Reference (REF) Description	Text describing or differentiating the variant of the medical device.	Text	N/A	N/A
Version (Software or Firmware)	The value given by the applicant to identify a specific revision of the software or firmware (for stand-alone medical devices and SaMD).	Text		
Unique Device Identifier				
Unique Device Identifier (UDI)	A series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous	Text	Issuing Agencies	n/a

Name, Term, Concept (Required)	Definition (Required)	Format (data type)	Name of Value Set used	Optional Value Sets
	identification of a specific medical device on the market. The UDI is comprised of the Device Identifier and Production Identifier. Note: The word "Unique" does not necessarily imply serialization of individual production units, but does allow tracking of medical devices through the supply chain.			
Device Identifier (DI)	A unique numeric or alphanumeric value specific to a model or version of a medical device.	Numeric or Alphanumeric	Issuing Agencies	n/a
Production Identifier (PI)	A numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, manufacturing date, and/or expiration date.	Text	Issuing Agencies	
Serial Number	A unique sequence of numbers or letter in a series used to identify an individual unit of a medical device.	Text	N/A	N/A
Lot or Batch Number	A value that represents one or more components or finished devices that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and are intended to have uniform characteristics and quality within specified limits.	Text	N/A	N/A
Manufacture Date	A date determined by the Regulated Entity in which the medical device is considered manufactured.	yyyy-mm-dd (ISO standard) or yymmdd	None specified	
Expiration Date	A date based on the results of	yyyy-mm-	ISO standard	

Name, Term, Concept (Required)	Definition (Required)	Format (data type)	Name of Value Set used	Optional Value Sets
	studies which demonstrate that the medical device will perform as intended and will meet its specifications until that date.	dd (ISO standard) or yymmdd		
Regulated Entity	The responsible party involved in a regulatory activity. The Regulated Entity may be identified by specific information to include a name, address, identifier and type of regulated entity.			
Name	The text value used to identify the Regulated Entity.	Text	None specified	
Address	The physical and/or mailing/postal location of the Regulated Entity.	Text	None specified	
Identifier	The alphanumeric value used to identify the Regulated Entity.	Numeric or Alphanumeric	None specified	
Type	The value assigned to identify the type of Regulated Entity.	Code	Manufacturer, Applicant, Marketing Authorization Holder (MAH), Fabricator, Original Equipment Manufacturer (OEM), Reprocessor, Importer, Distributor, Supplier, Contract Manufacturer, Authorized Agent/Representative/Correspondent, Labeler, Service Agent	
Kit	A collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as	Boolean (Y/N)	Yes/No	

Name, Term, Concept (Required)	Definition (Required)	Format (data type)	Name of Value Set used	Optional Value Sets
	an in vitro diagnostic or non-IVD medical device, or for the convenience of the user.			
Medical Device System	A medical device comprising a number of components and/or accessories intended to be used together to fulfill some or all of the medical device's intended functions, and is placed on the market as specified by its manufacturer (e.g., under a single name, or sold as one item).	Boolean (Y/N)	Yes/No	
Contains Biological Material	A value that indicates if the medical device is coated, impregnated or combined with biological materials such as cells, tissues or other materials (which may be of human, animal or microbial origin) that are intended for implantation, transplantation, infusion, or transfer into a human recipient.	Boolean (Y/N)	Yes/No	
Medical Device Usage	Describes the use and reuse of the medical device with respect to reprocessing. The type could be single use (SUD), reusable – single patient use, reusable – multi patient use or other (e.g., reprocessed SUD).			
Single Use	A medical device intended by the manufacturer to be used on an individual patient during a single procedure.	Boolean (Y/N)	Yes/No	
Reusable - Single Patient use device	A medical device intended by the manufacturer to be used on a single patient with reprocessing (e.g. cleaning, disinfection or sterilization) between uses.	Boolean (Y/N)	Yes/No	
Reusable - Multi-Patient use device	A medical device intended by the manufacturer to be used on multiple patients with reprocessing (e.g. cleaning disinfection or sterilization) between uses.	Boolean (Y/N)	Yes/No	

Name, Term, Concept (Required)	Definition (Required)	Format (data type)	Name of Value Set used	Optional Value Sets
Sterilization Information	The sterilization information for a medical device includes whether or not it is supplied sterile, needs sterilization before use and the method(s) of sterilization used.			
Need for sterilization before use	The manufacturer specifies whether or not the medical device must be sterilized before use. This is applicable to medical devices which are supplied sterile and intended for multiple use, or that require sterilization before first use and any intended subsequent use.	Boolean (Y/N)	Yes/No	
Supplied sterile	The manufacturer specifies whether or not the medical device is supplied sterile.	Boolean (Y/N)	Yes/No	
Method of sterilization	The manufacturer specifies the method(s) of sterilization if the medical device needs sterilization before use.	Code	None specified	Regional (e.g., USFDA per regulation)
Regulatory Information	The regulatory information related to the medical device including medical device type, medical device risk classification, submission and regulatory authorization or marketing numbers, and regulatory authorization or marketing status.			
Medical Device Type	The value assigned to describe the device type by a nomenclature system.	Code	GMDN	Region specific
Device Type - Type of Nomenclature	Indicates the code system used to specify the medical device type.	Text	GMDN (resolved using the code)	Region specific
Medical Device Risk Classification	A classification based on rules derived from the potential of a medical device to cause harm to a patient or user (i.e., the hazard it presents).	Code	GHTF (IMDRF) Risk Classification: I, II, III, IV	Region specific
Medical Device Risk Classification Type	Indicates the Regulatory Authority under which the device risk is classified.	Code		Region specific
Submission Number	A tracking number which is assigned to the regulatory activity when submitted by	Text	None specified	

Name, Term, Concept (Required)	Definition (Required)	Format (data type)	Name of Value Set used	Optional Value Sets
	the applicant.			
Submission Number Type	Indicates the Regulatory Authority assigning the Submission Number.	Code	Regional	
Regulatory Authorization or Marketing Number	A number issued when the medical device can be legally marketed.	Numeric or Alphanumeric	None specified	
Regulatory Authorization or Marketing Number Type	Indicates the Regulatory Authority assigning the Regulatory Authorization or Marketing Number.	Code		
Regulatory Authorization or Marketing Status	A decision or action assigned by the Regulatory Authority that indicates the marketing availability of the medical device.	Code	Regional	
Regulatory Authorization or Marketing Status Type	Indicates the Regulatory Authority assigning the Regulatory Authorization or Marketing Status.	Code		

7 Appendix B: Data Exchange Requirements

The following requirements served as a basis for the data exchange guidelines:

- The medical device name shall indicate the value assigned to identify the brand/trade/proprietary/commercial/general name of the device.
- The medical device name shall be provided as a text string value.
- The medical device name may have one or more names assigned to it.
- The medical device name may change its status.
- The medical device name may show its effective date for use.
- The medical device name type shall be provided as a coded value.
- The medical device name type shall indicate the code system associated with the coded value.
- The medical device name type shall have one type for every device name.
- The medical device model shall indicate the value assigned to identify the variation of the device.
- The medical device model shall be provided as a text string value.
- The medical device model shall only have one value assigned per variation of the device.
- The medical device catalog/reference number shall indicate the value assigned to identify the specific variation of the device that can be ordered.
- The medical device catalog/reference number shall be provided as a text string value.
- The medical device catalog/reference number may have one or more catalog numbers assigned to the medical device.
- The medical device catalog/reference number may be changed (and may include change in its description)
- A DI may have one or more catalog numbers associated.
- The medical device catalog/reference number and manufacturer should be included in any exchange.
- When medical device catalog/reference numbers are provided, a catalog/reference description should also be provided.
- The medical device catalog/reference description shall provide the value assigned to further describe the variation of the device that can be ordered.
- The medical device catalog/reference description shall be provided as a text string value.
- The medical device catalog/reference description shall only have one value assigned per variation of device that can be ordered.
- The medical device catalog/reference description may be changed (and may include change in its number
- The medical device version shall provide the value assigned to the software or firmware (including SaMD).
- The medical device version shall be provided as a text string value.
- The medical device version shall be provided for every version of the device as to differentiate its software or firmware
- The unique device identifier shall provide a unique value to identify the medical device.
- The unique device identifier shall include the device identifier and all relevant production identifiers used to identify the medical device.

