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HL7 Version 3 Implementation Guide: Regulated Product Submission,

Release 1

Informative Document
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1 Overview

This document provides technical details (conformance criteria) on using Regulated Product Submission (RPS). It is expected that implementers will create their own documentation in conjunction with this document. Outside the scope of this document is information on the creation of RPS for a specific product and instructions on the use of extensible markup language (XML).

The intended audience of this document is application and software developers that will either create or consume an RPS message. It is likely that specific documentation will be created for regulatory affairs personal that will explain how RPS will be used for particular product type or for a particular regulatory authority.

RPS is a Health Level 7 (HL7) Standard under the stewardship of the Regulated Clinical Research Information Management (RCRIM) Technical Committee. For more information about HL7, please go to www.HL7.org.

The focus of the RPS message allows applicants to submit information electronically. The submitted information is structured as a collection of documents that is organized by a table of contents. The actual table of contents varies from product to product and is defined by regulatory authorities.

Submitted documents are assigned to support one or more table of contents heading. Furthermore, multiple documents can be assigned to a single table of contents heading. Since the same information can be submitted to support multiple applications, this standard supports the reuse of data.

Note: Each implementation of RPS might not use all of the function provided by the standard. For example, one implementation can address the reuse of data only between submission units in an application while another implementation can address the reuse of data across regulatory authorities. It is also possible that one regulatory authority requires certain information while another regulatory authority that same information is optional.

2 RPS XML Header

2.1 Stylesheet and schema location

Information: This information includes the required header information, including the location of the schema, for a regulated product submission.

Terminology: None

RPS location: This information is in the beginning of the RPS file.

XML details: The instructions at the start of RPS are the same for every submission unit, see below:

```
<?xml version="1.0" encoding="UTF-8"?>
 <PORP_IN000001UV xmlns="urn:hl7-org:v3" xmlns:mif="urn:hl7-org:v3/mif"
```


xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance" xsi:schemaLocation="urn:hl7-org:v3 rps.xsd" ITSVersion="XML_1.0">

Note: Each implementation might have a different schema. Although all schemas should be based on the base schema generated by HL7

2.2 Control Act Wrapper

Each implementation may use different pieces of the control act wrapper

3 Submission Unit

Information: The collection of files provided to the Regulatory Authority at one time.

Terminology: Submission unit type will be defined through different implementation guides and HL7 status codes. Please note HL7 terms are named differently but are semantically the same as regulatory terms.

RPS location: The <submissionUnit> element is a child of the <subject> element in the control act wrapper.

XML details:

```
<submissionUnit>
 <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
 <code code="xxx" codeSystemName="XXX" codeSystem="XXX"
codeSystemVersion="XX" displayName="Amendment"/>
  <statusCode code="active" codeSystemName="HL7" codeSystem="XX"
codeSystemVersion="X"/>
…More XML code goes here…
</submissionUnit>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).
- The <code> is the XXX code for the type of content of submission unit such as “amendment” (CXXX).
- The <statusCode> is either active or null

3.1 Context of Use

Information: Regulatory processes require the submission of documents from the Applicant to the Regulatory Authority. These documents vary in focus and are defined within their field of study (i.e., GLP or GCP guidelines) or by the review discipline (e.g., Integrated Summary of Safety, Pharmacokinetics Written Summary). The Context of use Act defines the use of the submitted document in the context of a submission unit. The document and its assignment to a particular code will be used to create a table of contents. This table of contents will be used by Regulatory Authorities to review an application. Based upon guidance from different regulatory agencies, a document can be submitted once and be referred to by other Context of use’s text attribute in the same submission unit, different

submission unit for the same application, or different submission units in a different application. There could be many context of use acts per submission unit.

Terminology: Types of context of use (table of contents heading) – code - will be defined through different implementation guides and HL7 status codes are used for status.

RPS location: The <component> element is a child of the <submissionUnit> element.

XML details:

