IMDRF International Medical Device Regulators Forum

Final Document

Title: Round 2, RPS Beta Testing Report

Authoring Group: Regulated Product Submission Working Group

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Table of Contents

1.0 Introduction 4

2.0 Scope 4

3.0 References 4

4.0 Definitions 4

5.0 Testing Summary 5

5.1 Background 5

5.2 Method 6

5.3 Findings 7

5.3.1 Test Case Errors 7

5.3.2 IG Deficiencies 7

5.3.3 Further RPS WG Discussion Required 8

Appendix A: Draft IG Used for Round 2 Testing 9

Appendix B – IMDRF-001, version 2 56

Appendix C – IMDRF-004 61

Appendix D – IMDRF-006 65

Appendix E – Testing Results 72

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.

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1.0 Introduction

Regulated Product Submission (RPS) is a messaging standard produced by HL7 that is designed to enable electronic submission of regulated products – including drugs, devices, food and veterinary medicines. The IMDRF RPS Working Group evaluated the Regulated Product Submission (RPS) standard to assess whether the standard can meet medical device needs as a harmonized electronic submission format.

As part of the IMDRF evaluation the working group performed "beta" testing of medical device submission scenarios to verify the RPS standard can effectively convey required submission information. Testing was conducted in two phases (rounds). Results from the first round of testing is documented in IMDRF/RPS WG/N21FINAL:2014.

2.0 Scope

This document summarizes the testing approach and results from the second and final round of IMDRF beta testing.

3.0 References

IMDRF/RPS WG/N21FINAL2014 RPS Beta Testing Document
HL7 RPS Standard, DSTU (the version of the standard that was used during testing)

4.0 Definitions

RPS: Regulated Product Submission. An HL7 standard currently being tested by the IMDRF RPS Working Group.

HL7: Health Level 7.

Test Case: One message within a Test Case Scenario.

Test Case Scenario: A collection of 3 – 5 test cases that are tested together in a particular order. The test case scenario follows a business process that is being tested.

Message: The XML file accompanying the documents contained in the submission unit. The XML file structure is defined by the RPS standard and provides information about how the files included should be reviewed.

Submission Unit: A package of documents to support a regulatory activity that is sent and received together. In paper terms, this is the fed-ex box containing a packet of information sent from industry to the regulator. In RPS terms, this includes the "message" / submissionUnit.xml file as well as the accompanying submission files.

Submission: A collection of Submission Units that support a single regulatory request or activity. The Submission is the regulatory activity for which information is sent to a regulator; and is typically what is approved (or disapproved) as a result of the review.

Bundled Submission: A Submission Unit that creates or revises a Submission in more than one Application.

Submission Group: An element in the RPS message that can be used to identify relationships between Submissions within an Application. As an example, the Submission Group may be used to show a relationship between all regulatory activities within an Application that relate to a specific group of products.

Application: A collection of Submissions to a country or region that are related based on business and regulatory practices.

Context of Use (COU): The table of contents section within a submission that a document should be placed in. For example, CH 2.2 General Summary of Submission.

Document: Information in the message about the files that make up the submission unit.

Keywords: A value assigned to a Context of Use or Document to allow a reviewer to distinguish between multiple Documents assigned to the same table of contents section.

Keyword Definition: The portion of the RPS XML message that defines details of keywords used within the Application.

Application Reference: A reference in the RPS message to indicate there is a related application that has relevance to the Application being submitted. The reference is simply a pointer to another Application number. It is not specific to content within the referenced Application. The type of relationship indicates the reason for relating the applications together.

5.0 Testing Summary

5.1 Background

HL7 standards such as RPS provide a large set of possible data and relationships that can make up the electronic message to describe a package of documents sent to regulators. Use of an HL7 standard requires creation of an Implementation Guide (IG). The IG describes which portions of the RPS standard will be used (and not used) for devices. The IG also provides detail on how elements of the RPS standard will be used to support medical device business processes.

Use of the RPS standard requires software tools to both create and view an RPS submission. Because sponsors and regulators may use software from different vendors, it is important that the RPS message consistently convey information that is interpreted in the same way by a variety of software tools.

Because of these factors, an RPS submission may fail to meet medical device requirements for one or more of the following reasons:

- The RPS Standard does not provide functionality that meets device needs;
- The IG developed does not clearly convey IMDRF rules for how the RPS standard should be used
- Different software vendors interpret requirements in the IG differently
- The Test Case scenario contained errors or was unclear

5.2 Method

Because the RPS standard has been tested for use in pharmaceutical submissions, IMDRF testing is focused on test scenarios that reflect processes and requirements unique to medical devices.

This second round of testing focused on a re-test of one test case scenario from the first round of testing, and two new regional test case scenarios. A brief description of each scenario tested, and the key requirements it covers is below. The full test case scenarios can be found in Appendices B, C and D.

- IMDRF-001 version 2. This was a re-test of the US Bundled PMA Supplement covered during the first round of testing.
- IMDRF-004 is a regional scenario based on requirements in Brazil. It tests the ability of the RPS standard to manage certificates issued by external agencies that support approval of one or more Applications over time.
- IMDRF-006 is a regional scenario based on requirements in the EU. It tests the definition of an Application in EU as a combination of applicant and EU directive annex under which the Application is made. Under this definition, Submissions for many products over time would be grouped under a single Application. This creates a unique requirement to manage multiple lifecycles (one for each separate Submission) within a single Application. The Submission Group element of the RPS message is evaluated for this purpose.

The IMDRF Working Group asked the same vendors who participated in round 1 testing to participate in round 2. All participating vendors were provided with a revised draft IG that had been adjusted based on lessons learned in the first round of testing (Appendix A), and with detailed test case scenarios (Appendices B, C and D). Vendors were asked to provide sample RPS messages for each test case scenario. This resulted in a test sample from multiple vendors for each scenario.

Test samples were reviewed by IMDRF RPS Working Group members to assess whether the samples adequately supported the business scenario, and to assess consistency of interpretation across vendors. Multiple findings were consolidated into broad finding categories. Each category was analyzed to determine the cause of the issue.

5.3 Findings

Analysis of test samples provided by the vendors uncovered fourteen areas requiring further action. The findings can be divided into three categories: errors in the Test Case Scenario, areas where additional detail and guidance should be provided in the IG, and areas requiring further discussion within the RPS WG to clarify the business requirements. A table showing all findings is included in Appendix E. Each summarized finding is cross-referenced to the row(s) in Appendix E to which it pertains.

5.3.1 Test Case Errors

There were 2 errors in Test Case Scenarios that resulted in inconsistency of vendor samples. Both errors are described below. These errors should be corrected before the Test Case Scenarios are used in future testing.

- IMDRF-004 TC#2 intended to use a Certificate from TC#1. Unfortunately there was a typographical error that changed the certificate expiration date between TC#1 and TC#2. This resulted in vendors assuming two independent certificates existed, when there was only one. Refer to Appendix E, row 8.
- IMDRF-006 (all test cases) described in detail how each submission unit impacted Submission Groups. Unfortunately it did not specify when a Submission Unit should create a new Submission (rather than adding to an existing Submission). As a result the vendor samples were inconsistent in whether a new Submission was created. **Refer** to Appendix E, row 9.

5.3.2 IG Deficiencies

There were nine findings that require updates to the Implementation Guide. Each of the required IG updates is listed below.

- Clarify that a Keyword definition must be provided once in an Application, and does not need to be provided with each message where the Keyword is used. The IG will also clarify that only Keywords used in the Application should be defined (no unused Keyword Definitions are permitted). Refer to Appendix E, row 1.
- Add details as to the expected Keyword Definition format. Validation checks should be defined to ensure one approach is used. Refer to Appendix E, row 2.
- The IG currently allows Keywords to be used at both the Document and Context Of Use (COU) level. However it does not provide enough guidance on the business scenarios when the Keyword should be applied to the Document rather than the Context of Use. The IG should also give specific guidance for how to manage Document Keywords over the lifecycle of an Application. Refer to Appendix E, row 3.
- Modify the IG language so it is clear that Priority Numbers are always required on a Context of Use. Validation checks should be defined to ensure they are always present.

Refer to Appendix E, row 4.

- Provide COU Code System values and Controlled Vocabulary. Refer to Appendix E, row 10.
- The IG should reflect that Related COUs cannot refer to COU IDs within the same Submission Unit. If this occurs, the RPS message should fail validation. Refer to Appendix E, row 11.
- Specify that Status Code on the Submission element as required. The Submission Status code would default to Active, but would be set to Inactive if a regulatory activity is withdrawn. The IG should also include more detailed instructions to describe RPS message elements to be addressed when a Submission is withdrawn by the applicant. Refer to Appendix E, row 12.
- Clarify Applicant Holder is always required. Refer to Appendix E, row 13.
- Clarify the business scenarios that require use of Submission Group. Validation criteria should be used to mitigate invalid use of Submission Group. Refer to Appendix E, row 14.

5.3.3 Further RPS WG Discussion Required

There were three findings that require further discussions within the RPS WG to determine whether / how they should be addressed.

- IMDRF-004 evaluates management of Certificates that support multiple Applications. The use of Document Keywords to manage Certificate detail worked well. However it is unclear whether there is value in using the Related Application element to tie Applications together when they rely on the same Certificate. Refer to Appendix E, row 5.
- Some vendor samples used the TOC section number as part of the Document Title. Because the TOC section number is also a Context of Use controlled vocabulary value and a single document may be assigned to multiple Contexts of Use, the inclusion of section number in the document title may cause confusion. Further discussion is required to determine if the IG should prohibit use of TOC Section numbers in Document Titles. Refer to Appendix E, row 6.
- The RPS message allows a Language attribute on both Document Text and Document Title. The Text Language attribute is intended to denote the language of the document content. The Title Language attribute denotes the language of the document title. The current IG on requires inclusion of the Text Language attribute. This assumes the language used in a Document Title will always match the language used in the document content. Additional discussion within the RPS WG is required to validate this assumption. Refer to Appendix E, row 7.

Appendix A: Draft IG Used for Round 2 Testing

IMDRF International Medical Device Regulators Forum

Draft

International Medical Device Regulators Forum

Title: Beta Testing – Regulated Product Submission Implementation Specification

Authoring Group: IMDRF RPS Work Group

Date: April 17, 2014

Table of Contents

1. Submission Contents, Folder and File Structure 8
1.1 Submission Unit Contents 8
1.2 File/Folder Naming Conventions 8
1.2.1 Allowable Characters 9
1.2.2 Length 9
1.3 Pathname Conventions and Best Practices 10
1.4 Checksums 10
1.5 Compressed Archive 10

2. Essential Components of the HL7 RPS Submission 10
2.1 Controlled Vocabularies 10
2.1.1 Controlled Vocabularies specified by IMDRF 11
2.1.2 Controlled Vocabulary specified by HL7 12
2.2 OIDS and UUIDS 12
2.2.1 Object Identifiers 13
2.2.2 Universally Unique Identifiers 13
2.3 Data Types 13
2.4 HL7 RPS XML Schema 14
2.5 XML Components 15

3. Submission Life Cycle 21
3.1 Application 21
3.1.1 application.id.item 22
3.1.2 application.code 23
3.2 Application Reference 23
3.2.1 applicationReference.id 24
3.2.2 applicationReference.reasonCode 25
3.3 Category Event 26
3.3.1 categoryEvent.code 26
3.4 Submission 27
3.4.1 submission.id 27
3.4.2 submission.code 28
3.5 Submission Unit 29
3.5.1 submissionUnit.id 29
3.5.2 submissionUnit.code 29
3.5.3 submissionUnit.title 30
3.5.4 submissionUnit.statusCode 30
3.6 Submission Group 31
3.6.1 submissionGroup.id 31

4. Submitter or Applicant 32

5. Submission Contents 32
5.1 Context of Use 32
5.1.1 contextOfUse.id 33
5.1.2 contextOfUse.code 33
5.1.3 contextOfUse.statusCode 34

5.1.4 ..... contextOfUse.setId 34
5.1.5 ..... contextOfUse.versionNumber 35
5.2 ..... Context of Use Priority Number 36
5.2.1 ..... component.priorityNumber 36
5.3 ..... Document 37
5.3.1 ..... document.id 38
5.3.2 ..... document.title 38
5.3.3 ..... document.text 39
5.4 ..... Document Reference 40
5.4.1 ..... documentReference.id 41
5.5 ..... Keywords 41
5.5.1 ..... keyword.code 42
5.6 ..... Keyword Definitions 42
5.6.1 ..... keywordDefinition.code 43
5.6.2 ..... keywordDefinition.statusCode 44
5.6.3 ..... keywordDefinition.value 44
5.7 ..... Related Context of Use 45
5.7.1 ..... Sequel To 46
5.7.1.1 sequelTo.relatedContextOfUse.id 46
5.8 ..... Submission Reference 47
5.8.1.1 submissionReference.id.item 47
6. ..... Appendix: Life Cycle Considerations 48
6.1 ..... Context of Use Priority Number 48
6.2 ..... Managing Context of Uses 49
6.2.1 ..... Ordering Context of Use 50
6.3 ..... Reordering Context of Use 50
6.3.1 ..... Inserting Context of Use 51
6.3.2 ..... Remove/Inactivate Context of Use 52
6.3.3 ..... Replacing Context of Use 52
6.4 ..... Appendix: Submission Grouper 53
6.4.1 ..... Bundled Submissions – TCS IMDRF-001 53
6.4.1.1 Create a submission unit for all submissions in the bundle and use Submission Group to link the information. 53
6.4.2 ..... EU Submission Groups – IMDRF-006 54
6.4.2.1 Create a submission unit for each submission group in the message 54
6.5 ..... Appendix: Two-Way Communication 55
6.6 ..... Appendix: Controlled Vocabulary 55

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.