- The unique device identifier shall be provided as a text string value.
- The unique device identifier shall indicate the type of identifier based on the issuing agency or repository.
- The unique device identifier shall only have one value for each variant of the medical device.
- The device identifier shall provide a unique value to identify the variation of the medical device.
- The device identifier shall be provided as a text string value.
- The device identifier shall indicate the type of device identifier based on the issuing agency.
- The device identifier shall only have one value for each variant of the medical device.
- The DI number may be associated with one or more catalog numbers.
- The serial number shall provide a unique value assigned to identify the individual medical device.
- The serial number shall be provided as a text string value.
- The serial number shall only have one value for each individual medical device.
- The serial number shall indicate that its value represents a serial number.
- The lot or batch number shall provide a value assigned to the devices resulting from the same manufacturing process.
- The lot or batch number shall be provided as a text string value.
- The lot or batch number shall have only one value for each individual medical device.
- The lot or batch number shall indicate that its value represents the lot or batch number.
- The manufacture date shall provide a value that indicates when the device was manufactured.
- The manufacture date shall be provided as a date stamp with year, month and day represented.
- The manufacture date shall have only one value for each individual medical device.
- The manufacture date shall indicate that its value represents the manufacture date.
- The manufacture date shall be provided in a format that can be determined by the receiving system.
- The expiration date shall provide a value that indicates the end of the allowable storage period before device use
- The expiration date shall be provided as a date stamp with year, month and day represented.
- The expiration date shall have only one value for each individual medical device.
- The expiration date shall indicate that its value represents the expiration date.
- The expiration date shall be provided in a format that can be determined by the receiving system.
- The regulated entity name shall provide a value for the name of the regulated entity.
- The regulated entity name shall be provided as a text string value.
- The regulated entity name shall have only one value for each regulated entity provided in the exchange.
- The regulated entity name shall include it type of regulated entity. See Regulated Entity Type.

- The regulated entity address shall provide a value for each part of the physical or postal address for the regulated entity.
- The regulated entity street address shall include the street number, street name and any direction to the location (e.g., PO Box) of the regulated entity.
- The regulated entity street address shall be provided as a text string value.
- The regulated entity street address shall one or more values for each regulated entity address.
- The regulated entity city shall include the town or region for the location of the regulated entity.
- The regulated entity city shall be provided as a text string value.
- The regulated entity city shall only have one value for each regulated entity address.
- The regulated entity state shall include the state, region or province for the location of the regulated entity.
- The regulated entity state shall be provided as a text string value.
- The regulated entity state shall only have one value for each regulated entity address.
- The regulated entity zip code/postcode shall include the value to identify the location of the regulated entity.
- The regulated entity zip code/postcode shall be provided as a text string value.
- The regulated entity zip code/postcode shall only have one value for each regulated entity address.
- The regulated entity country shall include the value to identify the country location of the regulated entity.
- The regulated entity country shall be provided as a coded value.
- The regulated entity country shall indicate the code system associated with the coded value.
- The regulated entity country shall only have one value for each regulated entity address.
- The regulated entity type shall be provided to indicate the type of location (e.g., physical address or PO Box)
- The regulated entity type shall be provided as a coded value.
- The regulated entity address type shall indicate the code system associated with the coded value.
- The regulated entity identifier shall provide a value that represents the regulated entity in a specific code system.
- The regulated entity identifier shall be provided as a text string value.
- The regulated entity identifier shall only have one value for each regulated entity.
- The regulated entity type shall indicate the type of identifier provided.
- The regulated entity type shall provide the value that represents the role of the regulated entity in the exchange.
- The regulated entity type shall be provided as a coded value.
- The regulated entity type shall indicate the code system associated with the coded value.
- The regulated entity type shall only have one value for each regulated entity.
- The kit shall provide shall provide an indicator whether or not the medical device is considered a kit by regulation.
- The kit type shall be provided to indicate the type of kit as a coded value.

- The kit type shall be provided as a coded value.
- The kit shall be provided as a Boolean value.
- The kit shall indicate that its value represents the medical device is a kit.
- The kit shall only have one value for each medical device for the kit type.
- The medical device system shall provide shall provide an indicator whether or not the medical device is considered a system by regulation.
- The medical device system shall be provided as a Boolean value.
- The medical device system shall indicate that its value represents the medical device is a system
- The medical device system shall only have one value for each medical device for the system type.
- The contains biologic material shall provide an indicator whether or not the medical device contains biological material.
- The contains biological material shall be provided as a Boolean value.
- If the device contains a biological material, specify the origin (human, animal or microbial)
- The contains biological material shall indicate that its value represents the material contained in the medical device
- The contains biological material shall provide a coded value to identify the biological material contained in the medical device.
- The contains biological material shall indicate the code system associated with the coded value.
- The contains biological material shall only have one value for each medical device.
- The contains biological material shall indicate the species contained in the medical device
- The species shall provide a coded value to identify the species contained in the medical device.
- The species shall indicate the code system associated with the coded value.
- The contains biological material shall indicate the country of origin for the biological material contained in the medical device
- The country of origin shall provide a coded value to identify the country of origin for the biological material contained in the medical device.
- The country of origin shall indicate the code system associated with the coded value.
- The contains biological material shall indicate the type for the biological material contained in the medical device
- The tissue type shall provide a coded value to identify type of tissue for the biological material contained in the medical device.
- The tissue type shall indicate the code system associated with the coded value.
- The contains biological material shall indicate the derivative for the biological material contained in the medical device
- The derivative shall provide a coded value to identify type of derivative for the biological material contained in the medical device.
- The derivative type shall indicate the code system associated with the coded value.
- The contains biological material shall indicate the recombinant material for the biological material contained in the medical device

- The recombinant material shall provide a coded value to identify a recombinant material in the biological material is contained in the medical device.
- The contains biological material shall indicate the microbial or animal for the biological material contained in the medical device
- The recombinant material shall provide a coded value to identify type of biological material as microbial or animal contained in the medical device.
- The type microbial or animal shall indicate the code system associated with the coded value.
- A medical device may have one or more medical device usage values in one exchange.
- The single use shall provide an indicator whether or not the medical device usage is only for single use.
- The single use shall be provided as a Boolean value.
- The single use shall indicate that its value represents the medical device is only for single use.
- The single use shall indicate that its value represents the medical device is a reprocessed single use medical device
- The single use shall only have one value for each medical device for medical device usage.
- The reusable - single patient use device shall provide an indicator whether or not the medical device usage is reusable - single patient use.
- The reusable - single patient use device shall be provided as a Boolean value.
- The reusable - single patient use device shall indicate that its value represents the medical device is reusable - single patient use.
- The reusable - single patient use device shall only have one value for each medical device for medical device usage.
- The reusable - single patient use device shall indicate the number of reuses allowed for the device.
- The reusable - single patient use device shall indicate the value represents the number of reuses allowed for the device.
- The reusable - single patient use device shall indicate a numeric value for the number of reuses.
- The reusable - multi-patient use device shall provide an indicator whether or not the medical device usage is reusable - multi-patient use.
- The reusable - multi-patient use device shall be provided as a Boolean value.
- The reusable - multi-patient use device shall indicate that its value represents the medical device is reusable - multi-patient use.
- The reusable - multi-patient use device shall only have one value for each medical device for medical device usage.
- The reusable - multi-patient use device shall indicate the number of reuses allowed for the device.
- The reusable -multi-patient use device shall indicate the value represents the number of reuses allowed for the device.
- The reusable - multi-patient use device shall indicate a numeric value for the number of reuses.

- The need for sterilization before use shall provide an indicator whether or not the medical device needs sterilization before use.
- The need for sterilization before use shall be provided as a Boolean value.
- The need for sterilization before use shall indicate that its value is need for sterilization before use.
- The need for sterilization before use shall only have one value for this type of sterilization information.
- The supplied sterile shall provide an indicator whether or not the medical device is supplied sterile.
- The supplied sterile shall be provided as a Boolean value.
- The supplied sterile shall indicate that its value is supplied sterile.
- The need for sterilization before use shall only have one value for this type of sterilization information.
- The method of sterilization shall provide a value to indicate the method of sterilization required for the medical device.
- The method of sterilization shall be provided as a coded value.
- The method of sterilization shall indicate the code system associated with the coded value.
- The method of sterilization shall have one or more values for this type of sterilization information.
- Add the sterilizing entity (the person who sterilized the product using a specific sterilization method)
- The medical device type shall provide a value to indicate the type of medical device using a classification system.
- The medical device type shall be provided as a coded value.
- The medical device type may have one or many values for this type of device.
- The medical device type shall provide a value to indicate the system used to indicate the type of device.
- The medical device type shall indicate the code system associated with the coded value.
- The medical device type code system shall only have one value for each type provided.
- The medical device risk classification shall provide a value to indicate the classification of a medical device's risk category.
- The medical device risk classification shall be provided as a coded value.
- The medical device risk classification shall only have one value for the risk classification.
- The medical device risk classification shall provide a value to indicate the system used to indicate the risk classification of the medical device.
- The medical device risk classification shall indicate the code system associated with the coded value.
- The medical device risk classification code system shall only have one value for each type provided.
- The submission number shall provide a value to indicate the assigned number for the regulatory activity.
- The submission number shall be provided as a coded value.
- The submission number shall only have one value for each submission number.