```
<component>
  <contextOfUse>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX" extension=""/>
    <code code="" codeSystemName=" " codeSystem="" codeSystemVersion=""
displayName=""/>
    <title>XXX</title>
    <statusCode code="" codeSystemName="" codeSystem="" codeSystemVersion=""/>
    <setId root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX" extension=""/>
    <versionNumber value="1"/>
…More XML code goes here…
  </contextOfUse>
</component>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).
- The <code> is the XXX code for the type of document such as "study report body" (CXXX). The code that specifies how the file is to be used within the review process (e.g. Protocol, Summary Introduction). Note: Context of use codes (table of contents headings) vary between different product types.
- The <title> is the display name for the document in the associated assignment
- The <statusCode> is either active or null. When setting a context of use to null, the <referenceBy2> and <fileReference> elements should not be provided. See section "Document Lifecycle"
- The <setID> is the unique identifier for the context of use that remains constant through all versions/revisions of the context of use. It is recommended that the setId and Id be the same for the first version of a context of use. See section "Document Lifecycle"
- The <versionNumber> is an integer that identifies the version of the context of use and along with the <id root> is unique for each version of the context of use. See section "Document Lifecycle"

3.1.1 Related Context of Use

Information: Provides a relationship between two contexts of use. See section "Document Lifecycle"

Terminology: HL7 document type codes are used for the sequel to relationship.

RPS location: The <sequelTo> element is a child of the <contextOfUse> element. The <sequelTo> directly follows the <versionNumber> element, if it exists; otherwise the <sequelTo> element follows the <setId> element.

XML details:

```
<sequelTo typeCode="XXXX">
  <relatedContextOfUse>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
  </relatedContextOfUse>
</sequelTo>
```

- The <id root> is a pointer to the <contextOfUse> element that the sequel to relationship is acting upon. For example, if the id of the parent context of use is "A1" then the id within the related context of use is "A1".

3.1.2 File Reference

Information: A file can be used many times. Each time the file is used, that file has a different context of use. Accordingly, each context of use must refer to one file.

Terminology: There is no controlled terminology for this information.

RPS location: The <referenceBy1> element is a child of the <contextOfUse> element. The <referenceBy1> directly follows the <sequelTo> element, if it exists. Otherwise, the <referenceBy1> directly follows the <versionNumber> element, if it exists. Otherwise the <referenceBy1> element follows the <setId> element.

XML details:

```
<referencedBy1>
  <fileReference>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
  </fileReference>
</referencedBy1>
```

- The <id root> is a pointer to the <file> element (see File later in this document).

3.1.3 Keyword

Information: A Keyword is a reference to the keyword definition Act. Keywords can be associated with different contexts of uses as defined through different implementation guides.

Terminology: There is no controlled terminology for this information.

RPS location: The <referenceBy2> element is a child of the <contextOfUse> element. The <referenceBy2> directly follows the <referenceBy1> element, if it exists. The <referenceBy2> directly follows the <sequelTo> element, if it exists. Otherwise, the <referenceBy2> directly follows the <versionNumber> element, if it exists. Otherwise the <referenceBy2> element follows the <setId> element.

XML details:

```
<referencedBy2>
  <keyword>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
  </keyword>
</referencedBy2>
```

- The <id root> is a pointer to the <keywordDefinition> element (see keyword definition later in this document).

4 Reviewable Unit

Information: The reviewable unit is a way to organize a submission into discrete units. Each reviewable unit can have a status. Generally, these units of information supports a particular discipline (e.g., clinical) and supports the opportunity to review parts of the total submission as opposed to the entire submission at once.

Terminology: Types of reviewable unit (e.g. clinical) – code - will be defined through different implementation guides and HL7 status codes are used for status.

RPS location: The <pertainsTo> element is a child of the <submissionUnit> element. The <pertainsTo> directly follows the last <component> element, if it exists. The <pertainsTo> element child is either the <reviewableUnit> element or the <submission> element.