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DOCUMENT HISTORY

Revision Date	Description of Change
May 31, 2013	Initial beta testing draft to vendors
April 17, 2014	Revised draft for additional beta testing with vendors. See Appendix for testing instructions not included in the main document.

INSTRUCTIONS TO READER

This is a technical document that provides instructions on how to implement the HL7 RPS standard for IMDRF. The following content will be provided in a consistent manner within the document and/or the reader may be prompted by visual cues about the context or referenced information being presented in the document.

Document Content

In the document there are several notations that are used to provide clarity to the subject matter. The following table provides visual cues that are used in the document.

Icon	Description
	Technical descriptions
	Items to be careful to follow
	Additional Instructions
	References to other documents

The document refers to XML components (e.g. elements and attributes) versus the concept that it represents. The text will take the following notation:

- XML elements and attributes
  - In narrative text, they will be Bold, Italicized text in Camel case, e.g., ***ContextOfUse***
  - Within the XML, they will be shown as notated below for the XML Snippets.
- Concept without attribution to the model or message
  - Plain text with first letter capitalized as it is a defined concept, e.g., Context of Use

XML Snippets

The following figure indicates the color coding used in the XML snippets and any meaning that should be inferred by the samples.

Text Color	Description ***Sample***
Teal	Schema components *<?xml version "1.0" encoding="UTF-8"?>*
Blue	XML notations < ….= "">
Brown	XML element *id code*
Red	XML attribute *root extension*
Black	Value of the element or attribute *2.16.840.1.113883*

Note: XML editors may display these XML components differently, please use the legend above for XML presented in this document.

Required Schema Attributes

The IMDRF HL7 RPS message contains additional attributes that have not been set to a fixed value to provide for future extensibility of the schema. When submitting an IMDRF HL7 RPS submission, these attributes need be sent in with fixed values specified in this document. The value for all other schema attributes will be specifically stated for each element when required.

For example: The ***subject@typeCode*** value must be equal to "DEV" to pass schema validation. Any other value in this field may cause the schema validation to fail.

In the example above, the value for the ***typeCode*** attribute should be "MANU". In the future, this may be fixed in the schema, but for increased extensibility of the schema, it has not been constrained any further.

XML Elements Tables

A table has been provided for each element in the XML message. When elements have multiple element parts or attributes, they are provided in one table. When there are no attributes or values for an element, the cell is grayed out to indicate that no value is required in the XML message.

Table Name: <element>

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
Business Rules				
XPATH				

Table Name: Each table is named for the elements it is representing in the XML – i.e., <element> or <element 2>.

Element: Identifies the XML element

Attribute: Identifies the XML attribute

Cardinality: Provides information on how many times the element/attribute can be repeated in the XML message.

Value(s) Allowed/Examples: Identifies the values allowed using simple data types and any associated examples. References to controlled vocabulary will also be provided

Description/Instructions: Provides a description of the element or attribute

Business Rules: Identifies any business rules that are in place for RPS.

XPATH: Identifies the location of the data element in the XML.

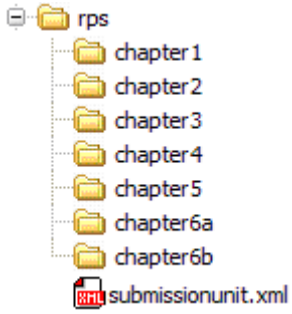
1. Submission Contents, Folder and File Structure

The folder and file structure specified for the document contents being transmitted along with the XML message will need to follow various specifications and rules as presented below in this section.

1.1 Submission Unit Contents

When submitting the contents of a Submission Unit, the following structure should be used:

Figure 1: RPS Folder Structure



NOTE: The folder structure is still under discussion in the IMDRF RPS Working Group.

The *First Level Folder* will be named "*rps*" and include the following contents:

- The RPS Message should be named "submissionunit.xml" (see figure above).
- The submitter should not send the schema files, the XML should reference the schema found on the HL7 site. Note: Pending Confirmation
- Folders for Chapters 1 – 6b and the content to be included in that submission unit should apply the following rules:
    - Folder structure for Chapters 1 through 6b folders should follow the structure provided in this document.
    - All files included in these folders should be accounted for in the XML Message[1]
    - Files previously sent do not need to be sent again[2]

1.2 File/Folder Naming Conventions

For the Beta Testing, the naming conventions for folders shall follow the folder names presented in the sample above. In addition, there are general naming conventions that include:

- Folder or file names shall have only lower case characters.
- File extensions –
    - All files should have one and only one file extension.
    - The file extension should be used to indicate the format of the file.

[1] If the file is not included in the XML Message, then the submission may be considered invalid.

[2] If a document is only referenced in the XML Message, it does not need to be included in the attachments.

For the Beta Testing, the naming conventions for folders shall follow the folder names presented in the sample above. Additional guidance for naming convention that is not specified in the sub-sections includes:

- Folder or file names should be written in lower case only.
- All files should have one and only one file extension.
- The file extension should be used to indicate the format of the file.

1.2.1 Allowable Characters

All implementations shall follow the IETF rules for Uniform Resource Locators (URLs) (except for period and asterisk) for file or folder name. The special characters indicated in the table below may be used.

Figure 2: Allowable Special Characters

Special Character	Description
$	Dollar sign, Peso sign
-	Hyphen, Dash
_	Underscore, understrike, low line, low dash
+	Plus sign
!	Exclamation mark
'	Apostrophe, Single quotation mark
(	Left parentheses, Left bracket (UK)
)	Right parentheses, Right bracket (UK)

Consult the IETF documentation on *Uniform Resource Identifier (URI): Generic Syntax RFC 3986.*

1.2.2 Length

The restrictions on file or folder name lengths should follow the specifications below:

- Maximum document (i.e., file) name length: 64
- Maximum folder name length: 64
- Maximum path length including first level folder: 180
    - *Note: this allows the folder structure to exist under a logical drive with high level folder that is applicable to the submitter's environment*
- File name extension = 3 or 4 characters

1.3 Pathname Conventions and Best Practices

The pathname convention should reference the relative folder path using the forward slash (/) character to separate the folders. For example, the following pathname indicates the relative location of the file to the XML submission that it originated E.g.,"module1/coversheet.pdf".

1.4 Checksums

The RPS XML message will contain checksums for all ***Document.text.integrityCheck*** elements. The SHA-256 integrity check algorithm should be applied to obtain a checksum for all files referenced in a ***document*** element within a given submission unit.

The purpose of the checksum is as follows:

- The integrity of each file can be verified by comparing the checksum submitted with the file and the computed checksum
- The checksum can be used to verify that the file has not been altered in the historical archive of the Regulatory Authority. This is especially useful as the files are migrated from one storage medium to another as in the case of backup to magnetic tape storage.

1.5 Compressed Archive

A compressed archive is any collection of files that have been added to an archive and the archive has been compressed to minimize the file size of the archive file (e.g., zip files – with file extension .zip). No zip files are permitted, unless allowed by Regional Implementation Guide.

2. Essential Components of the HL7 RPS Submission

This section will provide a brief overview of the essential components of the RPS specification. The essential components include:

- Controlled Vocabulary
- OIDS and UUIDS
- Data Types
- RPS XML Schema
- RPS XML Message

> ***Note to Implementers:*** *The schema does not include the business rules that need to be dynamic to the process. The business rules outlined in the subsequent sections should be handled by any system generating the XML message.*

2.1 Controlled Vocabularies

The RPS Message makes extensive use of controlled vocabularies. The information in the following sub-sections will outline the controlled vocabulary used to implement HL7 RPS for IMDRF. There are several different authoritative sources for the controlled vocabulary, which include IMDRF, Regional Controlled Vocabularies and HL7 for the Beta Testing period.

> ***Note to Implementers:*** *The controlled vocabulary required by the HL7 RPS standard enables system to system communications and is not always the ideal way to display concepts in a system graphical user interface (GUI). Be cautious not to apply the technical codes in the GUI, instead use the business friendly terms that are specified by Regional Authorities.*

The information in the following sub-sections will outline the controlled vocabulary used in developing a IMDRF RPS message. There are several different authoritative sources for the controlled vocabulary, and as such they are categorized below by the organization that controls the content.

> ***Note to Implementers:*** *During Beta Testing, the controlled vocabulary will be provided in a spreadsheet format.*

2.1.1 Controlled Vocabularies specified by IMDRF

The controlled vocabularies specified below are managed by IMDRF are provided in a spreadsheet, which includes Beta Testing values.

Note: that this document is for Beta Testing only and is subject to change including all code values provided to support testing.

- Context of Use Codes
- Keyword Type Codes
- Keywords

The controlled vocabularies specified below are managed by Regional Regulatory Authorities are provided in a spreadsheet, which includes Beta Testing values.

Note: that this document is for Beta Testing only and is subject to change including all code values provided to support testing.

- Application Codes
- Application Reference Reason Codes
- Category Event Codes
- Contact Party Codes
- Contact Party Status
- Media Type Codes

- Regulatory Status Codes
- Regulatory Review Time Codes
- Submission Codes
- Submission Unit Codes

2.1.2 Controlled Vocabulary specified by HL7

The controlled vocabularies specified by Health Level 7 (HL7) are provided below with a brief description of the terminology and location for obtaining detailed information.

- **HL7 Document Type Codes:** This vocabulary is provided in the HL7 version 3 Standard for the ***typeCode*** attribute on ***sequelTo*** elements within the XML message. These codes are only required for ***typeCode*** attributes that are not fixed in the XML Schema. The ***codeSystem*** OID (2.16.840.1.113883.5.1002) is not required in the XML message for any ***typeCode*** attribute.
- **HL7 Status Codes:** This vocabulary is provided in the HL7 version 3 Standard for the ***statusCode*** element part on various elements within the XML message. These are values that should be used in the XML message for ***statusCode.code***. The ***codeSystem*** OID is not required for the statusCodes. Note: Status codes can only use the values provided by HL7 (***codeSystem*** OID: 2.16.840.1.113883.5.14).[3]

Note: The IMDRF Testing Group will be submitting harmonization requests to request additional typeCode and statusCode values to meet their business needs. The concepts proposed in this IG have not been submitted at the time of distributing this version of the document.

> ***Note to Implementers:*** *The controlled vocabulary required by the HL7 RPS standard enables system to system communications and is not always the ideal way to display concepts in a system graphical user interface (GUI). Be cautious not to apply the technical codes in the GUI, instead use the business friendly terms that are specified in the Implementation Guide.*

2.2 OIDS and UUIDS

There are two types of unique identifiers, Object Identifiers (OIDs) and Universally Unique Identifiers (UUIDs).

[3] For Beta Testing, a specific value set has not been selected for the FDA CDRH RPS Implementation.

2.2.1 Object Identifiers

An OID is a sequence of numbers that uniquely identify an object and represent a hierarchically-assigned namespace. OIDs are formally defined using the International Telecommunications Union ASN.1 standard[4]. OIDS are represented as follows:

- String of digits separated by periods: 2.16.840.1.113883
- list of named branches: {joint-iso-itu-t(2) country(16) us(840) organization(1) hl7(113883)}

The current OIDS for the IMDRF include:

- PENDING

In the HL7 RPS submission, OIDs will be used to provide the codeSystem value for each element that requires a code. Each required element with a code will indicate when an OID should be provided. For example, the XML Snippet below illustrates the code element with a code and codeSystem:

```
<code code="C101708" codeSystem="2.16.840.1.113883.3.26.1.1"/>
```

2.2.2 Universally Unique Identifiers

A UUID is a hexadecimal number in the form of 8-4-4-4-12, including 32 digits and 4 hyphens.[5] UUIDs are formally defined by ISO/IEC 11578:1996 and ITU-T Rec X.667 | ISO/IEC 9834-8:2005. UUIDs are represented as follows:

- String of digits separated by hyphens: 36589652-7894-6589-3256-321852697531

In the HL7 RPS Submission, UUIDs will be used for any instance identifier root attribute value. Each required element with an identifier (e.g., id or code) will indicate when a UUID should be provided. For example, the XML Snippet below illustrates the id@root attribute for the RPS Submission:

```
<id root="e48f95a8-c34f-4a3f-8664-fcd1dc6f9493"/>
```

The use of UUIDs enables for the objects to be uniquely identified in a central repository (e.g., database) of submission unit contents from all submitters. If UUIDs are not used, the content and objects may be incorrectly identified and used in the receiving system.