- The submission number type shall provide the value to indicate the system used to assign the submission number.
- The submission number type shall indicate the code system associated with the coded value.
- The submission number type shall only have one value for each type provided.
- The regulatory authorization or marketing number shall provide a value to indicate the assigned number for the authorization or approval of a regulatory activity.
- The regulatory authorization or marketing number shall be provided as a coded value.
- The regulatory authorization or marketing number shall only have one value for each regulatory authorization or marketing number.
- There shall be one and only one regulatory authorization or marketing number for a medical device.
- There may be one or more regulatory authorization or marketing numbers for a medical device.
- The regulatory authorization or marketing number type shall provide the value to indicate the system used to assign the regulatory authorization or marketing number.
- The regulatory authorization or marketing number type shall indicate the code system associated with the coded value.
- The regulatory authorization or marketing number type shall only have one value for each type provided.
- The regulatory authorization or marketing status shall provide a value to indicate the assigned status for the authorization or approval of a regulatory activity.
- The regulatory authorization or marketing status shall be provided as a coded value.
- The regulatory authorization or marketing status shall only have one value for each regulatory authorization or marketing number.
- The regulatory authorization or marketing status type shall provide the value to indicate the system used to assign the regulatory authorization or marketing status.
- The regulatory authorization or marketing status type shall indicate the code system associated with the coded value.
- The regulatory authorization or marketing status type shall only have one value for each type provided.

8 Appendix C: Data Exchange Guideline Template

Instructions to Reader

The following table will be used to organize the various data exchange guidelines and specific implementation considerations.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Element/Attribute Name		Element			
XPATH		Attribute			

Element/Attribute Name – indicates the actual element/attribute in the exchange standard.
XPATH – provides the exchange standards XML location in the message.
Datatype – indicates the required datatype (e.g., string, numeric) in the exchange standard for the value provided for the XML element.
Element – indicates the XML element that is used to represent the common data element.
Attribute – indicates the XML attribute that is used to represent the common data element.
Representation in Exchange Standard – provides an XML snippet of the element and attribute and its value for the common data element.
Implementation Notes – indicates the information that should be contained in the data element values.

Note: the table may have one or more Data Element/Attributes for each of the common data elements. The entire section will be repeated for the number of elements and attributes needed for each common data element.

9 Appendix D: Data Exchange Guidelines

9.1 Medical Device Name

9.1.1 Medical Device Brand Name – RPS

The following data representations are applicable to this data element:

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedProduct.name@xsi:type	String	Element	name	<name xsi:type="EN">	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/subject2/review/subject1/manufacturedProduct/manufacturedProduct/name/@xsi:type		Attribute	xsi:type		xsi:type = value is always “EN”
manufacturedProduct.part@type	String	Element	part	<part type="GIV" value="medical device name"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/subject2/review/subject1/manufacturedProduct/manufacturedProduct/name/part/@type		Attribute	type		type = value is always “GIV”
manufacturedProduct.part@value	String	Attribute	value		value = brand name value
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/subject2/review/subject1/manufacturedProduct/manufacturedProduct/name/part/@value					

XML Snippet

```
<subject2>
  <review>
    <subject1>
      <manufacturedProduct>
        <manufacturedProduct>
          <name xsi:type="EN">
            <part type="GIV" value="medical device name"/>
          </name>
        </manufacturedProduct>
      </manufacturedProduct>
    </subject1>
  </review>
</subject2>
```

9.1.2 Medical Device Common Name – RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedProduct.asNamedEntity.code	String	Element	code	<code code="code123" codeSystem="2.16.840.1.113883"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/subject2/review/subject1/manufacturedProduct/manufacturedProduct/asNamedEntity/assigningTerritory/code/@code	String	Attribute	code		code = code for “common name”

/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/subject2/review/subject1/manufacturedProduct/manufacturedProduct/asNamedEntity/assigningTerritory/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
manufacturedProduct.asNamedEntity.name	String	Element	name	<name>common name</name>	name = value specified by the sender.
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/subject2/review/subject1/manufacturedProduct/manufacturedProduct/asNamedEntity/assigningTerritory/name		Attribute	n/a		

XML Snippet

```
<asNamedEntity>
  <assigningTerritory>
    <code code="code123" codeSystem="2.16.840.1.113883"/>
    <name>common name</name>
  </assigningTerritory>
</asNamedEntity>
```

9.1.3 Medical Device Brand Name - SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedProduct.name	String	Element	<name>	<name>brand name</name>	name = brand name value

XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/name		Attribute	n/a		

XML Snippet

```
<subject>
  <manufacturedProduct classCode="MANU">
    <manufacturedProduct>
      <code code="DI_number" codeSystem="1.3.160"/>
      <name>Medical Device Name</name>
```

9.1.4 Medical Device Common Name - SPL

The following pattern may be used to exchange additional or alternate medical device names in a message.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedProduct.asNamedEntity.code	String	Element	code	<code code="code123" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asNamedEntity/assigningTerritory/code/@code	String	Attribute	code		code = code for "common name"

/document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asNamedEntity/assigningTerritory/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
manufacturedProduct.asNamedEntity.name	String	Element	name	<name>common name</name>	name = value specified by the sender.
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asNamedEntity/assigningTerritory/code/@code		Attribute	n/a		

XML Snippet
The following XML snippet depicts the entire element used to convey the additional or alternate medical device name:

```
<asNamedEntity>
  <assigningTerritory>
    <code code="code123" codeSystem="2.16.840.1.113883"/>
    <name>common name</name>
  </assigningTerritory>
</asNamedEntity>
```

9.1.5 Medical Device Brand Name - ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
identifiedDevice.inventoryItem.manufacturedModelName	String	Element	manufacturerModelName	<manufacturerModelName	

XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/manufacturerModelName/@mediaType		Attribute	mediaType	mediaType="text/plain" >Brand Name</manufacturerModelName>	mediaType = value should always be “text/plain”
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/manufacturerModelName			value		value = brand name

XML Snippet

```
<manufacturerModelName mediaType="text/plain">THE ONE DEVICE</manufacturerModelName>
```

9.1.6 Medical Device Common Name - ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedDeviceModel.code.originalText	String	Element		<originalText mediaType="text/plain" >All in one pump</originalText>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/originalText/@mediaType		Attribute	mediaType		mediaType = value should always be “text/plain”

XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/originalText			value		value = common name

XML Snippet

```
<originalText mediaType="text/plain">All in one pump</originalText>
```

9.1.7 Medical Device Brand Name – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
brandName	String	Element		brandName	

9.1.8 Medical Device Common Name – N87

Currently, the model is not included in the message.

9.1.9 Medical Device Brand Name - FHIR

Note – Currently under development.

9.1.10 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- The element under manufactured product should only be used when providing the Brand/Trade/Proprietary Name.

- The ***asNamedEntity*** should be used to specify the Common Name.
  - A code must be available to specify the type of medical device name as “common name”.
  - A code system must be available for the value set of type of medical device name. Note: This is a candidate for IMDRF vocabularies.
  - A name value should be a sender-specified value and should not duplicate the medical device type. Use the medical device type for a shared common name/type.
  - Also, if there is another medical device name type that needs to be implemented, this element may be used with a different code value.
- Note: The medical device name is not represented in the FHIR Device resource.

9.2 Model

The following data representations are applicable to this data element.

9.2.1 Model - RPS

Currently, the model is not included in the message.