XML details:

```
<pertainsTo>
  <reviewableUnit>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX" extension=""/>
    <code code="XXX" codeSystemName="NCI EVS" codeSystem="XXXX.XXXX.XXX"
codeSystemVersion="X" displayName="Clinical"/>
    <statusCode code="XX" codeSystemName="HL7" codeSystem="XXX"
codeSystemVersion="X"/>
…More XML code goes here…
  </reviewableUnit>
</pertainsTo>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).
- The <code> is the XXX code for the type of reviewable unit such as “clinical study” (CXXX). Note: reviewable unit codes vary between different product types.
- The <statusCode> is either active or null.

5 Submission

Information: The submission is a compilation of the contents of one or more submission units supporting a specific regulatory purpose or decision. In most cases, the compilation of the submission units is

utilized in the assessment of a product's quality, safety and effectiveness. Regulatory authorities are concerned with when the submission is received, as opposed to when an applicant sends a submission. Since it is not know by the applicant when the regulatory authority will receive the submission, there is no date attribute associated with the submission. In a future release of RPS, when the regulatory authority sends a response to the applicant, RPS will need to capture the receipt date of the submission.

Terminology: Types of submission (e.g. original, supplement) – codes - will be defined through different implementation guides and HL7 status codes are used for status.

RPS location: The <pertainsTo> element is a child of the <submissionUnit> element or the <reviewableUnit> element. If the <pertainsTo> element is a child of the <submissionUnit> element then the <pertainsTo> directly follows the last <component> element, if it exists. If the <pertainsTo> element is a child of the <reviewableUnit> element then the <pertainsTo> directly follows the last <statusCode> element.

XML details:

```
<pertainsTo>
  <submission>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX" extension=""/>
    <code code="" codeSystemName=" " codeSystem="" codeSystemVersion=""
displayName=""/>
    <statusCode code="" codeSystemName="" codeSystem="" codeSystemVersion=""/>
…More XML code goes here…
  </submission>
</pertainsTo>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).
- The <code> is the XXX code for the type of submission such as "original" (CXXX). Note: submission codes vary between different product types.
- The <statusCode> is either active or null.

6 Application

Information: The application is all submissions that are grouped together for regulatory purposes; such as, a request for approval to either market a product or to allow the applicant to start testing of a proposed product. Over time, an application will typically consist of multiple submissions and regulatory assessments. For example, the marketing application for a drug product can generate multiple regulatory decisions. The first decision may support the initial marketing approval of the product for a specific indication. Subsequent regulatory decisions may approve or deny additional indications for the drug product. The application thus contains multiple submissions, each with their own regulatory action. Each of those submissions (e.g., initial marketing application, supplemental marketing application) would generally be comprised of multiple submissions units.

Terminology: Types of application (e.g. NDA, PMA) – code - will be defined through different implementation guides.

RPS location: The <pertainsTo> element is a child of the <submission> element. The <pertainsTo> directly follows the <statusCode> element, if it exists.

XML details:

```
<pertainsTo>
  <application>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX" extension=""/>
    <code code="" codeSystemName=" " codeSystem="" codeSystemVersion=""
displayName=""/>
…More XML code goes here…
  </application>
</pertainsTo>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).
- The <code> is the XXX code for the type of application such as "NDA" (CXXX). Note: application codes vary between different product types.

6.1 Keyword Definition

Information: A keyword definition contains name value pairs that are used within the context of an application. Each keyword is an item of information that provides context for the document(s) in a context of use. Keywords are used only to further define the context of a Context of use, and the Keywords, by themselves, have no intrinsic value. In order to provide better structure and organize the table of contents, keywords may be aligned with specific context of uses. When keywords are used clarifications will be provided by regulatory authorities.

Terminology: Types of keyword (e.g. manufacturer) – code - will be defined through different implementation guides and HL7 status codes are used for status.

RPS location: The <referencedBy> element is a child of the <application> element. The <referencedBy> directly follows the <code> element, if it exists.

XML details:

```
<referencedBy>
  <keywordDefinition>
    <id root="XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
    <code code="" codeSystemName=" " codeSystem="" codeSystemVersion=""
displayName=""/>
    <statusCode code="" codeSystemName="" codeSystem=""
codeSystemVersion=""/>
    <value displayName="991245"/>
  </keywordDefinition>
</referencedBy>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).

- The <code> is the XXX code for the type of keyword such as “manufacturer” (CXXX). Note: keyword codes vary between different product types.
- The <statusCode> is either active or null.
- The <value> is value based on the <code> element.

6.1.1 Replacement of Keyword Definition

Information: Previous keyword definition is used to replace an existing keyword definition. Once a keyword definition is replaced, that original keyword definition should no longer be used.

Terminology: There is no controlled terminology for this information

RPS location: The <replacementOf> element is a child of the <keywordDefinition> element. The <replacementOf> directly follows the <value> element.