2.3 Data Types

Data Types are another essential component of the HL7 RPS specification. In order to provide all of the information required in the XML message, the data types are represented as elements and attributes. The data type for the elements and attributes are as follows:

---

[4] International Telecommunication Union, x680: Information technology – Abstract Syntax Notation One (ASN.1): Specification of basic notation

[5] International Telecommunication Union, x667: Information technology – Open Systems Interconnection – Procedures for the operation of OSI Registration Authorities: Generation and registration of Universally Unique Identifiers (UUIDs) and their use as ASN.1 object identifier components

- Alpha – allowing only alpha characters to be used (e.g., FDA product code "IRT")
- Alphanumeric – allowing alpha, numeric and special characters[6] to be used in a string. XML should follow W3C standards for alphanumeric values.
- Numeric – only allows numeric characters (e.g., 0 through 9.E+-) to be used in a string for integers and real numbers.
- Boolean: allows a true or false value to be provided.
- nullFlavors: these are used when required values need to be left blank. Null favors are based on HL7 Messaging standard, and constraints will be mentioned for each XML element.[7]

2.4 HL7 RPS XML Schema

This section will outline the required schema files for the RPS Message.[8] The schemas are organized by category and sub-categories in the table below.

NOTE: The schemas below have been flattened and provided as a separate file for IMDRF Beta Testing activities.

	Major Category	Schema Files	
1	**Core Schemas:** A common schema set for all HL7 v3 messages	infrastructureRoot-r2.xsd voc-r2.xsd datatypes-rX-cs.xsd iso-21090hl7-r2_datatypes.xsd	Referenced by core schema files: infrastructureRoot.xsd datatypes.xsd datatypes-base.xsd NarrativeBlock.xsd voc.xsd
2	**RPS Schema:** A schema set for the RPS compliant message	**Interactions:** PORP_IN000001UV01.xsd **Message Type:** PORP_MT000001UV01.xsd	**Control Act:** MCAI_MT700201UV01.xsd MCAI_MT900001UV01.xsd **Transmission**: MCCI_MT0001000UV01.xsd

[6] Only UTF-8 character set is allowed.

[7] Currently, nullFlavors are not used in the HL7 RPS submission.

[8] At the time of publication, no changes have been made to the HL7 Schema, but there are several outstanding issues that may require a FDA CDRH specific version of the schema files.

		Referenced Schema Files	
3	**Common Product Model Schema:** The Common Product Model schemas referenced by the RPS Schemas.	POCP_MT010100UV.xsd POCP_MT010200UV.xsd POCP_MT010300UV.xsd POCP_MT010400UV.xsd POCP_MT010600UV.xsd POCP_MT020100UV.xsd POCP_MT020200UV.xsd POCP_MT030100UV.xsd POCP_MT030200UV.xsd POCP_MT030300UV.xsd POCP_MT040100UV.xsd POCP_MT050100UV.xsd POCP_MT050200UV.xsd POCP_MT050400UV.xsd	POCP_MT060000UV.xsd POCP_MT060100UV.xsd POCP_MT060200UV.xsd POCP_MT070000UV.xsd POCP_MT070100UV.xsd POCP_MT070200UV.xsd POCP_MT080200UV.xsd POCP_MT080300UV.xsd POCP_MT081100UV.xsd POCP_MT082100UV.xsd POCP_MT090100UV.xsd
4	**Common Message Elements Schema:** The CMETs referenced by the Common Product model or RPS Schemas	COCT_MT030203UV07.xsd COCT_MT040203UV01.xsd COCT_MT050002UV07.xsd COCT_MT070000UV01.xsd COCT_MT090100UV01.xsd COCT_MT090300UV01.xsd	COCT_MT150000UV02.xsd COCT_MT150003UV03.xsd COCT_MT240003UV02.xsd COCT_MT440001UV.xsd COCT_MT710000UV07.xsd

2.5 XML Components

The following HL7 RPS message components are based on HL7 Version 3 Regulated Product Submission (RPS) Release 2 Draft Standard for Trial Use (DSTU). The information for each element is provided in discrete sections, i.e., they are not nested in the same structure of the XML Schema.

The following table provides a breakdown of the RPS XML structure with the relevant elements presented in this document.

Table 1: XML Structure

XML Structure

The RPS Message begins by identifying the ***subject*** element. The payload message starts with the ***submissionUnit*** element and relates the rest of the elements to the Submission Unit being sent. The ***submissionUnit*** element contains the following elements and their attributes:
• ***callBackContact.contactParty***
• ***subject.categoryEvent***
  o ***subject.categoryEvent (sub-category)***
• ***component.contextOfUse***
  o ***links.relatedContextOfUse***
  o ***sequelTo.relatedContextOfUse***
  o ***derivedFrom.documentReference***
  o ***subjectOf.submissionReference***
  o ***referencedBy.keyword***
• ***componentOf.submisison***

```
<subject typeCode="SUBJ">
        <submissionUnit>
            <id></id>
            <code></code>
            <title></title>
            <statusCode></statusCode>
            <callBackContact>
                <contactParty>
                    <id></id>
                    <statusCode></statusCode>
                    <contactPerson>
                        <name xsi:type="BAG_EN">
                            <item><part/></item>
                        </name>
                        <telecom xsi:type="BAG_TEL">
                            <item></item>
                        </telecom>
                    </contactPerson>
                </contactParty>
            </callBackContact>
            <subject>
                <categoryEvent>
                    <code></code>
                    <subject>
                        <categoryEvent>
                            <code></code>
                        </categoryEvent>
                    </subject>
                </categoryEvent>
            </subject>
            <component>
                <priorityNumber value=""/>
                <contextOfUse>
                    <id></id>
                    <code></code>
                    <title></title>
                    <statusCode></statusCode>
```

XML Structure

```
                    <setId></setId>
                    <versionNumber value=""/>
                    <primaryInformationRecipient>
                        <territorialAuthority>
                            <governingAuthority>
                            </governingAuthority>
                        </territorialAuthority>
                    </primaryInformationRecipient>
                    <links typeCode="ELNK">
                        <relatedContextOfUse>
                            <id></id>
                        </relatedContextOfUse>
                    </links>
                    <sequelTo typeCode="RPLC">
                        <relatedContextOfUse>
                            <id></id>
                        </relatedContextOfUse>
                    </sequelTo>
                    <derivedFrom>
                        <documentReference>
                            <id></id>
                        </documentReference>
                    </derivedFrom>
                    <subjectOf negationInd="">
                        <submissionReference>
                            <id xsi:type="DSET_II">
                                <item></item>
                            </id>
                        </submissionReference>
                    </subjectOf>
                    <referencedBy>
                        <keyword>
                            <code></code>
                            <statusCode></statusCode>
                        </keyword>
                    </referencedBy>
                </contextOfUse>
            </component>
```

This section of the XML relates to specifying the ***Submission*** element. The following elements may follow the Submission:

- **sequenceNumber** (included as an element of the relationship between ***submissionUnit*** and Submission)
- **callBackContact.contactParty**
- **subject1.mode**
- **subject2.review**
- **subject3.regulatoryReviewTime**
- **subject4.regulatoryStatus**
- **subject5.submissionGroup**

XML Structure

```
<componentOf>
  <sequenceNumber></sequenceNumber>
    <submission>
      <id></id>
      <code></code>
      <callBackContact>
        <contactParty>
          <id></id>
        </contactParty>
      </callBackContact>
      <subject1>
        <mode>
          <id></id>
        </mode>
      </subject1>
      <subject2>
        <review>
        </review>
      </subject2>
      <subject3>
        <regulatoryReviewTime>
          <code></code>
        </regulatoryReviewTime>
      </subject3>
      <subject4>
        <regulatoryStatus>
          <code></code>
        </regulatoryStatus>
      </subject4>
      <subject5>
        <submissionGroup>
          <id></id>
        </submissionGroup>
      </subject5>
```

XML Structure

This section of the XML relates to the ***application*** element. The application section contains the following elements and their attributes:

holder.applicant
informationRecipient.territorialAuthority
subject.reviewProcedure
reference.applicationReference
component.document
component.document
referencedBy.keyword
referencedBy.keywordDefinition
replacementOf.previousKeywordDefinition

```
      <componentOf>
        <application>
          <id>
            <item root="" extension=""/>
          </id>
          <code></code>
```

XML Structure

```
<holder>
    <applicant></applicant>
</holder>
<informationRecipient>
    <territorialAuthority>
        <governingAuthority>
            <id></id>
            <name>
                <part value=""/>
            </name>
        </governingAuthority>
    </territorialAuthority>
</informationRecipient>
<subject>
    <reviewProcedure>
        <code></code>
    </reviewProcedure>
    </subject>
    <reference>
        <applicationReference>
            <id></id>
        </applicationReference>
    </reference>
```

XML Structure

```
<component>
    <document>
        <id></id>
        <code></code>
        <title></title>
        <text integrityCheckAlgorithm="SHA256" value=""
    language="">
            <reference value=""/>
        <integrityCheck></integrityCheck>
        </text>
        <statusCode></statusCode>
        <versionNumber value=""/>
        <component>
            <priorityNumber value=""/>
                <document>
                    <id></id>
                </document>
        </component>
        <referencedBy>
            <keyword>
                <code></code>
                <statusCode></statusCode>
            </keyword>
        </referencedBy>
    </document>
</component>
    <referencedBy>
        <keywordDefinition>
            <code></code>
            <statusCode></statusCode>
            <value >
                <item>
                    <displayName></displayName>
                </item>
            </value>
            <replacementOf>
                <previousKeywordDefinition>
                    <code></code>
                    <value >
                        <item>
                            <displayName></displayName>
                        </item>
                    </value>
                </previousKeywordDefinition>
            </replacementOf>
        </keywordDefinition>
    </referencedBy>
```

These are the closing element tags for the key elements in the RPS message.

XML Structure

```
                                    </application>
                                </componentOf>
                            </submission>
                        </componentOf >
                    </submissionUnit>
```

3. Submission Life Cycle

This section will outline the XML elements required to identify the regulatory activity included in the submission unit. A submission unit may follow one of the following patterns:

- Single regulatory activity life cycle – one submission and one application related to the content being submitted in the submission unit
- Bundled regulatory activity life cycle – more than one submission and application related to the content being submitted in the submission unit. Each submission in the bundle is identified and all content in the submission unit is related to all submissions in the bundle unless otherwise noted.

Additional business requirements will be specified in regional implementation guides (e.g. FDA Modular Submission)

3.1 Application

An application is the collection of regulatory activities for the specific application type being submitted – e.g. specified in Regional Implementation Guides. The application element will identify the type of application and a unique identifier as well as the local identifier issued by the Regulatory Authority. There is usually one application identified in a submission unit, or more than one for a bundled submission. The following XML snippet shows the ***application*** element:

```
…
[This XML section will repeat for each application element.  A submission element is a componentOf
an application element]- need to have a generic example here
…
<componentOf>
   <application>
      <id>
         <item root="12345678-1234-1234-1233-123456789012" extension="PMA200002"/>
      </id>
      <code code="C80442" codeSystem="2.16.840.1.113883.3.26.1.1"/>
            …
            [Additional information may appear after the addition of the application.code, for
            example any of the following elements related to application – component,
            referencedBy, informationRecipient, reference, subject, or holder]
            …
   </application>
</componentOf>
```

3.1.1 application.id.item

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id.item		[1..1]		This is a container element of the following attributes by which it uniquely identifies the application.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier.
	extension	[1..1]	Alpha Numeric	This attribute provides a location to specify a regional requirement
Business Rules	The ***id.item@root*** attribute should stay the same for an ***id.item@extension*** value through the entire life cycle of the regulatory activity.			
XPATH				
root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/id/item/@root			
extension	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/id/item/@extension			

3.1.2 application.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
code		[1..1]		This is a container element that organizes the coded value for the application.
	code	[1..1]	Alpha Numeric	The code is a unique value that indicates the type of content in the application based on Regional Controlled Vocabulary
	codeSystem	[1..1]	Valid OID	The codeSystem is a unique identifier that indicates the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules	There must be one and only one ***code.code*** attribute specified for an application.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/code/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/code/@codeSystem			

3.2 Application Reference

An application reference allows the submitter to indicate any related applications – i.e, regional document references (e.g., Master File) or predicate device applications. When providing a reference to an existing application on file, a reason code should be provided to indicate how the application is being referenced in the current submission unit. Application references should be provided once for an application as it will be applicable to all regulatory activities in that application. The following XML snippet shows the ***applicationReference*** element:

```
<reference>
        <applicationReference>
                <id root="GUID#1" extension="M130001"/>
                <reasonCode>
                        <item code="C99999" codeSystem="OID"/>
                </reasonCode>
        </applicationReference>
```