9.2.2 Model - SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asIdentifiedEntity.id	String	Element	id	<id root="2.16.840.1.113883.13" extension="model"/>	root = OID
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@extension		Attribute	extension		extension = value for the model
asIdentifiedEntity.code	String	Element	code	<code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/		Attribute	code		code = controlled vocabulary code for

component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@code					“model”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set

XML Snippet

```
<asIdentifiedEntity>
  <id root="2.16.840.1.113883.13" extension="model"/>
  <code code="C99285" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

9.2.3 Model - ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedDeviceModel.id	String	Element	id	<id extension="ABCDE"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/id/@extension		Attribute	extension		extension = value for model

XML Snippet

```
<manufacturedDeviceModel>
  <id extension="ABCDE"/>
```

9.2.4 Model - FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Model@value	String	Element	model	<model value="Model123"/>	
XPATH: /Device/model/@value		Attribute	value		value = value for model

XML Snippet

```
<model value="Model123"/>
```

9.2.5 Model – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
modelNum	String	Element		modelNum	

9.2.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Model

9.3 Catalog/Reference (REF)

The following data representations are applicable to this data element.

9.3.1 Catalog/Reference (REF) – RPS

Currently, the Catalog/Reference (REF) is not included in the message.

9.3.2 Catalog/Reference (REF) – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asIdentifiedEntity.id	String	Element	id	<id root="2.16.840.1.113883.13" extension="catalog number"/>	root = OID
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@extension		Attribute	extension		extension = value for the catalog
asIdentifiedEntity.code	String	Element	code	<code code="C99286" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@code		Attribute	code		code = controlled vocabulary code for "catalog/reference"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set

XML Snippet

```
<asIdentifiedEntity>
    <id root="2.16.840.1.113883.13" extension="catalog number"/>
    <code code="C99286" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

9.3.3 Catalog/Reference (REF) – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asManufacturedProduct.id@extension	String	Element	id	<id extension="SMTFY999"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/id/@extension		Attribute	extension		extension = value of catalog/reference

XML Snippet

```
<asManufacturedProduct>
  <id extension="SMTFY999"/>
```

9.3.4 Catalog/Reference (REF) – FHIR

Note – Currently under development.

9.3.5 Catalog/Reference (REF) – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
catalogNum	String	Element		catalogNum	

9.3.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- The catalog number needs further coverage in standards. Reassess maturity of standards when developing implementation guides.

9.4 Catalog/Reference (REF) Description

The following data representations are applicable to this data element:

- No existing standards include this specific element. This is a requirement that should be included in future standards

9.4.1 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Need to assess which standards need to be enhanced to include this information in the future.

9.5 Version (Software or Firmware)

The following data representations are applicable to this data element.

9.5.1 Version – RPS

Currently, the Version is not included in the message.

9.5.2 Version – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asIdentifiedEntity.id	String	Element	id	<id root="2.16.840.1.113883.13" extension="version number"/>	root = OID
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@extension		Attribute	extension		extension = value for the version
asIdentifiedEntity.code	String	Element	code	<code code="codeVSN" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufactur		Attribute	code		code = controlled vocabulary code for "version"

edProduct/manufacturedProduct/asIdentifiedEntity/code/@code					
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set

XML Snippet

```
<asIdentifiedEntity>
  <id root="2.16.840.1.113883.13" extension="version number"/>
  <code code="codeVSN" codeSystem="2.16.840.1.113883.3.26.1.1"/>
</asIdentifiedEntity>
```

9.5.3 Version – ICSR

Currently, the Version is not included in the message. Consider using ***deviceObservation*** element to convey this information, or adding a new element that will be semantically in line with version of the medical device.

9.5.4 Version – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.version	String	Element	version	<version value="10.23-23423"/>	
XPATH: **/Device/version/@value**		Attribute	value		value = software or hardware version number

XML Snippet

```
<version value="10.23-23423"/>
```

9.5.5 Version – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
deviceSoftwareVer	String	Element		deviceSoftwareVer	

9.5.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Version should follow regional regulations for capturing firmware or software version numbers.

9.6 Unique Device Identifier (UDI)

The following data representations are applicable to this data element.

9.6.1 UDI – RPS

Currently, the UDI is not included in the message.

9.6.2 UDI – SPL

Currently, the UDI is not included in the message.

9.6.3 UDI – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asManufacturedProduct.code		Element	code	<code code="(01)10857674002017(17)141120(10)1234AB" />	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/code/@code		Attribute	code		code = UDI value

XML Snippet

```
<code code="(01)10857674002017(17)141120(10)1234AB" />
```

9.6.4 UDI – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.udiCarrier	String	Element	udiCarrier	<udiCarrier value="(01)00000123000017(10)ABC123(17)120415"/>	
XPATH: /Device/udi/@value		Attribute	value		value = UDI value

XML Snippet

```
<udiCarrier value="(01)00000123000017(10)ABC123(17)120415"/>
```

9.6.5 UDI – N87

Currently, the UDI is not included in the message.

9.6.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- The issuing agency is not represented as the code system. The issuing agency is part of the UDI.

9.7 Device Identifier (DI)

The following data representations are applicable to this data element.

9.7.1 DI – RPS

Currently, the DI is not included in the message.

9.7.2 DI – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturedProduct.code	String	Element	code	<code code="12345678901234" codeSystem="1.3.160"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/code/@code		Attribute	code		Code= DI value
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/code/@codeSystem	String	Attribute	codeSystem		CodeSystem = OID for Issuing Agency

XML Snippet

```
<subject>
  <manufacturedProduct classCode="MANU">
    <manufacturedProduct>
      <code code="12345678901234" codeSystem="1.3.160"/>
```

9.7.3 DI – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
identifiedDevice.id	String	Element	id	<id extension="10857674002017"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/id/@extension		Attribute	extension		Extension = DI value

XML Snippet

```
<id extension="10857674002017"/>
```

9.7.4 DI – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.type.coding.system	String	Element	system	<system value="http://hl7.org/fhir/NamingSystem/gs1-di"/>	
XPATH: /Device/type/coding/system/@value		Attribute	value		Value = URI for system which will always be "http://hl7.org/fhir/NamingSystem/gs1-di"

Device.type.coding.code	String	Element	code	<code value="10857674002017"/>	
XPATH: /Device/type/coding/code/@value		Attribute	value		value = DI value

XML Snippet

```
<type>
  <coding>
    <system value="http://hl7.org/fhir/NamingSystem/gs1-di"/>
    <code value="10857674002017"/>
  </coding>
</type>
```

9.7.5 DI – N87

Currently, the DI is not included in the message.

9.7.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- The DI value should include the issuing agency. The issuing agency is represented differently across the standards, as an OID or URI.

9.8 Production Identifier - Serial Number

The following data representations are applicable to this data element.

9.8.1 Serial Number – RPS

Currently, the Serial Number is not included in the message.

9.8.2 Serial Number – SPL

The serial number may be represented as a numeric value.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asIdentifiedEntity.code	String	Element	code	<code code="codeSNO" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@code		Attribute	code		code = value for "serial number"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem		Attribute	codeSystem		codeSystem = OID for valid value set
asIdentifiedEntity.id	String	Element	id	<id root="2.16.840.1.113883.13" extension="serial number"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@root		Attribute	root		root = OID for namespace of serial number
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@extension		Attribute	extension		extension = value of serial number

XML Snippet

```
<asIdentifiedEntity>
    <id root="2.16.840.1.113883.13" extension="serial number"/>
    <code code="codeSNO" codeSystem="2.16.840.1.113883"/>
</asIdentifiedEntity>
```

The serial number may be represented as a Boolean value.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C101671" codeSystem="2.16.840.1.113883.3.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@code		Attribute	code		code = value for "serial number"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always "BL"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/val		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

ue/@value					

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C101671" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

9.8.3 Serial Number – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
identifiedDevice.id	String	Element	id	<id extension="XYZ45678"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/id/@extension		Attribute	extension		extension = value of serial number

XML Snippet

```
<identifiedDevice>
  <id extension="XYZ45678"/>
```

9.8.4 Serial Number – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
identifier.type.coding.system	String	Element	system	<system value="http://hl7.org/fhir/identifier-type"/>	
XPATH: /Device/identifier/type/coding/system/@value		Attribute	value		Value = value should always be “http://hl7.org/fhir/identifier-type”
identifier.type.coding.code	String	Element	code	<code value="SNO"/>	
XPATH: /Device/identifier/type/coding/code/@value		Attribute	value		value = value should always be “SNO”
identifier.type.text	String	Element	text	<text value="Serial Number"/>	
XPATH: /Device/identifier/type/text/@value		Attribute	value		value = value should always be “Serial Number”
identifier.value	String	Element	value	<value value="AMID-342135-8464"/>	
XPATH: /Device/identifier/value/@value		Attribute	value		value = Serial number value

XML Snippet

```
<identifier>
  <type>
    <coding>
      <system value="http://hl7.org/fhir/identifier-type"/>
      <code value="SNO"/>
    </coding>
    <text value="Serial Number"/>
  </type>
  <value value="AMID-342135-8464"/>
</identifier>
```

9.8.5 Serial Number – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
serialNum	String	Element		serialNum	

9.8.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Serial number is considered an identifier – and the value may be represented in multiple ways in SPL.