XML details:

```
<replacementOf>
  <previousKeywordDefinition>
    <id root=“XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
  </previousKeywordDefinition>
</replacementOf>
```

- The <id root> is a pointer to the <keywordDefinition> element (see keyword definition in this document).

6.2 File

Information: A file prepared by an Applicant for review by the Regulatory Authority (e.g., a PDF file). A context of use refers to a file. Many context of uses can refer to the same file. Lifecycle occurs on the context of use not on the file.

Terminology: For media type the terminology uses Internet Engineering Task Force (IETF) / Internet Assigned Numbers Authority (IANA) Mime Internet media types are permitted. See: http://www.iana.org/assignments/media-types/application/. For language the ISO language codes will be used. Please consult regulatory authorities for a full list of allowable file formats and language codes.

RPS location: The <component> element is a child of the <application> element. The <component> directly follows the <referencedBy> element, if it exists. Otherwise, the <component> directly follows the <code> element.

XML details:

```
<component>
  <file>
    <id root=“XXXXXXXX-XXXX-XXXX-XXXX-XXXXXXXXXXXX"/>
    <text language="en" mediaType="application/pdf"
integrityCheck="xxxxxxxxxxxxxxxx" integrityCheckAlgorithm="SHA-256">
```

```
      <reference value="356h.pdf"/>
    </text>
  </file>
</component>
```

- The <id root> is a universally unique identifier (UUID) or an object identifier (OID).
- The <text> element is comprised of several attributes
    - mediaType - Identifies the type of the encapsulated data and identifies a method to interpret or render the data. This specification treats the entire media type as one atomic code symbol in the form defined by IANA, i.e., top level type followed by a slash "/" followed by media subtype. Currently defined media types are registered in a database [http://www.iana.org/assignments/media-types/index.html] maintained by IANA. Currently more than 160 different MIME media types are defined, with the list growing rapidly. In general, all those types defined by the IANA may be used.
    - Language - For character based information the language property specifies the human language of the text. The language code should be the ISO language code.
    - integrityCheck - The integrity check is a short binary value representing a cryptographically strong checksum that is calculated over the binary data. The purpose of this property, when communicated with a reference is for anyone to validate later whether the reference still resolved to the same data that the reference resolved to when the encapsulated data value with reference was created.
    - integrityCheckAlgorithm - Specifies the algorithm used to compute the integrityCheck value. The cryptographically strong checksum algorithm Secure Hash Algorithm-1 (SHA-1) is currently the industry standard. It has superseded the MD5 algorithm only a couple of years ago, when certain flaws in the security of MD5 were discovered. Currently the SHA-1 hash algorithm is the default choice for the integrity check algorithm. Note that SHA-256 is also entering widespread usage.
- The <reference value> element and attribute is where you should put the relative reference for the file that you are submitting (e.g. summaries/introduction.pdf)

Appendix 1 – Controlled terms for each application type

Controlled terms are defined by regulatory authorities or international bodies such as International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), and Global Harmonization Task Force (GHTF) and alike. Vendors and Sponsors utilize the controlled terms in the transmission of an RPS message to a regulatory authority

When two or more terms have the same meaning in different business context, it is common that a functional term is used. This functional term has one definition that applies to all of business context where the original term is used. However, when creating systems, business users prefer to see business friendly terms instead of the more generic functional terms. For example, HL7 has a concept of obsolete for status codes. When applying these status codes in a regulatory publishing system, the words withdrawn might be displayed to the user instead of obsolete (other terms could be appropriate as well).

To create a RPS for any new submission type the following terms need to be defined.

- Application (e.g. New Drug Application (NDA), Premarket Approval (PMA))
- Submission (e.g. original, supplement, variation)
- Reviewable unit (e.g. clinical)
- Submission unit (e.g. amendment)
- Keyword (e.g. manufacturer)
- Context of use -table of contents heading – (e.g. summary of safety)

The following terms are used for all RPS messages

- HL7 Status codes – for application, submission, reviewable unit, submission unit, keyword and context of use
- HL7 document type codes are used for the sequel to relationship between context of use and related context of use
- For media type the terminology uses Internet Engineering Task Force (IETF) / Internet Assigned Numbers Authority (IANA) Mime Internet media types are permitted. See: http://www.iana.org/assignments/media-types/application/.
- For language the ISO language codes will be used.