</reference>

3.2.1 applicationReference.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..*]		This is a container element of the following attributes by which it uniquely identifies the application that is being referenced.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier.
	extension	[1..1]	Alpha Numeric	This attribute provides a location to specify a regional specific application tracking number.
Business Rules				
XPATH				
Root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/reference/applicationReference/id@root			
extension	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/reference/applicationReference/id@extension			

3.2.2 applicationReference.reasonCode

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
reasonCode		[1..*]		This is a container element that organizes the coded value for the reason an application is being referenced.
	code	[1..1]	Alpha Numeric .	The code is a unique value that indicates the reason for referencing an application based on Regional Controlled Vocabulary
	codeSystem	[1..1]	Valid OID	The codeSystem is a unique identifier that indicates the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules	Provide as many application references as necessary for the application being submitted.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/reference/applicationReference/reasonCode/item/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/componentOf/application/reference/applicationReference/reasonCode/item/@codeSystem			

3.3 Category Event

The category event allows the sender to identify the type of submission unit being sent – this can be a category and subcategory. This is in addition to a code value assigned to the submission unit. A controlled vocabulary sets for the allowable values – i.e., these are not user-defined values. The following XML snippet shows the ***categoryEvent*** element:

```
<subject>
    <categoryEvent>
        <--Category-->
        <code code="" codeSystem=""/>
        <subject>
            <--Sub-category, if applicable-->
            <categoryEvent>
                <code code="" codeSystem=""/>
            </categoryEvent>
        </subject>
    </categoryEvent>
</subject>
```

3.3.1 categoryEvent.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
code		[0..1]		This is a container element that organizes the coded value for the category event.
	code	[1..1]	Alpha Numeric *e.g., pending example*	The code is a unique value that indicates the category event(s) based on Regional Controlled Vocabulary
	codeSystem	[1..1]	Valid OID	The codeSystem is a unique identifier that indicates the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules	There category is serialized only by two levels – i.e., there can only be a category and subcategory per submission unit.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/subject/categoryEvent/code/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/subject/catego			

	ryEvent/code/@codeSystem

3.4 Submission

A submission is considered the Regulatory Activity, which often results in a decision or action against the complete set of regulatory content submitted for consideration. Each application type will have valid submission types. This will be specified by each regulatory authority.

(Should we provide examples for some authorities here) For testing purposes, the submission identifier should be globally unique and assigned by the submitter.

The following XML snippet shows the submission element:

```
<componentOf>
    <submission>
        <id xsi:type="DSET_II">
            <item root=""/>
        </id>
        <code code="" codeSystem=""/>

        …

        [add description of additional information here]

        …

    </submission>

</componentOf>
```

3.4.1 submission.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id.item		[1..1]		This is a container element of the following attributes by which it uniquely identifies the submission.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier.
	extension	[1..1]	Alpha Numeric	This attribute provides a location to specify a regional-specific submission value.
Business Rules	Pending business rules.			
XPATH				

root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/id/item/@root
extension	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/id/item/@extension

3.4.2 submission.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
code		[1..1]		This is a container element that organizes the coded value for the submission.
	code	[1..1]	Alpha Numeric *e.g., Original*	The code is a unique value that indicates the submission value based on regional Controlled Vocabulary
	codeSystem	[1..1]	Valid OID	The codeSystem is a unique identifier that indicates the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules				
XPATH				
Code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/code/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf /submission/code/@codeSystem			

3.5 Submission Unit

The submission unit is the discrete unit of content that is submitted by the Submitter in one XML message. A submission unit usually represents the content for one submission (or reviewable unit) at a point in time or as a bundled submission. This will be defined by each Regulatory Authority. The following XML snippet shows the ***submissionUnit*** element:

```
<subject typeCode="SUBJ">
        <submissionUnit>
            <id root=""/>
            <code code="" codeSystem=""/>
            <title value=""/>
            <statusCode code=""/>

        </submissionUnit>
</subject>
```

3.5.1 submissionUnit.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..1]		This is a container element of the following attributes by which it uniquely identifies the Submission Unit.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier.
Business Rules				
XPATH				
id	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/id/@root			

3.5.2 submissionUnit.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
code		[1..1]		This is a container element that organizes the coded value for the submission unit.
	code	[1..1]	Alpha Numeric *e.g., pending example*	The code is a unique value that indicates the submission unit value based on regional

				Controlled Vocabulary
	codeSystem	[1..1]	Valid OID	The codeSystem is a unique identifier that indicates the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules				
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/code/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/code/@codeSystem			

3.5.3 submissionUnit.title

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
title		[0..1]		This is a container element that organizes the title of the submission unit.
	value	[1..1]	String *e.g.,*	This attribute is for a string value that describes the submission unit.
Business Rules				
XPATH				
value	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/title/@value			

3.5.4 submissionUnit.statusCode

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
statusCode		[0..1]		This is a container element that organizes the coded value for the status code.
	code	[1..1]	Alpha Numeric	The code is a unique value that indicates the

			e.g., active	status code based on HL7 vocabulary.
Business Rules				
XPATH				
Code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/statusCode/@code			

3.6 Submission Group

The submission group should be used for bundled submissions or logical groupings of regulatory activities.

- When submitting the option for bundles that uses the grouper to identify all submissions in the bundle – i.e., there is one submission unit per submission where the submission group links all submissions in the bundle.
- When submitting the logical groupings of regulatory activities, the group will be defined by a submission group. Submission groups can be used across multiple regulatory activities.

The following XML snippet shows the ***submissionGroup*** element:

```
<subject5>
        <submissionGroup>
                <id root="000e72a3-adee-47a8-84f7-85e8ba5e3b55"/>
        </submissionGroup>
</subject5>
```

NOTE: The IMDRF RPS Group would like to test the versioning of submission content for each submission and handling the grouping or bundling of submission once the content is received. See section 6.4 for additional details.

The following element should only be provided for the business scenarios that warrant a grouper element – such as bundled submissions or logical grouping of regulatory activities.

3.6.1 submissionGroup.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..1]		This is a container element of the following attributes by which it uniquely identifies the Submission Group
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier.
Business Rules	The submission group id shall be used to indicate when a submission is part of a group. A submission group shall have more than one submission with a			

	submission group identifier for a submission to be considered bundled.
XPATH	
id	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/subject5/submissionGroup/id/@root

4. Submitter or Applicant

The applicant or sponsor of the regulatory submission will be specified by the Regional Implementation Guides.

5. Submission Contents

The submission contents include all of the metadata required to describe the contents of a regulatory submission, including the description of the document and its placement in a table of contents (i.e., under headings and subheadings).

5.1 Context of Use

The Context of Use is the heading or subheading within a table of contents for which the submission contents (i.e., the documents) should be organized (e.g., sterility, software, labeling). The following XML snippet shows the ***contextOfUse*** element:

```
<component>
        <priorityNumber value="100"/>
        <contextOfUse>
            <id root="12345678-1234-1234-1235-123456789012"/>
            <code code="imdrf_123" codeSystem="2.16.840.1.113883.3.989.2"/>
            <statusCode code="active"/>
            <setId root="12345678-1234-1234-1234-12987654321"/>
            <versionNumber value="1"/>

                …
                [Additional information may appear after the addition of the contextOfUse
                versionNumber (if one exists, otherwise this will follow the setId (which is
                required), for example any of the following elements related to contextOfUse –
                primaryInformationRecipient, links, sequelTo]
                …

           <derivedFrom>
                <documentReference>
                    <id root="12345671-2313-5364-2786-123875636748"/>
                </documentReference>
           </derivedFrom>
                …
                [Additional information may appear after the addition of the
                contextOfUse.versionNumber (if one exists, otherwise this will follow the setId
                (which is required), for example any of the following elements: subjectOf,
                referencedBy,]
```

```
            …
        </contextOfUse>
</component>
```

The following tables provide a complete set of XML elements and attributes required for the ***contextOfUse*** element, and any special instructions.

The ***classCode*** and ***moodCode*** are not required in the RPS XML message, the ***classCode*** is fixed to "ACT" and ***moodCode*** is fixed to "EVN".

5.1.1 contextOfUse.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..1]		This is a container element that organizes the context of use.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier.
Business Rules	The ***id@root*** should be unique for every ***contextOfUse*** submitted. The Context of Use ***id@root*** value should only be reused to reactivate a previously inactive Context of Use.			
XPATH				
root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/id/@root			

5.1.2 contextOfUse.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
		[1..1]		This is a container element that organizes the coded value for the context of use.
	code	[1..1]	Alpha Numeric *e.g., pending example*	The code is a unique value that indicates the Context of Use code based on IMDRF and Regional Controlled Vocabulary.

	codeSystem	[1..1]	Valid OID	The code system is a unique identifier that indicates the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules	The ***code*** element is required when the ***contextOfUse.statusCode*** is active. The ***code*** element is not required if the ***contextOfUse.statusCode*** is inactive.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/code/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/code/@codeSystem			

5.1.3 contextOfUse.statusCode

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
statusCode		[1..1]		This is a container element that has a controlled terminology code that indicates the status of the Context of Use.
	code	[1..1]	Alpha *e.g., active*	The code is a specified value that indicates whether the Context of Use is still relevant or if it has been removed.
Business Rules	The ***statusCode@code*** must always be sent in the message.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/statusCode/@code			

5.1.4 contextOfUse.setId

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*

setId		[1..1]		This is a container element, which is a unique identifier for the Context of Use that remains constant through all versions/revisions of the Context of Use.
	root	[1..1]	Valid UUID	A unique identifier.
Business Rules	The ***setId*** for the first version of a Context of Use should be used for all subsequent versions of that Context of Use within an Application. The ***versionNumber*** and the ***setId@root*** pair should be unique for each version of the Context of Use and only one instance can appear in the submission unit.			
XPATH				
root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/setId/@root			

5.1.5 contextOfUse.versionNumber

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
versionNumber		[0..1]		This is a container element, which is an integer value that identifies the version of the Context of Use.
	value	[1..1]	Numeric *e.g., 1, 2, 3*	An integer that increments the Context of Use ***versionNumber.***
Business Rules	The ***versionNumber*** and the ***setId@root*** pair should be unique for each version of the Context of Use. The first version of the document should start with the value "1" and increment by 1.			
XPATH				
versionNumber	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/versionNumber/@value			

5.2 Context of Use Priority Number

If there are more than one Context of Use elements with the same ***contextOfUse.code*** values, the headings may be placed in order by providing a priority number. The following XML snippet shows the ***priorityNumber*** element:

```
<component>
        <priorityNumber  value="1"/>
        <contextOfUse>
                <id root=""/>
                <code code="" codeSystem=""/>
                <title value=""/>
                <statusCode code=""/>
                <setId root=""/>
                <versionNumber value=""/>
```

5.2.1 component.priorityNumber

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
priotityNumber		[1..1]		This is a container element for the priority number and its value.
	value	[1..1]	*Numeric* *e.g., 1,2,3*	The value attribute provides a whole number to be used for ordering the Context of Use element.
	updateMode	[0..1]	*Alpha* *e.g., R=Replace*	The ***updateMode*** attribute provides the coded value to indicate if the ***priorityNumber*** has been changed for the Context of Use.
Business Rules	The priority number should be provided for each ***contextOfUse*** element. The value shall be an integer up to 6 digits (e.g., 1 – 999999) for the ***contextOfUse*** element with the same Context of Use code value. It is recommended to start with "100" and intervals of 100 (e.g., "200", "300", etc.) for the initial submission of a CoU. This allows increments of one and tens to be used when reordering and/or inserting CoU. The priority number will be used to order the Context of Use elements for display. If the order of the documents needs to be changed, the ***updateMode*** attribute should be used to indicate if the ***priorityNumber*** has been replaced.			
XPATH				
value	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/priorityNumber/@value			

updateMode	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/priorityNumber/@updateMode

5.3 Document

The document element is used for the purposes of transmitting the information about each document related to an application. Documents (e.g., PDF files) are prepared by the Applicant for review by the Regulatory Authority. One document can be associated with multiple ***contextOfUse*** elements, and may be used in multiple submission units. The following XML snippet shows the ***document*** element:

```
<component>
        <document>
           <id root="12345678-1234-1234-1234-98987654321"/>
           <title value="General Information"/>
           <text integrityCheckAlgorithm="SHA256" language="en">
              <reference value="../gen-info.pdf"/>
              <integrityCheck>618102bf07065bcc1250594201fe448515f0fa51</integrityCheck>
           </text>
           ...
                [Additional information may appear after the addition of the text (if one exists, otherwise
                this will follow the component. For example, depending on the type of document the
                following elements may be available to select from the document – component,
                sequelTo, referencedBy]
           …
        </document>
</component>
```

The ***classCode*** and ***moodCode*** are not required in the RPS XML message, the ***classCode*** is fixed to "ACT" and ***moodCode*** is fixed to "EVN".