9.9 Production Identifier - Lot or Batch Number

The following data representations are applicable to this data element.

9.9.1 Lot or Batch Number – RPS

Currently, the Lot or Batch Number is not included in the message.

9.9.2 Lot or Batch Number – SPL

The lot or batch number may be represented as numeric value.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asIdentifiedEntity.code	String	Element	code	<code code="codeLBN" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@code		Attribute	code		code = value for "lot or batch number"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/code/@codeSystem		Attribute	codeSystem		codeSystem = OID for valid value set
asIdentifiedEntity.id	String	Element	id	<id root="2.16.840.1.113883" extension="lot or batch number"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@root		Attribute	root		root = OID for namespace of lot or batch number
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asIdentifiedEntity/id/@extension		Attribute	extension		extension = value of lot or batch number

XML Snippet

```
<asIdentifiedEntity>
    <id root="2.16.840.1.113883" extension="lot or batch number"/>
    <code code="codeLBN" codeSystem="2.16.840.1.113883"/>
</asIdentifiedEntity>
```

The lot or batch number may be represented as a Boolean value.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “lot or batch number”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always “BL”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the lot or batch number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C101672" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

9.9.3 Lot or Batch Number – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
identifiedDevice.lotNumberText	String	Element	lotNumber Text	<lotNumberText mediaType="text/plain">1234AB</lotNumberText>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/lotNumberText/@mediaType		Attribute	mediaType		mediaType = value is “text/plain”
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/lotNumberText	String	Attribute	value		value = value is the lot/batch number

XML Snippet

```
<lotNumberText mediaType="text/plain">1234AB</lotNumberText>
```

9.9.4 Lot or Batch Number – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.lotNumber	String	Element	lotNumber	<lotNumber value="1234-5678"/>	
XPATH: /Device/lotNumber/@value		Attribute	value		value = value of lot or batch number

XML Snippet

```
<lotNumber value="1234-5678"/>
```

9.9.5 Lot or Batch Number – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
batchNum	String	Element		batchNum	

9.9.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- [Add implementation consideration here]

9.10 Production Identifier - Manufacturing Date

The following data representations are applicable to this data element.

9.10.1 Manufacturing Date – RPS

Currently, the Manufacture Date is not included in the message.

9.10.2 Manufacturing Date – SPL

The manufacturing date may be represented as a Boolean value.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C101669" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for "manufacturing date"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always "BL"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C101669" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

9.10.3 Manufacturing Date – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
identifiedDevice.existenceTime	Date	Element	ExistenceTime	<existenceTime value="20000101"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/existenceTime/@value		Attribute	value		value = manufacturing date

XML Snippet

```
<existenceTime value="20000101"/>
```

9.10.4 Manufacturing Date – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.manufactureDate	Date	Element		<manufactureDate value="2015-08-08"/>	
XPATH: /Device/manufactureDate/@value		Attribute			value = manufacture date

XML Snippet

```
<manufactureDate value="2015-08-08"/>
```

9.10.5 Manufacturing Date – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
deviceMfrDate	String	Element		deviceMfrDate	

9.10.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- The date is represented differently in each of the standards.

9.11 Production Identifier - Expiration Date

The following data representations are applicable to this data element.

9.11.1 Expiration Date – RPS

Currently, the Expiration is not included in the message.

9.11.2 Expiration Date – SPL

The expiration date may be represented as a Boolean value.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C101670" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/		Attribute	code		code = value for “expiration date.”

component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code					
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always "BL"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C101670" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

9.11.3 Expiration Date – ICSR

Data Element/Attribute	Datatype	Elements/Attributes	Representation in Exchange Standard	Implementation Notes

identifiedDevice.expirationDate	Date	Element	expiration Date	<expirationTime value="20141120"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/expirationTime/@value		Attribute	value		value = expiration date

XML Snippet

```
<expirationTime value="20141120"/>
```

9.11.4 Expiration Date– FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.expiry	String	Element	expiry	<expiry value="2020-08-08"/>	

XML Snippet

```
<expiry value="2020-08-08"/>
```

9.11.5 Expiration Date – N87

Currently, the Expiration is not included in the message.

9.11.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- The value for expiration date is represented in different formats in the standards. The ISO date standard is YYYYMMDD.

9.12 Regulated Entity - Type

The following data representations are applicable to this data element.

9.12.1 Type of Regulated Entity– RPS

Note: Only Contact Party is represented with a Type value. Applicant can be represented without a type code.

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
contactParty.code	String	Element	ContactParty	<code code="codeCNT" codeSystem="2.16.840.1.113883.3.989.5.1.2.2.1.11.1"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/callBackContact[1]/contactParty/code/@code		Attribute	code		code = value for "contact type"
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[1]/submission/callBackContact[1]/contactParty/code/@codeSystem	String		codeSystem		codeSystem = OID for "contact type"

XML Snippet

```
<contactParty classCode="CON">
    <id root="417e5c25-2001-40d1-af34-f1f285614187"/>
    <code code="codeCNT" codeSystem="2.16.840.1.113883.3.989.5.1.2.2.1.11.1"/>
    <statusCode code="active"/>
```

9.12.2 Type of Regulated Entity – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
assignedEntity1.code	String	Element	code	<code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/code/@code		Attribute	code		code = value for "regulated entity"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/code/@codeSystem			codeSystem		codeSystem = OID for "regulated entity" code

XML Snippet

```
<assignedEntity>
  <representedOrganization>
    <assignedEntity1>
      <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

9.12.3 Type of Regulated Entity – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturerOrReprocessor.code		Element	ManufacturerOrReproc	<code code="C53616" codeSystem="2.16.840.1.11388	

			essor	3.3.26.1.1" codeSystemName="Type_of_Manufacturer"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/code/@code		Attribute	code		code = code for "Regulated Entity"
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/code/@codeSystem		Attribute	codeSystem		codeSystem = OID for regulated entity code system
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/code/@codeSystemName		Attribute	codeSystemName		codeSystemName = name of published code system

XML Snippet

```
<manufacturerOrReprocessor>
<code code="C53616" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="Type_of_Manufacturer"/>
```

9.12.4 Type of Regulated Entity – FHIR

Note: Type is not provided in FHIR, there is an element for contacts and manufacturer.

9.12.5 Type of Regulated Entity – N87

Currently, the Type of Regulated Entity is not included in the message.

9.12.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Types of regulated entities may be expressed in the exchange standard in multiple locations depending on the context of the regulated entity.
- Contacts may be used with the appropriate type code, but will include additional information about the person or organization due to the element requirements.

9.13 Regulated Entity – Name

The following data representations are applicable to this data element.

9.13.1 Name of Regulated Entity – RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
representedOrganization.name	String	Element	Name.part	<part value="Acme Devices"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/callBackContact/contactParty/contactPerson/asAgent/representedOrganization/name/part/@value Or /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/componentOf/application/holder/applicant/sponsorOrganization/name/part/@value		Attribute	value		value = name of the regulated entity

As contact organization:

```
<representedOrganization>
    <name>
        <part value="Acme Devices"/>
    </name>
</representedOrganization>
```

As applicant

```
<holder>
  <applicant>
    <sponsorOrganization>
      <id>
        <item root="1.3.6.1.4.1.519.1" extension="999999999"/>
      </id>
      <name>
        <part value="Acme Devices"/>
      </name>
    </sponsorOrganization>
  </applicant>
</holder>
```

9.13.2 Name of Regulated Entity – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
representedOrganization.name	String	Element	represented Organization	<name xsi:type="ON">Acme Device</name>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/name/@xsi:type		Attribute	xsi:type		xsi:type = value is always “ON”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganizatio		Attribute	name		name = value of the regulated entity name

n/assignedEntity1/representedOrganization/name					

XML Snippet