Appendix 2 – Context of Use Overview

1 Background

A single document can be in multiple tables of content headings of an application and can also be in multiple applications. For this reason, we have defined the Context of use Act (Act as defined by HL7) that provides the relationship of a document to a table of content heading. Since a submission unit can contain multiple Context of use, this class can be used to indicate each assignment of a document to a section. Looking across multiple submission units, it is possible to record a single document's context in multiple applications as needed.

RPS is primarily focused on document management, it would seem that the Context of use Act would be the obvious choice to the entry point of this message. However, applicants transmit information to regulatory authorities in the form of submission units containing multiple Context of use. These submission units support the overall application. Accordingly, the entry point for this message is the Submission Unit Act.

Regulatory authorities receive submissions to address a variety of regulatory issues. The information contained in these submissions is divided into numerous files. Frequently, files in one submission unit are related to files in earlier submission units. Because the information is divided into numerous files sent over time, it is often difficult to efficiently process and review the information.

The objective of the Regulated Product Submission message is to define one message structure that can be used for all regulated products. It is intended that this message will be used for regulated products, including but not limited to, foods, medical devices, biologics, human therapeutics, and veterinary medicine. It is important to note that the wide range of products that is contemplated leads to providing a generic structure for the actual specification.

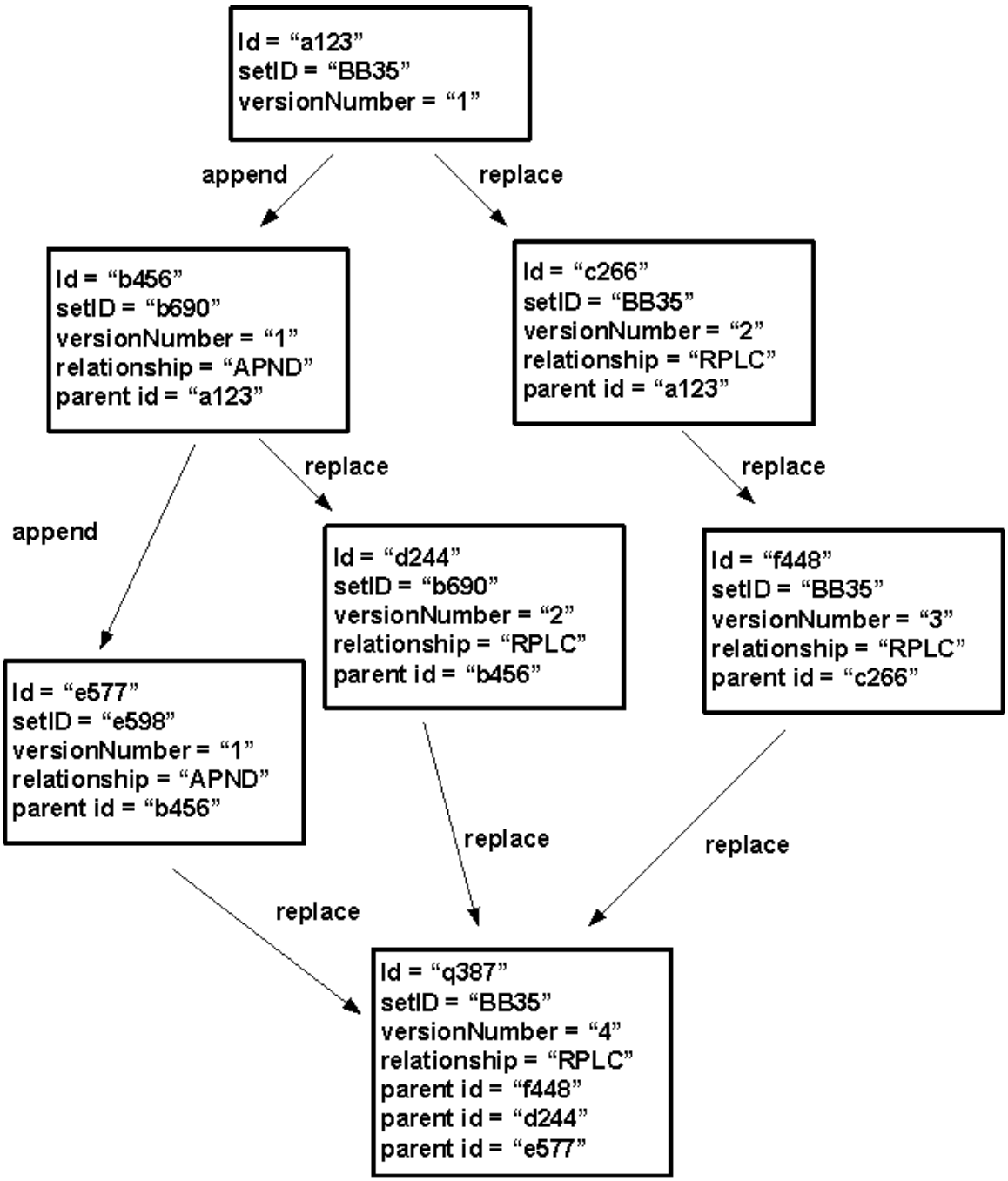
2 Document Lifecycle

An original document is the first version of a document. It gets a new unique value for Context of use id attribute, a new value for Context of use setId attribute, and has the value of Context of use versionNumber attribute is set to equal "1".

An addendum (usually submitted in an amendment) is an appendage to an existing document that contains supplemental information. The appendage is itself an original document, as described in the previous paragraph. The parent document being appended is referenced via an ActRelationship (as defined by HL7), where the ActRelationship typeCode attribute is set to equal "APND" (for "appends"). The parent document being appended remains in place and its content and status are unaltered. If the parent document is replaced, the addendum is now associated with the most current parent document in the parent document set (see setId). If a new document replaces both the previous document and the addendum, the Context of use setId attribute will be the same as the previous documents Context of use setId attribute and will have an ActRelationship typeCode attribute is set to equal "RPLC" (for "replace") for both the previous document and the addendum.