5.3.1 document.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..1]		This is a container element for the document identifier.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier of the ***document.***
Business Rules	The ***id@root*** should be unique for every ***document*** element, i.e., there should not be two documents submitted with the same ***id@root*** value.			
XPATH				
root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/id/@root			

5.3.2 document.title

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
title		[1..1]		This is the container for the ***title*** element of a document.
	value	[1..1]	Alpha Numeric Sender-specified title *e.g., "General Information"*	This is the ***title*** attribute for the document. *This is a sender-specified value for each document.*
	updateMode	[0..1]	Alpha E.g., A = Add, R= Replace	This is the ***updateMode*** attribute that is used if updating the ***document.title*** element.
Business Rules	The ***title*** element should be used to indicate a human-readable value when displaying the document file to others. When sending a change in the ***title*** element, the ***title@updateMode*** attribute should be provided.			
XPATH				
value	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/title/@value			
updateMode	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/title/@updateM			

	ode

5.3.3 document.text

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
text		[0..1]		This is a container element that provides additional information about the document.
	integrityCheckAlgorithm	[1..1]	SHA256	This is the type of integrityCheckAlgorithm that was used for the checksum values provided in integrityCheck element.
	language	[0..1]	Alpha Refer to ISO 639.1 for two-letter language codes	This is the language attribute to indicate the language for the document.
text.reference		[0..1]		This is a container element within the text element for a document.
	value	[1..1]	Alpha Numeric *File path of the document*	This is the value attribute that provides the location of the document with the relative path and filename of the document.
text.integrityCheck		[1..1]	Alpha Numeric *e.g., "618102bf07065bcc1250594201fe448515f0fa61"*	This is the integrity check element, which has the checksum value.

Business Rules	The ***text*** element should only be used when sending a document for the first time. The ***text@language*** attribute is optional. For file reuse, the ***text*** element must indicate the same ***reference@value***, ***text@IntegrityCheckAlgorithm*** and ***text.integrityCheck*** values of the previously submitted document element.
XPATH	
integrityCheckAlgorithm	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/text/@integrityCheckAlgorithm
text@value	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/text/@value
text.reference@vaue	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/text/reference/@value
integrityCheck	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/text/integrityCheck

5.4 Document Reference

The document reference element associates a document to the context of use. The document is identified by the id value found for the document in the submission unit or previously provided by the submitter (i.e., the document may not be included in the XML message). The following XML snippet shows the ***documentReference*** element:

```
<derivedFrom>
    <documentReference>
        <id root=""/>
    </documentReference>
</derivedFrom>
```

The ***classCode*** and ***moodCode*** are not required in the RPS XML message, the ***classCode*** is fixed to “ACT” and ***moodCode*** is fixed to “EVN”.

Conditions that apply to the ***documentReference*** element:

- Zero to one ***documentReference*** elements can be sent for each ***contextOfUse.***
- For a contextOfUse.statusCode= active – the ***documentReference*** element is required.
- For a contextOfUse.statusCode= inactive – the ***documentReference*** element should not be provided.

5.4.1 documentReference.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..1]		This is a container element for a reference to a Document.
	root	[1..1]	Valid UUID	This attribute is for a global unique identifier of the Document being referenced.
Business Rules	The ***id@root*** is a reference to a document sent in the submission unit or a previously submitted submission unit.			
XPATH				
root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/derivedFrom/documentReference/id/@root			

5.5 Keywords

Keywords are code values that indicate a keyword that is used in conjunction with the Context of Use value (i.e., table of content heading) to organize submission contents.

The following XML provides an example of how to provide the keyword as a reference on either a Context of Use or Document.

The following XML snippet shows the ***keyword*** element:

```
<referencedBy>
   <keyword>
      <code code="IMDRF-Species-4" codeSystem="2.16.840.1.113883.3.989.2"/>
   </keyword>
</referencedBy>
```

The ***classCode*** and ***moodCode*** are not required in the RPS XML message, the ***classCode*** is fixed to "ACT" and ***moodCode*** is fixed to "EVN".

Conditions that apply to the ***keyword*** element:

- Zero to many ***keyword*** elements can be sent for each ***document or contextOfUse*** element.

5.5.1 keyword.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
code		[1..1]		This is a container element that identifies the keyword.
	code	[1..1]	Alpha Numeric e.g., "M123456" for Manufacture Site	This is the ***code*** attribute that identifies the code value for the keyword.
	codeSystem	[1..1]	Valid OID	This is the ***codeSystem*** OID that is a unique identifier for the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules	The display name for the ***code*** needs to be retrieved from the corresponding code system.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/referencedBy/keyword/code/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/component/document/referencedBy/keyword/code/@codeSystem			

5.6 Keyword Definitions

The Keyword definitions allow the submitter to send a set of keyword definitions that should be used in conjunction with the headings to organize the submission contents.

The following XML sample shows one ***keywordDefinition*** of type, manufacturer:

```
<referencedBy>
    <keywordDefinition>
        <code code="IMDRF-manufacturer"
        codeSystem="2.16.840.1.113883.3.989.2"/>
        <statusCode code="active"/>
        <value>
```

```
        <item code="MANU001" codeSystem="CompanyOID-
    ManufacturerKeyword">
            <displayName value="Big Device Manufacturer"/>
        </item>
    </value>
</keywordDefinition>
</referencedBy>
```

The ***classCode*** and ***moodCode*** are not required in the RPS XML message, the ***classCode*** is fixed to "ACT" and ***moodCode*** is fixed to "EVN".

Conditions that apply to the ***keywordDefinition*** element:

- Zero to many ***keywordDefinition*** elements can be sent for each ***application*** element
- A ***keywordDefinition*** should be provided for sender-specified keywords.

5.6.1 keywordDefinition.code

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
code		[1..1]		This is a container element that identifies the type of keyword definition.
	code	[1..1]	Alpha Numeric *e.g., "IMDRF-manufacturer"*	This is the ***code*** attribute for the coded value of the type of keyword definition.
	codeSystem	[1..1]	Valid OID	This is the ***codeSystem*** OID that is a unique identifier for the controlled vocabulary system. *This should be the OID registered for the code system.*
Business Rules	The ***code*** must be from a valid Keyword code type.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/referencedBy/keywordDefinition/code/@code			

codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/referencedBy/keywordDefinition/code/@codeSystem

5.6.2 keywordDefinition.statusCode

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
statusCode		[1..1]		This is a container element that identifies the status of the keywordDefinition.
	code	[1..1]	Alpha *e.g., active*	This is the code value for the status.
Business Rules	The ***code*** attribute should always have a value of "active".			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/referencedBy/keywordDefinition/statusCode/@code			

5.6.3 keywordDefinition.value

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
value		[1..1]		This is a container element for the keyword defined for the keyword code provided for keywordDefinition.
value.item		[1..1]		This is a container element to specify an individual keyword identifier.
	code	[1..1]	Alpha Numeric Sender specified value *e.g., MANU001*	This is the ***code*** attribute for the keyword being defined.
	codeSystem	[1..1]	Valid OID	This is the ***codeSystem*** OID that is a unique identifier

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
				for the controlled vocabulary system.
value.item.displayName		[1..1]		This is a container element to specify the ***displayName,*** which is the value of the keywordDefinition code.
	value	[1..1]	Alpha Numeric Sender specified value e.g., "Big Device Manufacturer"	This is the value attribute for the ***displayName*** of the keyword being defined.
	updateMode	[0..1]	Alpha e.g., A= Add R=Replace	The update mode should be used to make changes to the keywordDefinition's display name value.
Business Rules	Each ***keywordDefinition*** can only contain one sender-specified keyword. The ***displayName@value*** is the only attribute that can be updated, at which time the ***displayName@updateMode*** should be provided.			
XPATH				
code	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/referencedBy/keywordDefinition/value/item/@code			
codeSystem	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/referencedBy/keywordDefinition/value/item/@codeSystem			
value	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/componentOf/submission/componentOf/application/referencedBy/keywordDefinition/value/item/displayName/@value			

5.7 Related Context of Use

A related Context of Use is used in the Context of Use life cycle when one Context of Use element is replaced with another.

5.7.1 Sequel To

A sequelTo relationship is used when one context of use is replaced by another. This element is typically sent by the applicant when a context of use reorganizes content in the table of contents headings. This element will indicate the context of use that has been replaced as it is associated with the replacement context of use element.

The following XML snippet shows the ***relatedContextOfUse*** element:

```
<sequelTo typeCode="RPLC">
        <relatedContextOfUse>
                <id root="UUID"/>
        </relatedContextOfUse>
</sequelTo>
```

The ***classCode*** and ***moodCode*** are not required in the RPS XML message, the ***classCode*** is fixed to "ACT" and ***moodCode*** is fixed to "EVN".

5.7.1.1 sequelTo.relatedContextOfUse.id

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id		[1..1]		This is a container element for a related contextOfUse as referenced by an identifier.
	root	[1..1]	Valid UUID	This is the root element that provides the global unique identifier for the ***relatedContextOfUse*** element being replaced.
Business Rules	One ***contextOfUse*** element can be replaced by one or more ***relatedContextOfUse*** elements.			
XPATH				
root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/links/relatedContextOfUse/id/@root			

5.8 Submission Reference

This element should only be used with bundled submissions to indicate when content is not applicable to all submissions in the bundle – i.e., this is a negation indicator that negates the submission for a context of use. A submission reference is used on the Context of Use element when the content associated with the context of use does not apply to one or more of the submissions identified in the bundled submission unit. The submitter can identify one or more submissions by the id value (i.e, submissionReference.id.item@root). The following XML snippet shows the ***submissionReference*** element:

NOTE: This is a candidate for removal from IMDRF Implementation Guide. All submission units will relate to one submission at a time.

```
<subjectOf negationInd="true">
    <submissionReference>
        <id xsi:type="DSET_II">
            <item root="UUID"/>
            <item root="UUID"/>
        </id>
    </submissionReference>
</subjectOf>
```

5.8.1.1 submissionReference.id.item

Element	Attribute	Cardinality	Value(s) Allowed *Examples*	Description *Instructions*
id.item		[1..*]		This is a container element for submission reference.
	root	[1..1]	Valid UUID	This is the root element that provides the global unique identifier for the ***submissionReference*** element being provided.
Business Rules	Use this element to show which submissions do not relate to a Context of Use.			
XPATH				
id.item@root	/PORP_IN000001UV/controlActProcess/subject/submissionUnit/component/contextOfUse/subjectOf/submissionReference/id/item/@root			

6. Appendix: Life Cycle Considerations

The following sections provide additional information about the life cycle of elements in the RPS Message.

6.1 Context of Use Priority Number

The Context of Use element can be ordered by using the priority number to show the order in which the Context of Use elements should be displayed when they have the same ***ContextOfUse.code***. However, that only applies when the keywords are also the same. The example below depicts an example of how both priority number and keywords are used in relation to the Context of Use.

```
<component>
    <priorityNumber value="100"/>
    <contextOfUse>
        <id root="12345678-9999-8888-7777-098765432109"/>
        <code code=" IMDRF92" codeSystem="2.16.840.1.113883.3.989.2"/>
        <statusCode code="active"/>
        <setId root="12345678-9999-8888-7777-111111111112"/>
        <versionNumber value="1"/>
        <derivedFrom>
        <!—Reference to Simple Document-->
            <documentReference>
                <id root="11111111-2222-3333-4444-999999999999"/>
            </documentReference>
        </derivedFrom>
        <referencedBy>
            <keyword>
                <code code="MANU001"codeSystem="2.16.840.1.113883.X"/>
            </keyword>
        </referencedBy>
    </contextOfUse>
</component>
<component>
    <priorityNumber value="200"/>
    <contextOfUse>
        <id root="12345678-9999-8888-7777-098765432221"/>
        <code code=" IMDRF92" codeSystem="2.16.840.1.113883.3.989.2"/>
        <statusCode code="active"/>
        <setId root="12345678-9999-8888-7777-665544332211"/>
        <versionNumber value="1"/>
        <derivedFrom>
        <!—Reference to Simple Document-->
            <documentReference>
                <id root="11111111-2222-3333-4444-777777777777"/>
            </documentReference>
        </derivedFrom>
        <referencedBy>
```

```
            <keyword>
                <code code="MANU001"codeSystem="2.16.840.1.113883.X"/>
            </keyword>
        </referencedBy>
    </contextOfUse>
</component>
```

6.2 Managing Context of Uses

The life cycle management of a ***contextOfUse*** is covered in this section. Once a ***contextOfUse*** is submitted with its id, ***setId*** and version number, it starts the life cycle for that ***contextOfUse***. The following rules have been harmonized:

- The unique identifier will be the key along with the ***setId*** to ensure that the life cycle is managed.
- Each change to the ***contextOfUse*** will need to reference the id and ***setId***.
- If replacing a Context of Use, the two instances must have the same ***contextOfUse.code*** and associated Keywords (i.e., this will allow it to appear in exactly the same location when it is replaced.
- The replacement of Context of Use will inactivate the ***contextOfUse*** element that was previously sent (i.e., the ***relatedContextOfUse*** element(s)).