```
<assignedEntity>
  <representedOrganization>
    <assignedEntity1>
      <code code="C101684" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      <representedOrganization>
        <id root="1.3.6.1.4.1.519.1" extension="053588527"/>
        <name xsi:type="ON">Acme Device</name>
```

9.13.3 Name of Regulated Entity – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
manufacturerOrReprocessor.name		Element	name	<name>USA Device Manufacturer</name>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/name		Attribute			name = value of regulated entity name

XML Snippet

```
<manufacturerOrReprocessor>
<code code="C53616" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="Type_of_Manufacturer"/>
  <name>USA Device Manufacturer</name>
```

9.13.4 Name of Regulated Entity – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.manufacturer	String	Element	manufacturer	<manufacturer value="Acme Devices, Inc"/>	
XPATH: /Device/manufacturer/@value		Attribute	value		

XML Snippet

```
<manufacturer value="Acme Devices, Inc"/>
```

9.13.5 Name of Regulated Entity – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
mfrContactName	String	Element		mfrContactName	

9.13.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Name of regulated entity may represent any sender-specified value.
- If a regulated entity identifier is also provided – the sender-specified value may not be consistent with the value on file for the identifiers. Implementation should specify what value will be used by the receiver – i.e., the one in the message or the one resolved by using the identifier.

9.14 Regulated Entity – Address

The following data representations are applicable to this data element.

9.14.1 Address of Regulated Entity – RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
sponsorOrganization.addr	String	Element		<part xsi:type="ADXP" value="123 Main Street" type="STR"/> <part xsi:type="ADXP" value="Anytown" type="CTY"/> <part xsi:type="ADXP" value="NY" type="STA"/> <part xsi:type="ADXP" value="10159" type="ZIP"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/holder/applicant/sponsorOrganization/addr/part/@xsi:type		Attribute	xsi:type		xsi:type = value is always “ADXP”
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/componentOf/application/holder/applicant/sponsorOrganization/addr/part/@value	String	Attribute	value		value = value is the value of the address part
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/componentOf/application/holder/applicant/sponsorOrganization/addr/part/@type	String	Attribute	type		type = value is an HL7 code value for the address part

XML Snippet

```
<addr>
    <part xsi:type="ADXP" value="123 Main Street" type="STR"/>
    <part xsi:type="ADXP" value="Anytown" type="CTY"/>
    <part xsi:type="ADXP" value="NY" type="STA"/>
    <part xsi:type="ADXP" value="10159" type="ZIP"/>
</addr>
```

9.14.2 Address of Regulated Entity – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
addr.streetAddressLine XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/streetAddressLine	String	Element	value	<streetAddressLine>123 Main Street</streetAddressLine>	streetAddressLine = full street address for regulated entity
addr.city XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/city	String	Element	value	<city>Anytown</city>	city = city for regulated entity address
addr.state XPATH: /document/component/structuredBody/	String	Element	value	<state>NY</state>	state = state for regulated entity address

component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/state					
addr.postalCode XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/postalCode	String	Element	value	<postalCode>10159</postalCode>	postalCode = zip code for regulated entity
addr.country XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/country	String	Element	value	<country>USA</country>	country = country for regulated entity
addr.deliveryInstallationType	String	Element	code	<deliveryInstallationType code="codePS" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/deliveryInstallationType/@code	String	Attribute	code		code = value for type of address

XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[1]/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/addr/deliveryInstallationType/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for type of address

XML Snippet

```
<representedOrganization>
  <id root="1.3.6.1.4.1.519.1" extension="053588527"/>
  <name xsi:type="ON">Acme Device</name>
  <addr>
    <streetAddressLine>123 Main Street</streetAddressLine>
    <city>Anytown</city>
    <state>NY</state>
    <postalCode>10159</postalCode>
    <country>USA</country>
    <deliveryInstallationType code="codePS" codeSystem="2.16.840.1.113883"/>
  </addr>
</representedOrganization>
```

9.14.3 Address of Regulated Entity – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
addr.streetAddressLine XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/	String	Element	value	<streetAddressLine>555 Manufacturer Drive</streetAddressLine>	streetAddressLine = full street address for regulated entity

identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/addr/streetAddressLine					
addr.city XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/addr/city	String	Element	value	<city>Manufacturer City</city>	city = city for regulated entity address
addr.state XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/addr/state	String	Element	value	<state>CA</state>	state = state for regulated entity address
addr.postalCode XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/addr/postalCode	String	Element	value	<postalCode>12345-1234</postalCode>	postalCode = zip code for regulated entity
addr.country XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/	String	Element	value	<country>USA</country>	country = country for regulated entity

identifiedDevice/identifiedDevice/asManufacturedProduct/manufacturerOrReprocessor/addr/country					

XML Snippet

```
<addr>
  <streetAddressLine>555 Manufacturer Drive</streetAddressLine>
  <city>Manufacturer City</city>
  <state>CA</state>
  <postalCode>12345-1234</postalCode>
  <country>USA</country>
</addr>
```

9.14.4 Address of Regulated Entity – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
address.line	String	Element	line	<line value="123 Main Street"/>	
XPATH: /Location/address/line/@value		Attribute	value		value = street address
address.city	String	Element	city	<city value="Anytown"/>	
XPATH: /Location/address/city/@value		Attribute	value		
address.state	String	Element	state	<state value="NY"/>	
XPATH: /Location/address/state/@value		Attribute	value		

address.postalCode	String	Element	postalCode	<postalCode value="10159"/>	
XPATH: /Location/address/postalCode/@value		Attribute	value		
address.country	String	Element	country	<country value="USA"/>	
XPATH: /Location/address/country/@value		Attribute	value		
physicalType.coding.system	String	Element		<system value="http://hl7.org/fhir/location-physical-type"/>	
XPATH: /Location/physicalType/coding/system /@value		Attribute			
physicalType.coding.code	String	Element		<code value="bu"/>	
XPATH: /Location/physicalType/coding/code/ @value		Attribute			
physicalType.coding.display	String	Element		<display value="Building"/>	
XPATH: /Location/physicalType/coding/display /@value		Attribute			

XML Snippet

```
<Location xmlns="http://hl7.org/fhir">
  <id value="053588527"/>
  <address>
    <line value="123 Main Street"/>
    <city value="Anytown"/>
    <state value="NY"/>
    <postalCode value="10159"/>
    <country value="USA"/>
  </address>
  <physicalType>
    <coding>
      <system value="http://hl7.org/fhir/location-physical-type"/>
      <code value="bu"/>
      <display value="Building"/>
    </coding>
  </physicalType>
</Location>
```

9.14.5 Address of Regulated Entity – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
mfrAddress	String	Element		mfrAddress	
mfrCity				mfrCity	
mfrCountry				mfrCountry	
mfrPostcode				mfrPostcode	

9.14.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Location resource is a reference from the Device resource.

9.15 Regulated Entity – Identifier

The following data representations are applicable to this data element.

9.15.1 Identifier for Regulated Entity– RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
sponsorOrganization.id	String	Element	id.item	<item root="1.3.6.1.4.1.519.1" extension="999999999"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/componentOf/application/holder/applicant/sponsorOrganization/id/item/@root		Attribute	root		root = namespace OID for regulated entity identifier
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/componentOf/application/holder/applicant/sponsorOrganization/id/item/@extension		Attribute	extension		extension = identifier for regulated entity

XML Snippet

```
<holder>
    <applicant>
        <sponsorOrganization>
            <id>
                <item root="1.3.6.1.4.1.519.1" extension="999999999"/>
            </id>
```

9.15.2 Identifier for Regulated Entity – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
representedOrganization.id	String	Element	id	<id root="1.3.6.1.4.1.519.1" extension="99999999"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@root		Attribute	root		root = namespace OID for regulated entity identifier
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/document/author/assignedEntity/representedOrganization/assignedEntity1/representedOrganization/id/@extension			extension		extension = identifier for regulated entity

XML Snippet

```
<representedOrganization>
    <id root="1.3.6.1.4.1.519.1" extension="99999999"/>
</representedOrganization>
```

Identifier for Regulated Entity – ICSR
Currently there is not an identifier for the regulated entity.

9.15.3 Identifier for Regulated Entity – FHIR

Currently there is not an identifier for the regulated entity.

9.15.4 Identifier for Regulated Entity – N87

Currently there is not an identifier for the regulated entity.

9.15.5 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Identifiers are not implemented in all of the standards.

9.16 Kit

The following data representations are applicable to this data element:

9.16.1 Kits – RPS

Currently, the Kit is not included in the message.

9.16.2 Kits – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C50021" codeSystem="2.16.840.1.11388 3.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “kit”

XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always "BL"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C50021" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
```

9.16.3 Kits – ICSR

Currently, the Kit is not included in the message.