A replacement document provides updated information for a previously submitted existing document. The replacement document gets a new globally unique ID value, while the replacement document uses the same value for Context of use setId attribute as the parent document being replaced, and increments the value of Context of use versionNumber attribute by 1. (Note that version number must be incremented by one when a document is replaced, but can also be incremented more often to meet local requirements.) The parent document is considered superseded, but is still retained in the system for historical reference. The parent document being replaced is referenced via an ActRelationship, where the ActRelationship typeCode attribute is set to equal "RPLC" (for "replaces").

These relationships are summarized in the following illustration:



A context of use is a file that is being referenced in a particular submission unit with a particular code value. The same file can have several context of use. Accordingly, it is possible that the same file with different context of use have different statuses. In addition, a context of use is associated to a submission through a submission unit.

When a document is released to regulatory authorities, its status becomes "active" (active and null are HL7 terms – null is equivalent to revoke/withdraw in regulatory terms). Documents that are "active" are rendered "null" when they are replaced with a revision. A document can also be rendered “null” by a

status change. If a document is rendered “null”, that document can be reactivated. Null documents cannot be revised.

Appendix 3 - RPS Message Packaging

1 Introduction

The RPS message must be transmitted from sender to receiver following some simple guidelines. The following guidelines are proposed, arranged by category.

2 Folders and Files

2.1 Naming

2.1.1 Root folder

Root folder = "SenderID-TransmissionID"

where SenderID = company OID with hyphens in place of periods.

e.g. company OID = 1.3.6.1.4.1.2, therefore the SenderID = "1-3-6-1-4-1-2"

Contents: ONLY 2 FILES:

XML file – "rps.xml"

checksum file – "rps-checksum.txt"

ONLY ONE sub-folder = "rps-files"

2.2 Compressed archive

An RPS can be sent as a single compressed archive such as ZIP or TGZ with the naming convention: SenderID-TransmissionID.zip (or tgz). Please consult regulatory authorities for how to send an RPS message electronically.

2.3 Nesting level

- Under the subfolder "rps-files":
  - Sub-folder maximum 25
    - Any more than 25 is difficult to manage
  - nested sub-folders maximum 4
    - no additional restrictions except allowable characters and name lengths

2.4 Length

- Maximum file name length: 64
- Maximum folder name length: 64
- Maximum path length including root folder: 150 (allows RPS structure to exist under a logical drive with high level folder for submitter)

2.5 Allowable characters - File and Folder Names

Follow the IETF rules for URLs (except for period and asterisk). Therefore only alphanumeric, the special characters "$-_+!'()," may be used (note – double quotation marks appear here for formatting and not allowed). Please consult regulatory authorities for a full list of allowable characters.