The following are reasons for changes to the ***contextOfUse*** through its life cycle:

- **New Version:** To version a ***contextOfUse***, a different document will need to be indicated in the ***documentReference*** element.
- **Removal (Inactivation) of Context of Use:** If the Context of Use needs to be removed at any time during the life cycle of the submission, a submission unit may indicate the removal of the Context of Use by changing the ***statusCode*** element.
- **Reactivation of Context of Use:** If the Context of Use needs to be reactivated after it has been withdrawn or inactivated at any time during the life cycle of the submission, a submission unit may indicate the reactivation of the Context of Use by changing the ***statusCode*** element.
- **Replacement of Context of Use:** If a Context of Use needs to be replaced over time, the ***contextOfUse.code*** value and keyword(s) of the new ***contextOfUse*** element should be the same as the one being replaced. The document referenced by the new ***contextOfUse*** element should be different.

6.2.1 Ordering Context of Use

If a ***submissionUnit*** includes components with the same ***contextOfUse*** code and ***keyword*** code, a priority should be set on the ***component*** to specify the relative display position of the ***contextOfUse*** relative to the other ***contextOfUse*** elements.

```
<component>
        <priorityNumber value="100"/>
        <contextOfUse>
            <id root="12345678-1234-1234-2222-123456789011"/>
            <code code="CDRH6.2" codeSystem="2.16.840.1.113883.3.989.2"/>
            <statusCode code="active"/>
            <setId root="12345678-1234-1234-1234-12987654321"/>
            <versionNumber value="1"/>
            <derivedFrom>
                    <!--Document #2"-->
                <documentReference>
                    <id root="11111111-2222-3333-4444-777777777777"/>
                </documentReference>
            </derivedFrom>
         </contextOfUse>
</component>
<component>
        <priorityNumber value="200"/>
        <contextOfUse>
            <id root="23567845-1234-1234-1234-123456789012"/>
            <code code="CDRH6.2" codeSystem="2.16.840.1.113883.3.989.2"/>
            <statusCode code="active"/>
            <setId root="12345678-9512-1234-4512-12987654322"/>
            <versionNumber value="1"/>
            <derivedFrom>
                    <!--Document #2-->
                <documentReference>
                    <id root="11111111-2222-3333-4444-777777771277"/>
                </documentReference>
            </derivedFrom>
         </contextOfUse>
</component>
```

6.3 Reordering Context of Use

There will be times when the ***contextOfUse*** elements may be sent in the incorrect order for display and the sender wants to correct the order. Reordering can also occur when a new Context of Use element needs to be added (see Section **Error! Reference source not found.** for additional information) or removed (See Section **Error! Reference source not found.** for additional information).

When the ***contextOfUse*** elements need to be reordered, the following basic rules should be followed:

- If a new component is added during the reordering, that ***contextOfUse*** element does not use the ***contextOfUse.priorityNumber@updateMode*** attribute.
- ***contextOfUse.priorityNumber@updateMode*** is used for the component being renumbered

The following example is the basic reordering of the previous context of use that was sent in the incorrect order. Note: the sender should never or rarely send a submission unit just to reorder ***contextOfUse*** elements. The previous Context of Use with a priority number of 100 does not need to be sent again in this submission unit.

The following example shows the reordering of a previously submitted Context of Use (note that only the required elements and attributes are sent) to have a placement prior to the Context of Use with priority number of 100.

#2– Reordering a Context of Use

```
<component>
        <priorityNumber value=“90”/>
        <contextOfUse>
            <id root=“23567845-1234-1234-1234-123456789012”/>
            <statusCode code=“active”/>
            <setId root=“12345678-9512-1234-4512-12987654322”/>
         </contextOfUse>
</component>
```

Note: the example above does not address the additional keywords that may be applied to the Context of Use. For the purposes of the example above, the assumption is that they have the same keywords.

6.3.1 Inserting Context of Use

In subsequent submission units of a submission (i.e., regulatory activity), it may be necessary to add a Context of Use with the same ***contextOfUse.code*** as a previous sequence. The following example adds a new Context of use with the same ***ContextOfUse.code*** as in the previous examples.

#2 – Inserting Context of Use

```
<component>
        <priorityNumber value=“95”/>
        <contextOfUse>
            <id root=“23567845-1234-1234-1234-123456789013”/>
            <code code="CDRH6.2" codeSystem="2.16.840.1.113883.3.989.2"/>
            <statusCode code=“active”/>
            <setId root=“12345678-9512-1234-4512-12987654323”/>
            <versionNumber value=“1”/>
```

```
        </contextOfUse>
</component>
```

6.3.2 Remove/Inactivate Context of Use

In subsequent submission units of a submission (i.e., regulatory activity), it may be necessary to remove a ***ContextOfUse*** element within the regulatory activity. In this case, the submission will no longer display the Context of Use, i.e., it is not replaced by another ***ContextOfUse*** element.

#2– Removing a Context of Use

```
    <component>
      <contextOfUse>
        <id root="12345678-1234-1234-1234-123456789012"/>
        <statusCode code="inactive"/>
        <setId root="12345678-1234-1234-1234-12987654321"/>
      </contextOfUse>
    </component>
```

Note: The priority number of the Context of Use does not need to be provided.

6.3.3 Replacing Context of Use

In subsequent submission units of a submission (i.e., regulatory activity), it may be necessary to replace a Context of Use element within a new ***ContextOfUse*** element. In this case, the submission will no longer display the previously submitted Context of Use as active, i.e., it has been replaced by another ***ContextOfUse*** element.

The ***relatedContextOfUse*** is used in the scenario to show that one ***contextOfUse*** is related to another ***contextOfUse*** over a period of time. This is a simple relationship and does not include anything but a reference of the unique identifier of the ***relatedContextOfUse***.

```
<component>
      <priorityNumber value="100"/>
      <contextOfUse>
        <id root="12345678-1234-1234-1234-123456789012"/>
        <code code="C79305" codeSystem="2.16.840.1.113883.3.26.1.1" />
        <statusCode code="active"/>
        <setId root="12345678-1234-1234-1234-12987654321"/>
        <versionNumber value="2"/>
        < sequelTo typeCode="RPLC">
            <relatedContextOfUse>
              <id root="87454521-9874-6541-5124-159842345687"/>
            </relatedContextOfUse>
        </sequelTo>
      </contextOfUse>
</component>
```

6.4 Appendix: Submission Grouper

6.4.1 Bundled Submissions – TCS IMDRF-001

A Bundled Submission includes more than one submission and application related to the content being submitted in the submission unit. Each submission in the bundle is identified and all content in the submission unit is related to all submissions in the bundle unless otherwise noted.

The "bundled" concept has historically been created for the management of paper submissions when the same changes needed to be made to multiple submissions for the same regulatory purpose – e.g., manufacturing change that is applicable to all products at the site.

6.4.1.1 Create a submission unit for all submissions in the bundle and use Submission Group to link the information.

The bundle will be defined by a submission group that is provided for each submission. Each submission will have its own submission units and the content will be applicable to only that submission. Each submission unit pertains to one submission and application, and therefore keywords will need to be defined for each application in the bundle. Since submission contents are managed at the submission level we ask that the following rules be implemented:

- Each submission has its own submission unit element.
- Each submission unit has unique Context of Use elements.
- The Context of Use elements have life cycle for that regulatory activity/submission.
- Any submission content shared across submission units in the message (information exchange) shall be provided once and referenced in all other uses.
- The document element should be provided in one of the submission units in the message if it is included as a physical file in the submission package.
- The submission grouper should be the same for all submissions in the bundle.*

* Note: we would like to determine if this element is necessary, or if the message itself serves as the grouping mechanism.

The following issues should be considered when conducting testing of bundled submissions:

- Submission contents are managed within each submission – i.e., context of use life cycle is not maintain across all submissions in the bundle
- Submission Group is used to link all submissions in a bundle to ensure nothing gets left behind in the regulatory processing of the bundle and to ensure the scope of the change is clear to the regulator.
- Submission Grouper does not indicate how many submissions are in the bundle; and processing individual submission units may be complicated by processing errors – i.e., incorrect ordering of processing submission units that create the bundle.

- Need to receive and process the submission unit with all of the content prior to validating that all documents are available for use by other submissions.
- Allows one or more submissions in the bundle to be updated independently without specifying the submissions in the bundle.

6.4.2 EU Submission Groups – IMDRF-006

The submission grouper will be used to indicate what content is relevant to the each group within the overall application.

6.4.2.1 Create a submission unit for each submission group in the message

The message shall contain one submission unit for each group in the test case scenario. Some messages will have more than one group represented. All groups are associated to the same application. The submission grouper allows two or more regulatory activities to be linked together.

Since submission contents are managed across submission groups we ask that the following rules be implemented:

- Each submission group has its own submission unit element.
- Each submission unit has unique Context of Use elements.
- The Context of Use elements have life cycle for that regulatory activity/submission.
- Any submission content shared across submission units in the message (information exchange) shall be provided once and referenced in all other uses.
- The document element should be provided in one of the submission units in the message if it is included as a physical file in the submission package.

6.5 Appendix: Two-Way Communication

The approach used by regulatory authorities would be contained in a regional implementation guide.

6.6 Appendix: Controlled Vocabulary

A spreadsheet will be developed for Beta Testing. It will be a combination of IMDRF and regional requirements.

Appendix B – IMDRF-001, version 2

Test Case No.:	***IMDRF-001 (abbreviated)***
Test Case Title:	Bundling Submissions -
Test Case Domain:	Devices
Region(s)	US FDA
IMDRF Storyboard No.	2.2.1.2 Adding submission units to an existing submission (PORP_SN000002UV) 2.2.1.3 Creating a new submission to an application (PORP_SN000003UV) 2.2.1.5 One submission unit to multiple applications (PORP_SN000005UV) 2.2.1.6 One submission unit to multiple submissions (PORP_SN000006UV) 2.2.1.8 Withdrawing a submission (PORP_SN000008UV) 2.2.1.9 Send Submission Unit to Regulatory Authority (PORP_SN000030UV) 2.2.2.1 Adding new files to a submission (PORP_SN000009UV)

Business Objective: This storyboard provides a business case for bundling submissions for the purpose of applying the same change across multiple regulatory activities.

Test Objectives:

- The submission contents shared across submissions in the bundle should be clear for each submission on its own.
- The submission contents that branches for one or more submissions in the bundle should be clear for each submission on its own.
- The submission content that merges for one or more submissions in the bundle should be clear for each submission on its own.
- The submission contents that are removed from one or more submissions in the bundled should be clear for the affected submissions.
- The submission contents that are withdrawn at the regulatory activity level should be clear for the affected submission and not impact other regulatory activities remaining in the bundle.

Test Case #1: Initial Information Exchange	
Description: This initial bundled submission – i.e., exchange messages – includes a supplement to three Applications (3 PMAs) and defines the following changes throughout the business scenario: • The ***design changes*** being made will require 2 types of mechanical testing: fatigue testing (applies to Pacing leads – PMA#3), and electrical testing which applies only to the catheter families (PMA#1 and PMA #2). • ***Packaging changes*** are being made to extend shelf life. • ***Labeling changes*** must be made based on the design and packaging changes. The resulting submission will be a bundled supplement to 3 PMAs.	
Test Case Objective: • The Applicant is sending the initial content of this module.	
Test Case 1 Requirements*:* • The message shall contain submission content applicable to only one submission/regulatory activity in the bundle. • The message shall contain submission content applicable to only some of the submissions/regulatory activities in the bundle. • The message shall contain submission content applicable all submissions/regulatory activities in the bundle. • The message shall contain submission contents for the design change and sterilization that have three keywords: study description, study identifier and date of initiation.	
Design changes	
COU and Document	Keywords
CH.3.3.1.1 – Physical and Mechanical – Summary • 1 PDF document for PMA #3 (filename: fatigue test summary)	The design changes for PMA #3 include CoU keywords: • Test: Flex testing, • Protocol Number: TRP2112 • Date of Initiation: January 5, 2013
CH.3.3.1.1 – Physical and Mechanical – Summary • 1 PDF document for PMA #1 and PMA #2 • Filename: electrical test summary	The design changes for PMA #1 and PMA #2 share the same CoU keywords: • Test: Impedance testing • Protocol Number: TRP300 • Date of Initiation: November 2, 2012
CH.3.3.1.2 – Physical and Mechanical – Full Report • 1 PDF document for PMA #3 • Filename: fatigue test summary	The design changes for PMA #3 include CoU keywords, • Test: Flex testing • Protocol Number: TRP2112 • Date of Initiation: January 5, 2013