9.16.4 Kits – FHIR

Currently, the Kit is not included in the message.

9.16.5 Kits – N87

Currently, the Kit is not included in the message.

9.16.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Kits may be handled as extension in FHIR, but there is not the appropriate implementation details to provide guidance. Pending additional work in FHIR

9.17 Medical Device System

The following data representations are applicable to this data element.

9.17.1 Medical Device System – RPS

Currently, the Medical Device System is not included in the message.

9.17.2 Medical Device System – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code		
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “medical device system”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set

characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always “BL”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

9.17.3 Medical Device System – ICSR

Currently, the Medical Device System is not included in the message.

9.17.4 Medical Device System – FHIR

Currently, the Medical Device System is not included in the message.

9.17.5 Medical Device System – N87

Currently, the Medical Device System is not included in the message.

9.17.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Code values for Medical Device System will need to be created.

9.18 Contains Biological Material

The following data representations are applicable to this data element.

9.18.1 Contains Biological Material – RPS

Currently, this element not included in the message.

9.18.2 Contains Biological Material – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="codeCBM" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for "contains biological material"
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always "BL"
XPATH: /document/component/structuredBody/		Attribute	value		Value = value to indicate if the

component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value					serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="codeCBM" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
```

9.18.3 Contains Biological Material – ICSR

Currently, this element not included in the message.

9.18.4 Contains Biological Material – FHIR

Currently, this element not included in the message.

9.18.5 Contains Biological Material – N87

Currently, this element is not included in the message.

9.18.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- There are many requirements that are not met for Contains Biological Material. These will need to be reassessed at the time of implementation.

9.19 Single Use Device

The following data representations are applicable to this data element.

9.19.1 Single Use Device – RPS

Currently, this element not included in the message.

9.19.2 Single Use Device – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C53602" codeSystem="2.16.840.1.11388 3.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “single use”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always “BL”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
    <characteristic>
        <code code="C53602" codeSystem="2.16.840.1.113883.3.26.1.1"/>
        <value xsi:type="BL" value="true"/>
    </characteristic>
</subjectOf>
```

9.19.3 Single Use Device – ICSR

Currently, this element not included in the message.

9.19.4 Single Use Device – FHIR

Currently, this element not included in the message.

9.19.5 Single Use Device – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
deviceUsage	String	Element		deviceUsage	Controlled vocabulary is in progress

9.19.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- No additional implementation considerations.

9.20 Reusable - Single Patient Use Device

The following data representations are applicable to this data element.

9.20.1 Reuseable - Single Patient Use Device – RPS

Currently, this element not included in the message.

9.20.2 Reuseable - Single Patient Use Device – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="codeRSP" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “reusable single patient use”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always “BL”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="codeRSP" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
```

9.20.3 Reuseable - Single Patient Use Device – ICSR

Currently, this element not included in the message.

9.20.4 Reuseable - Single Patient Use Device – FHIR

Currently, this element not included in the message.

9.20.5 Reuseable - Single Patient Use Device – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
deviceUsage	String	Element		deviceUsage	

9.20.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- No additional implementation considerations.

9.21 Reusable - Multi-Patient Use Device

The following data representations are applicable to this data element.

9.21.1 Reuseable - Multi Patient Use Device – RPS

Currently, this element not included in the message.

9.21.2 Reuseable - Multi Patient Use Device – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="codeMPU" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “reusable – multi patient use”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always “BL”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="codeMPU" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="true"/>
  </characteristic>
</subjectOf>
```

9.21.3 Reuseable - Multi Patient Use Device – ICSR

Currently, this element not included in the message.

9.21.4 Reuseable - Multi Patient Use Device – FHIR

Currently, this element not included in the message.

9.21.5 Reuseable - Multi Patient Use Device – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
deviceUsage	String	Element		deviceUsage	

9.21.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- No additional implementation considerations.

9.22 Sterilization Method

The following data representations are applicable to this data element.

9.22.1 Sterilization Method – RPS

Currently, this element not included in the message.

9.22.2 Sterilization Method – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C84382" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for sterilization method
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	String	Element	value	<value xsi:type="CD" code="C101712" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always CD for sterilization method
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@code		Attribute	code		code = value for the type of sterilization method

XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C84382" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="CD" code="C101712" codeSystem="2.16.840.1.113883.3.26.1.1"/>
  </characteristic>
</subjectOf>
```

9.22.3 Sterilization Method – ICSR

Currently, this element not included in the message.

9.22.4 Sterilization Method – FHIR

Currently, this element not included in the message.

9.22.5 Sterilization Method – N87

Currently, this element not included in the message.

9.22.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Implementation working groups should check the status of ISO sterilization methods.

9.23 Need for Sterilization Before Use

The following data representations are applicable to this data element.

9.23.1 Need for Sterilization Before Use – RPS

Currently, this element not included in the message.

9.23.2 Need for Sterilization Before Use – SPL

The presence of a sterilization method indicates that the device needs sterilization before use.

9.23.3 Need for Sterilization Before Use – ICSR

Currently, this element not included in the message.

9.23.4 Need for Sterilization Before Use – FHIR

Currently, this element not included in the message.

9.23.5 Need for Sterilization Before Use – N87

Currently, this element not included in the message.

9.23.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- Future implementations may need something more specific when determining if the sterilization method was applied by the manufacturer or end-user. Revisit the requirements for additional clarification.

9.24 Supplied Sterile

9.24.1.1.1 Exchange Guidelines

The following data representations are applicable to this data element:

9.24.2 Supplied Sterile – RPS

Currently, this element not included in the message.

9.24.3 Supplied Sterile – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
characteristic.code	String	Element	code	<code code="C101676" codeSystem="2.16.840.1.113883.3.26.1.1"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf.characteristic/code/@code		Attribute	code		code = value for “supplied sterile”
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for valid value set
characteristic.value	Boolean	Element	value	<value xsi:type="BL" value="false"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@xsi:type		Attribute	xsi:type		xsi:type = value is always “BL”

XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf/characteristic/value/@value		Attribute	value		Value = value to indicate if the serial number is on the label (true or false)

XML Snippet

```
<subjectOf>
  <characteristic>
    <code code="C101676" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <value xsi:type="BL" value="false"/>
  </characteristic>
</subjectOf>
```

9.24.4 Supplied Sterile – ICSR

Currently, this element not included in the message.

9.24.5 Supplied Sterile – FHIR

Currently, this element not included in the message.

9.24.6 Supplied Sterile – N87

Currently, this element not included in the message.

9.24.7 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- No additional implementation considerations.

9.25 Regulatory Information - Medical Device Type

The following data representations are applicable to this data element.

9.25.1 Medical Device Type – RPS

Currently, this is not available in the message.

9.25.2 Medical Device Type – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
generalizedMaterialKind.code	String	Element	code	<code code="codeDT" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code/@code		Attribute	code		code = value for medical device type
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for medical device type code

XML Snippet

```
<asSpecializedKind>
  <generalizedMaterialKind>
    <code code="codeDT" codeSystem="2.16.840.1.113883"/>
  </generalizedMaterialKind>
</asSpecializedKind>
```

9.25.3 Medical Device Type – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
generalizedMaterialKind.code	String	Element	code	<code code="codeDT" codeSystem="2.16.840.1.113883" codeSystemName="Type_of_Device">	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/@code		Attribute	code		code = value for medical device type
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for medical device type code system
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/@codeSystemName	String	Attribute	codeSystemName		codeSystemName = name for medical device type code system

XML Snippet

```
<code code="codeDT" codeSystem="2.16.840.1.113883" codeSystemName="Type_of_Device">
```

9.25.4 Medical Device Type – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.type.coding.system	String	Element	system	<system value="http://snomed.info/sct"/>	
XPATH: /Device/type/coding/system/@value		Attribute	value		Value = URI for system which will be determined by the code system.
Device.type.coding.code	String	Element	code	<code value="25062003"/>	
XPATH: /Device/type/coding/code/@value		Attribute	value		value = coded value for the term
Device.type.coding.display	String	Element	display	<display value="Feeding tube, device"/>	
XPATH: /Device/type/coding/code/@value		Attribute	value		display = the value for the codified term

XML Snippet