See: http://www.ietf.org/rfc/rfc1738.txt

2.6 Pathname convention

Path references in RPS XML message should use only relative path names with the forward slash (/) separator.

2.7 Checksums

Every physical file should have a checksum value in the RPS message

2.8 Media types

IETF / IANA Mime Internet media types are permitted. See: http://www.iana.org/assignments/media-types/application/

Please consult regulatory authorities for a full list of allowable file formats.

3 Submission Packaging

For transmission over the Internet a single compressed archive file should be sent as specified above.

For submission units sent on hard media, the media type should be according to agency guidelines (e.g. DVD-RAM, CD-R) and the folder file structure specified above should be retained. Where agency guidelines do not specify, the following are recommended:

4 Implementation Note

The RPS message standard permits several different types of files to be included as content files. In certain cases, such as Portable Document Format (aka PDF) files, they will contain hypertext links to other files in the transmitted message package. It is required that implementers of the RPS message retain the file/folder naming and structure under the folder “rps-files” exactly as transmitted to ensure that these links are not broken by the receiving system.

5 Frequently Asked Questions

Q1. Why is the sender ID derived from the sending company OID – not the sender's OID?

A. A sender may send several applications/submissions in one message until they are processed the receiving side need to identify who is the sender so I thought "Sender ID" would provide that identification.

A sender may submit more than one submission on one day so we need "transmission ID" to identify who sent what and when.

Q2. Do we need the sender ID or should we remove it from the schema?

A. The assumption was to keep it and use the same id in the root folder so that now there is always a relationship.

Q3. What is the business or technical need for an "rps-checksum.txt" file?

A: Some agencies have chosen to include the checksum values for the submission of other electronic submission formats in a cover letter (on paper or PDF) as a security feature. This is the way it was envisioned to be used. Also, the checksums of individual files exist in the rps.xml. That means all of these are wrapped up in a single "super-checksum" as a quick check to see if anything in the message was changed.

Q4. What if the sender and company are not the same (e.g. - the sponsor contracts out publishing and transmittal to the Health Authority)?

A. ID's are there to be unique. It does not matter whose base OID is used.

Q5. Is there a business case for why we would want to identify which submission was sent by whom (with a unique sender ID)?

A. No, IDs should just be unique.

Q6. Why are we identifying a compression standard for transfer? How flexible will we be to adapting this to other proposals (such as no compression for submissions under XX Mb or another compression standard)?

A. These are some option we thought of based on electronic Common Technical Document (eCTD) and other experience. If there are other options we should discuss.

Q7. Why only 4 sub-directory levels?

A: the 4 levels are under "rps-files" which is under the top level folder. This is 6 levels. If it needs to exist on the sender's or receiver's logical drive/folder structure they have 2 left before they hit the ISO9660 limit of 8.

Q8. Should files not be at the same level as the rps.xml file?

A: All files are in a sub-folder “rps-files” or in sub-folders of that to simplify the identification of the “backbone” file (rps.xml).

Appendix 4 -Sample RPS XML Source

```
<?xml version="1.0" encoding="UTF-8"?>
<PORP_IN000001UV  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"
  xsi:schemaLocation="urn:hl7-org:v3 ../schemas/files/PORP_IN000001UV.xsd"
  xmlns="urn:hl7-org:v3"
  xmlns:mif="urn:hl7-org:v3/mif"
  ITSVersion="XML_1.0">
  <id/>
  <creationTime/>
  <interactionId/>
  <processingCode/>
  <processingModeCode/>
  <acceptAckCode/>
  <receiver>
    <device>
      <id root="test" extension="test"/>
    </device>
  </receiver>
  <sender>
    <device>
      <id root="test" extension="test"/>
    </device>
  </sender>
  <controlActProcess moodCode="EVN">
    <subject>
      <submissionUnit>
        <id root="ABB7ABA1-837C-43a8-ADFD-9D1847F39F87"/>
        <code code="RPS-amendment"/>
        <statusCode code="active" codeSystem="HL7"/>
         <component>
          <contextOfUse>
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