CH.3.3.1.2 – Physical and Mechanical – Full Report • 1 PDF document for PMA #1 and PMA #2 (electrical test summary)	The design changes for PMA #1 and PMA #2 share the same CoU keywords: • Test: Impedance testing • Protocol Number: TRP300 • Date of Initiation November 2, 2012
CH.3.3.1.2 – Physical and Mechanical – Full Report • 1 PDF document for PMA #3 (fatigue test summary)	The design changes for PMA #3 include CoU keywords • Test: Flex testing • Protocol Number: TRP2112 • Date of Initiation: January 5, 2013
CH.3.3.1.2 – Physical and Mechanical – Full Report • 1 PDF document for PMA #1 and PMA #2 • Filename: electrical test summary	The design changes for PMA #1 and PMA #2 share the same CoU keywords: • Test: Impedance testing • Protocol Number: TRP300 • Date of Initiation: November 2, 2012
Package Changes	
COU and Document	**Keywords**
CH.3.3.10.2.1 – Manufacturer Sterilization – Summary • 1 PDF document for all PMAs • Filename: Sterilization	The sterilization share the same CoU keywords: • Sterilization Method: EtO • Protocol Number: TRP9001 • Date of Initiation: January 15, 2013
Labeling changes	
COU and Document	**Keywords**
CH.5.1 – Labeling • 1 PDF for Labeling for PMA #1 • Filename: Label#1	**N/A**
CH.5.1 – Labeling • 1 PDF for Instructions for Use for PMA #1 • Filename: IFU#1	**N/A**
CH.5.1 – Labeling • 1 PDF for Labeling for PMA #2 • Filename: Label#2	**N/A**
CH.5.1 – Labeling • 1 PDF for Instructions for Use for PMA #2 • Filename: IFU#2	**N/A**

CH.5.1 – Labeling • 1 PDF for Labeling for PMA #3 • Filename: Label#3	**N/A**
CH.5.1 – Labeling • 1 PDF for Instructions for Use for PMA #3 • Filename: IFU #3	**N/A**

Test Case #2: Amendment to Initial Application	
Description: The FDA asked questions related to the design changes. The Applicant responds to the questions with an explanation of why the electrical testing methodology provides adequate testing for the catheter family in PMA #1. The Applicant also provides another version of the fatigue test report for the family of pacing leads in PMA #3.	
Test Case Objective: • Applicant is sending changes to submission content that life cycles for one submission in the bundle. • Note: In one case, the submission content was branched for content that initially applied to two submissions in the bundle. The second case, the submission is being versioned for one application.	
Test Requirements*:* • The message shall contain submission contents for one of the submissions/regulatory activities is versioned when it initially only pertained to two of the three submissions in the bundle. • The message shall contain submission contents for one of the submissions/regulatory activities is versioned when it initially only pertained to one submission in the bundle.	
Design Changes	
COU and Document	**Keywords**
CH.3.3.1.1 – Physical and Mechanical – Summary • 1 PDF document for PMA #1 • Filename: electrical test summary *(second version of the content for only one PMA of the two*	The design changes for PMA #include the CoU keywords: • Test: Impedance testing • Protocol Number: TRP300 • Date of Initiation: November 2, 2012
CH.3.3.1.2 – Physical and Mechanical – Full Report • 1 PDF document for PMA #3 • Filename: fatigue test summary *(second version of the content)*	The design changes for PMA #3 include CoU keywords: • Test: Flex testing, • Protocol Number: TRP2112 • Date of Initiation: January 5, 2013

Test Case #3: Withdraw Submission from Bundle	
Description: The FDA has raised questions about the proposed changes to the pacing lead family in PMA #3 that cannot be adequately addressed. As a result, the Applicant has decided to withdraw the request for changes to the PMA #3.	
Test Case Objective: • The applicant sends a submission to withdraw one submission/regulatory from the bundle.	
Test Requirements*:* • The message shall contain inactivate the previously submitted submission content. o *The submission contents that related to more than one submission/regulatory activity would only be inactivated for the PMA #3.* o *The submission contents that related only to the PMA #3 submission/regulatory activity would be inactivated.* o *The submission content that was previously versioned and related only to the PMA #3 submission/regulatory activity would be inactivated.*	
Withdraw Submission – Inactivate CoU	
COU and Document	**Keywords**
CH.3.3.1.1 – Physical and Mechanical – Summary • 1 PDF document for PMA #3 (fatigue test summary) *inactivate the CoU*	**N/A**
CH.3.3.1.2 – Physical and Mechanical – Full Report • 1 PDF document for PMA #3 (fatigue test summary) *inactivate the second version of the CoU*	**N/A**
CH.3.3.10.2 – Manufacturer Sterilization – Summary • 1 PDF document for PMA #3 *inactivated only for the PMA #3; the content under the same CoU stays active for the other PMA submissions*	**N/A**
CH.5.1 – Labeling • 1 PDF for Labeling for PMA #3 *inactivate the CoU*	**N/A**
CH.5.1 – Labeling • 1 PDF for Instructions for Use for PMA #3 *inactivate the CoU*	**N/A**

Appendix C – IMDRF-004

Test Case No.:	***IMDRF-0004***
Test Case Title:	**The Certification Body inform ANVISA about the Product Certification Support (Regulatory Status)**
Test Case Domain:	**ANVISA**
Region(s)	**Regional - Brazil**
IMDRF Storyboard No.	**IMDRF Storyboards 13 & 14**

Test Case Scenario Description

In Brazil submissions include one or more certificates that support the safety / compliance of the product. Certificates are issued to the applicant by external certification body. Under certain circumstances, the certification bodies may revoke the certificate - which has an impact on existing Applications. When a certificate is revoked, the certification body will notify ANVISA (this notification is not done in RPS).. ANVISA in turn notifies the applicant with information regarding the affected Applications.

Business Objective: This storyboard provides a business case for submits product certificate for one or more applications making possible manage this certification (the manage functionality is out of the RPS). This test scenario is intended to evaluate the use of context of use and keywords for ANVISA to manage certificates within Applications and Submissions, and the processes around those certificates. For the purposes of this scenario there are 2 Applications and 3 Certificates (see the table below).

Application 1	**Application 2**
Certificate 10001	**Certificate 10001** **Certificate 10002** **Certificate 10003**

Test Objectives:

- The certificate shared across multiple applications in the submissions should be clear for each application on its own.
- The re-use of the certificate should be clear.
- The update of certificate versions across multiple applications should be clear for each application on its own.
- The certificate replacement in the application should be clear.

Test Case #1: Submit an Application to ANVISA with one certificate	
Description: The sponsor (Rio Co.) submits an application to ANVISA. Application 1 contains a certificate (certificate 10001) covering Product A and Product B.	
Test Case Objective: • Setup for future test cases	
Test Case 1 Requirements*:* • Certificate information can be adequately represented in context of use and Document keywords	
Design changes – Placing a certificate in Application 1	
COU and Document	Keywords
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 pdf file • File name: Certificate 10001.pdf • Document Title: Product Certificate 10001	**DOCUMENT KEYWORDS** **Certificate Number:** 10001 **Certificate Version:** 1.0 **Products:** Product A ; Product B **Certification Body ID:** OCP 00017 **Certificate Expiry Date:** 2014/12/28 (YYYY/MM/DD)

Test Case #2: Submit an Application to ANVISA with multiples certificate	
Description: The sponsor (Rio Co.) submits another application to ANVISA. Application 2 contains 2 certificates (10002 and 10003 and a reuse request for certificate 1). Certificate 10002 covers Product C, Product D, Product E. Certificate 10003 covers Product F and Product G.	
Test Case Objective: • Setup for future test cases. Re-use Certificate 10001 for a new Application.	
Test Requirements*:* • A Certificate together with its metadata can be referenced in multiple Applications	
Design changes – Placing certificates in Application 2	
COU and Document	**Keywords**
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • Reference Certificate 10001.pdf from the Application in Test Case 1	**DOCUMENT KEYWORDS** **Certificate Number:** 10001 **Certificate Version:** 1.0 **Products:** Product A ; Product B

• Document Title: Product Certificate 10001	**Certification Body ID:** OCP 00017 **Certificate Expiry Date:** 2020/11/31 (YYYY/MM/DD)
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF file • File name: Certificate10002.pdf • Document Title: Product Certificate 10002	**DOCUMENT KEYWORDS** **Certificate Number:** 10002 **Certificate Version:** 1.0 **Products:** Product C ; Product D; Product E **Certification Body ID:** OCP 00017 **Certificate Expiry Date:** 2016/12/28 (YYYY/MM/DD)
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF file • File name: certificate10003.pdf • Document Title: Product Certificate 10003	**DOCUMENT KEYWORDS** **Certificate Number:** 10003 **Certificate Version:** 1.0 **Products:** Product F ; Product G **Certification Body ID:** OCP 00017 **Certificate Expiry Date:** 2015/02/28 (YYYY/MM/DD)

Test Case #3: Updating a certificate	
Description: The Sponsor sends ANVISA a new Submission Unit requesting approval for product ZZ within App2. The submission includes version 2 of certificate 10001 - and adds product ZZ to the App2. The revised certificate should be added to Application 2. It should only replace the certificate at the applications indicated by the applicant. The previous version should remain active at App1.	
Test Case Objective: • Update the version of a certificate within Application *2*.	
Test Requirements*:* • Certificate information can be appropriately updated to reflect submission of new certificate versions. • A certificate can be versioned in only some (not all) of the Applications it is used in • A revised certificate should result in a change to some of the keywords, but the rest of the keywords should persist.	
Design changes – Replacing certificate ONLY in Application 2	
COU and Document	**Keywords**
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate	**DOCUMENT KEYWORDS** **Certificate Number:** 10001

• 1 PDF file • File name: certificate10001v2.pdf • Document Title: Product Certificate 10001 Version only for Application 2	**Certificate Version: 2**.0 **Products:** Product A ; Product B; Product ZZ **Certification Body ID:** OCP 00017 **Certificate Expiry Date:** 2020/11/31 (YYYY/MM/DD)

Test Case #4: Updating a certificate	
Description: The sponsor sends ANVISA a new version of the certificate (updated) to replace the previews Certificate 10003, which is expired (inactive). To change the status of the application (to be active) is not automatic, its needs to be reviewed by ANVISA. It should only replace the certificate at the applications indicated by the applicant.	
Test Case Objective: • A new version of Certificate 10003 is provided, the inactivation of the Application 2 and Certificate 10003 is lifted.	
Test Requirements: • A expired (inactive) certificate can be replaced by a new version of the certificate •	
Design changes – Replacing certificate in Application 2	
COU and Document	**Keywords**
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF file • File name: Certificate10003.pdf • Document Title: Product Certificate 10003 **Version Certificate in Application 2**	**DOCUMENT KEYWORDS** **Certificate Number:** 10003 **Certificate Version:** 2.0 **Products:** Product F ; Product G **Certification Body ID:** OCP 00017 **Certificate Expiry Date:** 2016/02/28 (YYYY/MM/DD)

Appendix D – IMDRF-006

Test Case No.:	IMDRF-006
Test Case Title:	EU Lifecycles within an Application
Test Case Domain:	Devices
Region(s)	Regional – EU
IMDRF Storyboard No.	***IMDRF 006 EU***

Business Objective:

The business objective is to mirror an application for an Annex II Quality System and Design Examination Certification, with changes across the quality and design dossier submissions and design examination renewal.

Test Objectives:

- Evaluate use of Submission Grouper to manage content lifecycle of logical groups of Submissions within an Application.
- Use one submission message to create a new Submission Group that references content from another Submission group
- Use one submission message to add content to one submission group while applying that same content as a lifecycle of existing content in another submission group.
- Send one message consisting of multiple Submission Units that lifecycle content differently across multiple groups within an Application.
- A submission unit can refer to content previously submitted as an affirmation that it is still current.
- A single message can version 2 instances of the same COU differently in 2 different submission groups.

Test Case #1: Initial Quality System Submission
Description: • The Manufacturer/Applicant has submitted a formal application to the notified body for a conformity assessment in Europe for a total hip joint replacement (Class III) and associated instruments/accessories (Class IIb, Class IIa). The products will be

approved under Annex II of the MDD. The manufacturer does not have quality system certificate currently in place. They send in a new submission to support the Quality System review.