```
<type>
  <coding>
    <system value="http://snomed.info/sct"/>
    <code value="25062003"/>
    <display value="Feeding tube, device"/>
  </coding>
</type>
```

9.25.5 Medical Device Type – N87

Data Element/Attribute	Datatype	Elements/Attributes	Representation in Exchange Standard	Implementation Notes

nomenclatureSystem	String	Element		nomenclatureSystem	
nomenclatureCode				nomenclatureCode	
nomenclatureCodeDefinedInText				nomenclatureCodeDefinedInText	

9.25.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- URIs for each of the controlled vocabularies needs to be specified in place of an OID.

9.26 Medical Device Risk Classification

The following data representations are applicable to this data element.

9.26.1 Medical Device Risk Classification – RPS

Currently, this is not available in the message.

9.26.2 Medical Device Risk Classification – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
generalizedMaterialKind.code	String	Element	code	<code code="codeDT" codeSystem="2.16.840.1.113883"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code/@code		Attribute	code		code = value for medical device type

XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/manufacturedProduct/asSpecializedKind/generalizedMaterialKind/code/@codeSystem	String	Attribute	codeSystem		codeSystem = OID for medical device type code

XML Snippet

```
<asSpecializedKind>
  <generalizedMaterialKind>
    <code code="codeDT" codeSystem="2.16.840.1.113883"/>
  </generalizedMaterialKind>
</asSpecializedKind>
```

9.26.3 Medical Device Risk Classification – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
generalizedMaterialKind.code	String	Element	code	<code code="codeRSK" codeSystem="2.16.840.1.113883" codeSystemName="GHTF_RISK_CLASS">	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/@code		Attribute	code		code = value for risk class
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/	String	Attribute	codeSystem		codeSystem = OID for medical device type code system

code/@codeSystem					
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/code/@codeSystemName	String	Attribute	codeSystemName		codeSystemName = name for medical device type code system

XML Snippet

```
<asSpecializedKind>
    <generalizedMaterialKind>
        <code code="codeRSK" codeSystem="2.16.840.1.113883"/>
    </generalizedMaterialKind>
</asSpecializedKind>
```

9.26.4 Medical Device Risk Classification – FHIR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
Device.type.coding.system	String	Element	system	<system value="URI"/>	
XPATH: /Device/type/coding/system/@value		Attribute	value		Value = URI for system which will be determined by the code system.
Device.type.coding.code	String	Element	code	<code value="CLS1"/>	
XPATH: /Device/type/coding/code/@value		Attribute	value		value = coded value for the term
Device.type.coding.display	String	Element	display	<display value="GHTF Class 1"/>	

XPATH: /Device/type/coding/code/@value		Attribute	value		display = the value for the codified term

XML Snippet

```
<type>
  <coding>
    <system value="http://imdrf.org/newLink"/>
    <code value="CLS1"/>
    <display value="GHTF Class I"/>
  </coding>
</type>
```

9.26.5 Medical Device Risk Classification – N87

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
nomenclatureSystem	String	Element		nomenclatureSystem	
nomenclatureCode	String	Element		nomenclatureCode	
nomenclatureCodeDefinedInText	String	Element		nomenclatureCodeDefinedInText	

9.26.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- URIs for each of the controlled vocabularies needs to be specified in place of an OID.

9.27 Submission Number

The following data representations are applicable to this data element.

9.27.1 Submission Number – RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
submission.id	String	Element	item	<item root="ae57b6fe-6a18-4bac-a3aa-f7540078b25a"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[3]/submission/id/item/@root		Attribute	root		root = unique identifier for the submission/regulatory activity

XML Snippet

```
<submission>
  <id xsi:type="DSET_II">
    <item root="ae57b6fe-6a18-4bac-a3aa-f7540078b25a"/>
  </id>
```

9.27.2 Submission Number– SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
approval.id	String	Element	id	<id root="2.16.840.1.113883.3.150" extension="BK010028"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[3]/approval/id/@root		Attribute	root		root = namespace OID for the submission number
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[3]/approval/id/@extension			extension		extension = value for the submission number

XML Snippet

```
<subjectOf>
  <approval>
    <id root="2.16.840.1.113883.3.150" extension="BK010028"/>
    <code code="C80442" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <component typeCode="COMP">
      <approval>
        <!--Supplement #-->
        <id root="2.16.840.1.113883.3.150" extension="0"/>
        <code code="SUPP" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </approval>
    </component>
  </approval>
</subjectOf>
```

9.27.3 Submission Number – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asRegulatedProduct.id		Element	id	<id extension="P000001"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/asRegulatedProduct/id/@extension		Attribute	extension		extension = value of submission number

9.27.4 Submission Number – FHIR

Currently, this element is not included in the message.

9.27.5 Submission Number – N87

Currently, this element is not included in the message.

9.27.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- No additional implementation considerations.

9.28 Regulatory Authorization or Marketing Number

The following data representations are applicable to this data element:

9.28.1 Regulatory Authorization or Marketing Number – RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
submission.id	String	Element	item	<item root="ae57b6fe-6a18-4bac-a3aa-f7540078b25a"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[3]/submission/id/item/@root		Attribute	root		root = unique identifier for the submission/ regulatory activity

XML Snippet

```
<submission>
  <id xsi:type="DSET_II">
    <item root="ae57b6fe-6a18-4bac-a3aa-f7540078b25a"/>
  </id>
```

9.28.2 Regulatory Authorization or Marketing Number – SPL

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
approval.id	String	Element	id	<id root="2.16.840.1.113883.3.150" extension="BK010028"/>	
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[3]/approval/id/@root		Attribute	root		root = namespace OID for the submission number
XPATH: /document/component/structuredBody/component/section/subject/manufacturedProduct/subjectOf[3]/approval/id/@extension			extension		extension = value for the submission number

XML Snippet

```
<subjectOf>
  <approval>
    <id root="2.16.840.1.113883.3.150" extension="BK010028"/>
    <code code="C80442" codeSystem="2.16.840.1.113883.3.26.1.1"/>
    <component typeCode="COMP">
      <approval>
        <!--Supplement #-->
        <id root="2.16.840.1.113883.3.150" extension="0"/>
        <code code="SUPP" codeSystem="2.16.840.1.113883.3.26.1.1"/>
      </approval>
    </component>
  </approval>
</subjectOf>
```

9.28.3 Regulatory Authorization or Marketing Number – ICSR

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
asRegulatedProduct.id		Element	id	<id extension="P000001"/>	
XPATH: /PORR_IN040001UV01/message/controlActProcess/subject/investigationEvent/pertainsTo/procedureEvent/device/identifiedDevice/identifiedDevice/inventoryItem/manufacturedDeviceModel/asRegulatedProduct/id/@extension		Attribute	extension		extension = value of submission number

9.28.4 Regulatory Authorization or Marketing Number – FHIR

Currently, this element is not included in the message.

9.28.5 Regulatory Authorization or Marketing Number – N87

Currently, this element is not included in the message.

9.28.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- No additional implementation considerations.

9.29 Regulatory Authorization or Marketing Status

The following data representations are applicable to this data element.

9.29.1 Regulatory Authorization or Marketing Status– RPS

Data Element/Attribute	Datatype	Elements/Attributes		Representation in Exchange Standard	Implementation Notes
regulatoryStatus.code	String	Element	code	<code code="codeAPV" codeSystem="2.16.840.1.113883"/>	
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1/submission/subject2/review/subject3/regulatoryStatus/code/@code		Attribute	code		code = value for regulatory status
XPATH: /PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf1[3]/submission/subject2/review/subject3/regulatoryStatus/code/@codeSystem		Attribute	codeSystem		codeSystem = OID for regulatory status value set

XML Snippet

```
<subject2>
    <review>
    <subject3>
        <regulatoryStatus>
            <code code="codeAPV" codeSystem="2.16.840.1.113883"/>
        </regulatoryStatus>
    </subject3>
    </review>
</subject2>
```

9.29.2 Regulatory Authorization or Marketing Status – SPL

Currently, this is not available in the message.

9.29.3 Regulatory Authorization or Marketing Status – ICSR

Currently, this is not available in the message.

9.29.4 Regulatory Authorization or Marketing Status – FHIR

Currently, this is not available in the message.

9.29.5 Regulatory Authorization or Marketing Status – N87

Currently, this is not available in the message.

9.29.6 Implementation Considerations

The following conditions should be considered when incorporating the data exchange guidelines into the implementation guides:

- This requirement may need to be further developed in the standards.

Index