Test Case Objective:

- Initial Quality System Submission - Creation of a new Application

Test Case 1 Requirements*:*

- The Applicant is sending the initial content of this submission group – Start of lifecycle
- Set up for subsequent cases

Quality System SUB 1 G1

COU and Document	Keywords and Lifecycle
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF document • Filename: Cert # 55443.pdf Document Title: Sterilizer ABC QS Certificate	**Lifecycle:** NEW for G1 **COU Keywords** Certificate Type: Quality System **Document Keywords** Certification Body ID: 0123 Certificate Number: 55443
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF document • Filename: Cert # 55443.pdf • Document Title: Contractor 20 QS Certificate	**Lifecycle** NEW for G1 **COU Keywords** Certificate Type: Quality System **Document Keywords** Certification Body ID: 1122 Certificate Number: 12345
CH6A.5 **General Manufacturing Information** • 1 PDF document • Filename: Mfg Info.pdf • Document Title: Manufacturing Summary	**Lifecycle:** NEW for G1 **COU Keywords** Product: Hip Replacement Accessories **No Document keywords**

M6A.7 **Quality management system procedures** • 1 PDF Document • Filename: Complaints.pdf • Document Title: Complaint SOP	**Lifecycle:** NEW for G1 **COU Keywords** Procedure Number: P33221 **NO Document keywords**

Test Case #2: Class III Design Dossier	
Description: • The Manufacturer/Applicant has submitted a submission to cover the class III device (Device THR). The approval of this device will be supported by the quality system certificate issued upon approval of the submission from test case 1.	
Test Case Objective: • Create a new Submission Grouper (G2) within the application • Add CH1.5 Certificates from G1 to the new Submission Group G2 as new within that group • Add CH1.17 to G2 only as a setup for future test cases	
Test Case 2 Requirements*:* • A message can start a new submission group lifecycle within the Application • A message can reference content provided in previous submissions, but begin using that content within the new submission group lifecycle • The lifecycle of the referenced content within existing submission groups should not be affected by the content's use in the new Submission Group.	
Class III Design Dossier (New Regulatory Activity) and creation of Submission Grouper G2	
COU and Document	**Keywords and Lifecycle**
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF document • Filename: Cert # 55443.pdf • Document Title: Sterilizer ABC QS Certificate	Lifecycle: NEW for G2. (Reference document from Sub 1, G1) **COU Keywords** Certificate Type**:** Quality System **Document Keywords** Certification Body ID: 0123

	Certificate Number: 55443
CH1.17 Declaration of Conformity • 1PDF document • Filename: DoC.pdf • Document Title: Declaration of Conformity	**Lifecycle:** New for G2 only
	COU Keyword Product: THR
	NO Document Keywords

Test Case #3: Increase in Classification of Device	
Description: • This will create a new Design Dossier for a device within the same Application. The Design Dossier starts a new Submission Group	
Test Case Objective: • Creation of a new Submission Group G3 • New Context of Use CH1.5 added to G1 and G3 as new content to both submission groups • New content added to CH1.17 for G3 only • Add new content to COU CH6A.5 for both G1 and G3 • Provide new content that Versions COU CH6A.7 in G1 and adds a new COU CH6A.7 to G3	
Test Case 3 Requirements*:* • A message can add content to both a new Submission Group it creates, and an existing Submission Group within the Application. • The message can add new content for some, but not all, of the submission groups within an Application	
Increase in classification of a device Creation of Submission grouper G3, Revisions to G1	
COU and Document	**Keywords and Lifecycle**
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF document • Filename: z5646.pdf • Document Title: Sterilizer Delta QS	**Lifecycle** Note: NEW for G3 and G1
	COU Keywords: Certificate Type: Quality System

Certificate	Certification Body ID: 0776 Certificate Number**:** z5646
CH1.17 Declaration of Conformity • 1 PDF Document • Filename: DoC2.pdf • Document Title: Declaration of Conformity	**Lifecycle:** New for G3 only. NOTE this is a new COU and a new document – different from that provided in test case #2
	COU Keywords Product: Device 22
	NO Document keywords
CH6A.5 General Manufacturing Information • 1 PDF file • Filename Manufacturing Overview • Document Title: Manufacturing Overview	**Lifecycle:** New for G1 and G3. NOTE: This is a new document and COU from that provided in Test Case 1. The original content provided for CH6A.5 in G1 is also still valid.
	COU Keywords Product: Device 22
	NO Document Keywords
CH6A.7 Quality management system procedures • 1 PDF File **File Name:** Complaint2.pdf Document Title: Complaint SOP •	**Lifecycle:** New for G3, New Version for G1. For G1, this will require a related COU element to show replacement.
	COU Keyword Procedure Number: P33221
	No Document Keywords

Test Case #4: Renewal of Design Examination report

Description:

- The Design Examination Certificate covering both Submission Group 2 and 3 is expiring. The manufacturer submits documentation to renew the certificate. The Submission will lifecycle content for G2 and G3.

Test Case Objective:

- Renew an expiring certificate that covers multiple submission groups and multiple submissions within the same application
- Add CH1.5 **Quality Cert #:** 88776 to G2 and G3 as new content
- Lifecycle CH1.5 **Quality Cert #:** 55443 in G2 only
- Reference CH1.5 **Quality Cert #:** z5646 for G3 as affirmation content is still current
- Version CH1.17 content for G2
- Version CH1.17 content for G3

Test Case Requirements*:*

- A single message can perform multiple lifecycle operations across multiple existing submission groups
- The message can reference previously submitted content for one Submission Group only as an affirmation that it is still current.
- The message can lifecycle a COU in one submission group while not impacting lifecycle of the same content in another submission group
- The message can add new content for some, but not all, of the submission groups within an Application

Renewal of Design Examination SUB 4 G2 & G3

COU and Document	Keywords and Lifecycle
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF document • Filename: Cert # 88776.pdf • Document Title: Manufacturer 1 QS Certificate	**Lifecycle** Note: NEW G2 & G3
	COU Keywords: Certificate Type: Quality System
	Document Keywords Certification Body ID**:** 0123 Certificate Number**:** 88776
CH1.5 Quality Management System, Full Quality System or Product Certification Certificate • 1 PDF document • Filename: Cert # 55443.pdf	**Lifecycle** Version in G2 only
	COU Keywords: Certificate Type: Quality System

<table>
<tr><td>

- Document Title: Sterilizer ABC QS Certificate

</td><td>

Document Keywords
Certification Body ID: 0123
Certificate Number**:** 55443

</td></tr>
<tr><td rowspan="3">

CH1.5
Quality Management System, Full Quality System or Product Certification Certificate

- 1 PDF document
- Filename: Cert # z5646
- Document Title: Sterilizer Delta QS Certificate

</td><td>

Lifecycle
Reference existing document for G3 only to show it is still current. NOTE: this would be a new COU in the G3 regulatory activity with a reference back to the document previously submitted.

</td></tr>
<tr><td>

COU Keywords:
Certificate Type: Quality System

</td></tr>
<tr><td>

Document Keywords
Certificate Body ID**:** 0776
Certificate Number: z5646

</td></tr>
<tr><td rowspan="3">

CH1.17
Declaration of Conformity

- 1 PDF File
- Filename: DoC.pdf
- Document Title: Declaration of Conformity

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Lifecycle:
Version G2

</td></tr>
<tr><td>

COU Keywords
Product: THR

</td></tr>
<tr><td>

NO Document Keywords

</td></tr>
<tr><td rowspan="3">

CH1.17
Declaration of Conformity

- 1 PDF File
- Filename: DoC2.pdf
- Document Title: Declaration of Conformity

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Lifecycle
Version G3

</td></tr>
<tr><td>

COU Keywords
Product: Device 22

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NO Document Keywords

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Appendix E – Testing Results

Item #	Subject	Finding Summary	Example	Resolution
1	Keyword Definition	There was inconsistency in whether keyword definitions were included in each message. Some samples did not provide keyword definitions for keywords used in previous submission units for the same Application. In some cases unused Keyword Definitions were provided.	Not Applicable	IG will be updated to clarify that Keyword definition details are needed once in an Application, and do not need to be provided with each message. The IG will also clarify that only Keywords used in the Application should be defined (no unused Keyword Definitions are permitted).

Item #	Subject	Finding Summary	Example	Resolution
2	Keyword Definition	The sender used single value keyword definition elements as well as a collection of values within the same submission unit. The keyword definitions were provided for the second application as they were submitted in the first, but when providing the new keyword definitions - the same format was not used. The Products C, D and E were provided as a collection instead of individual keyword definition elements.	SAMPLE SHOWING A COLLECTION OF VALUES <keywordDefinition> <code code="Key_PROD" codeSystem="3.2.6.12603.1.17"/> <statusCode code="active"/> <value> <item code="22" codeSystem="OID"> <displayName value="Product A"/> </item> <item code="23" codeSystem="OID"> <displayName value="Product B"/> </item> </value> </keywordDefinition> SAMPLE SHOWING A SINGLE VALUE <keywordDefinition> <code code="Key_PROD" codeSystem="2.16.840.1.113883.3.989.2"/> <statusCode code="active"/> <value> <item code="Product A" codeSystem="CompanyOID-ProductKeyword"> </item> </value> </keywordDefinition> <keywordDefinition> <code code="Key_PROD" codeSystem="2.16.840.1.113883.3.989.2"/> <statusCode code="active"/> <value> <item code="Product B" codeSystem="CompanyOID-ProductKeyword"> </item> </value> </keywordDefinition>	The IG should be revised to be specific as to the expected keyword definition format. Validation checks should be defined to ensure one approach is used.

Item #	Subject	Finding Summary	Example	Resolution
3	Keywords	Samples did not consistently apply keywords to the appropriate level (COU or Document). In some cases document keywords were applied at the COU level. The IG allows Keywords to be applied to either the COU or Document. However it gives no business guidance on when each scenario should be used.	Not Applicable	The IG will be updated to provide business guidance on when keywords should be applied to the Document vs the COU level. The IG will also provide specific guidance for how to manage document keywords over the lifecycle of an application.
4	Priority Numbers	Priority Numbers not provided for some COUs	<component> <priorityNumber value="100"/> <contextOfUse> <id root="CCCCCCCC-CDCD-AAA1-90EA-00000000051A"/> <code code="CH.5.1" codeSystem="2.16.840.1.113883.3.989.2"/> <statusCode code="active"/> <setId root="FFFFFFFF-CDCD-AAA1-90EA-00000000051A"/> <versionNumber value="1"/>	Modify the IG language to make it clear that priority numbers are always required for COUs

Item #	Subject	Finding Summary	Example	Resolution
5	Certificates Shared Across Applications	It is unclear whether Related Applications should be used to manage Applications supported by the same certificate. The IG did not provide sufficient details around how to structure the message to support Certificates shared across Applications. Each vendor managed it differently.	Not Applicable	Add detail to the IG that explains how the message should be structured to reflect Certificates that support multiple Applications. Further RPS WG discussions are required to define details for the IG.
6	Documents	Document titles in some cases included a TOC section number / chapter value. With document reuse, this may cause confusion when the document is referenced under multiple COUs.	<document> <id root="0b99c54f-e206-44ec-9a98-b228195f068a"/> <title value="CH.3.3.1.1 - Physical and Mechanical - Summary - Electrical Testing" language="en"/>	Further discussion within the RPS WG is required to determine what the business rules for how Document Title should be used. Rules should be clear in the IG
7	Documents	Document language is placed on text and title elements; IG only has language on text. The document titles are assumed to follow the language of the document; is there a need to have multiple language values?	<document> <id root="0b99c54f-e206-44ec-9a98-b228195f068a"/> <title value="CH.3.3.1.1 - Physical and Mechanical - Summary - Electrical Testing" language="en"/>	Further discussion within the RPS WG is required to define how Document language should be managed in the IG

Item #	Subject	Finding Summary	Example	Resolution
8	Test Case Errors	In IMDRF-004, the Certificate 10001 document reference is not referenced in TC #2.	Not Applicable	The TC should have been a simple reference to a previously submitted document for Certificate #10001; however the expiration date was mistakenly changed causing implementers to create a new document instead of reusing a document. The TCS needs to be corrected before it is used for additional testing.
9	Test Case Errors	The Submission ID tag is repeated for a new submission unit that should have triggered a new Submission ID tag in samples for IMDRF-006.	Not Applicable	The TCS identified how each message updated content in Submission Groups. But it did not specify whether each Submission Unit added to an existing regulatory activity, or created a new regulatory activity - requiring a new Submission Root. The TCS should be updated before being used for additional testing
10	Controlled Vocabulary and Code Systems	CodeSystem value for CoU, and codes for status were used differently between the vendors for multiple Test Case Scenarios.	Not Applicable	The IG needs to be updated to provide COU CodeSystem values and Controlled Vocabulary

Item #	Subject	Finding Summary	Example	Resolution
11	Context of Use (COU) Lifecycle	There were instances where Related COU reference cites an ID from the same submission unit. This should result in a validation error. Within these test samples, it was probably an error in the manual generation of samples. But it highlights an area of validation that should be covered in the IG	Not Applicable	The IG will be updated to reflect that Related COUs cannot refer to COU IDs within the same Submission Unit.
12	Withdrawal of Submission from a bundle	IG only specifies status on submission unit. For the withrawal of the regulatory activity in the test case, the Submission Unit status was set to Active. But when withdrawing a submission from the bundle, there is no way to inactivate a Submission (Regulatory Activity). In addition, the message samples successfully inactivated the COUs related to the withdrawn submission. However the update mode was not used to modify the COU priority numbers. This may result in COUs being displayed in an order not intended by the applicant.	Not Applicable	Recommend adding Status Code to Submission as a required element in the IG. The Submission Status code would be set to Inactive if a regulatory activity is withdrawn. In addition detailed instructions should be added to the IG to describe RPS message elements to be considered with a Submission is withdrawn by the applicant.

Item #	Subject	Finding Summary	Example	Resolution
13	Application Holder	The Applicant holder was not specified in the message for IMDRF-004 samples from three vendors	Not Applicable	The IG should be updated to clarify Applicant Holder is always required.
14	Submission Group	Submission group was inappropriately used by some vendors in samples for IMDRF-004.	Not Applicable	The IG should be updated to clarify when use of Submission Group is needed. Validation criteria should be used to mitigate invalid use of Submission Group