Food and Drug Administration

US Department of Health and Human Services
Food and Drug Administration
Center for Veterinary Medicine

Electronic Submission of Animal Adverse Events
HL7 Individual Case Safety Report (ICSR)

Electronic Transmission Implementation Specifications
[Step By Step]

Version: 4.0.0

May 21, 2010

The document release supports the RQR1 release of the MedWatch$^{PLUS.}$ The contents within this document are based on the September, 2009 release of the HL7 ICSR draft schema.

Document Control Number:

Table 1: Document Change Record

Version Number	Date	Description
V 1.0	April 30, 2009	Original Draft
V 1.1	May 4, 2009	Document Reorganization
V 1.1.5	May 8, 2009	Major Review on May 8, 2009
V 1.2.0	May 14, 2009	Ready for Higher Level Review
V 1.2.1	June 15, 2009	Feedback from review
V 1.2.2	July 27, 2009	Updates based of Emerging HL7 ICSR Standard
V 1.2.3	August 28, 2009	xPath & XML Snippets Update
V 1.2.4	September 11, 2009	xPath & XML Snippets Update
V 1.2.5	October 13, 2009	Vocabulary Tables References
V 1.2.6	December 3, 2009	Vocabulary Table update, change in causality and other minor updates.
V 1.2.7	December 16, 2009	Vocabulary tables updated, resolved Supplemental Documents sections and Profile Id issues.
V 1.2.8	December 18, 2009	Supplemental documents update, Added Package type vocabulary, removal of Appendix A.23 Observation Types vocabulary, updated missing concept codes with dummy codes. Cleaned up typo errors. Added Observation locator description.
V 1.2.9	January 29, 2010	- Changes made by the harmonization with the Business Rules Validation Guide and CVM's Guidance documents. - Updated element names to match the Locator codes values. - Incorporated a new "Supplemental Documents" section. - Updated "Outcomes" section to match NCI Concept Codes. - Added "RA" concept code - Updated Null Flavor considerations - Numerous typos in text and snippets - Update missing requirement Ids - Added ICSR Vocabulary Locator Appendix A.23 - Remove Vocabulary A.37 Regulatory Authority and adjusted text - Clarified Breed Section
V 1.3.0	February 3, 2010	1st non-draft release
V 2.1.0	March 5, 2010	- Clarified "Sender" Category - Documented Telecom element standards - Added "Units of Presentation" to "Dosage Unit" - Updated Vocabulary Names - Fixed snippet errors - Change OID for Unified Code for Units of Measure - Updated the kinds of Supplemental documents allowed
V 3.1.0	April 23, 2010	RQR1 Release - Removed the Vocabulary tables from Section 6 -
V 4.0.0	May 21, 2010	RQR1 Production Release

Note: Items highlighted in yellow need to be re-assigned codes to resolve issue

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1 Introduction

The purpose of this document is to provide step by step directions to assist users, reporters, and technical staff in completing a well formed HL7 XML Individual Case Safety Report (ICSR) message for animal drug Adverse Event Reports (AER) and manufacturing/product defects messages. These submissions are intended to be sent electronically to the Food and Drug Administration (FDA) Center for Veterinary Medicine (CVM) through the FDA Electronic Submissions Gateway (ESG) and upon reception they will be processed by CVM's Adverse Event System.

1.1 Health Level 7 (HL7)

Health Level 7 is a standards development organization charted to enhance the cooperative exchange of health related messages. The HL7 organization in cooperation with the FDA has defined a standand which FDA has adopted for reporting adverse events to regulated authorities. The FDA/CVM Animal Adverse Event processing system has been developed to accept, store and process HL7 version 3 ICSR XML messages. This is the only electronic format that FDA/CVM will accept for adverse event submissions.

1.2 GL-42

The FDA in close coordination with the **International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products** (VICH) has established a standard set of definitions to describe the data elements that need to be submitted for compliant adverse event reports. This standard is called GL-42. This document provides a translation and mapping of GL42 compliant adverse event elements into HL7 ICSR elements.

The document that readers should reference for final guidance on CVM's GL-42 Adverse Event submission system is *#188 – Guidance for Industry – Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine*.

1.3 ICSR Documents

The FDA has generated a number of documents to assist stakeholders in preparing, formatting and transmitting electronic submissions of HL7 ICSRs. The following table lists the documents.

Title	Description	Organization Owner
#188 - Guidance for Industry - Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine	Guidance document on providing information (Data Elements) to the FDA CVM via Form 1932 - Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report	FDA CVM
Appendix 1 - Instructions for the Marketing Authorization Holder on Filling out Form FDA 1932 Veterinary Adverse Drug Reaction, Lack of Effectiveness, Product Defect Report	Appendix to Guidance for Industry - Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine	FDA CVM

HL7 Individual Case Safety Report (ICSR) Release 2 Normative: Implementation Guide for FDA Adverse Event and Product Problem Reporting	Technical conformance criteria for HL7 ICSR submissions to FDA.	FDA Data Council
Electronic Transmission Implementation Specifications [Step By Step]	Technical instructions for building compliant HL7 animal ICSRs	FDA CVM
Electronic Transmission Implementation Specifications [Validation Procedures]	Validation procedures for compliant HL7 animal ICSRs	FDA CVM
Generalized Data Models of GL-42, MedWatch+ ICSR	Pictorial views of the compliant GL-42 FDA CVM ICSR data models	FDA CVM
Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM	High level instructions to assist in transmitting and submitting HL7 FDA CVM complaint ICSRs	FDA CVM
HL7 ICSR Vocabularies	MS Excel spreadsheet listing the vocabularies of compliant GL-42ICSR data element selectionss	FDA CVM

Table 1-1 ICSR Documents

1.4 Adverse Event Report Types that are Accepted

FDA/CVM's adverse event processing systems will accept the following types of HL7 ICSRs:

- Adverse Event Reports
- Product Problem Reports
- Adverse Event + Product Problem Reports

1.5 Requirements to Obtain Unique Sender Identification Numbers (OID)

The HL7 ICSR requires submitters to obtain a unique organizational identifier called an OID. This OID is used to identify the organization submitting adverse event reports. In addition, the FDA/CVM adverse event processing system requires each submitting facility to either submit their FDA Federal Establishment Identifier (FEI) or they may use their unique DUNS assigned organization number. Procedures on obtaining an organizational OID can be found in *Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM*.

1.5.1 Unique D-U-N-S Number

D-U-N-S® numbers are unique numbers for each facility that may be obtained from Dun & Bradstret. The DUNS number is a nine digit number that will be required if you want to submit electronic adverse event reports to FDA/CVM. For more information see the *Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM*.

1.5.2 Unique Organizational OID

{Note for the Initial System Release this requirement has been relaxed. A unique system OID is NOT required. A substitute OID of "1.2.3.4" must be used in lieu of an assigned OID.}

This unique organizational identifier can be obtained from either the International Standards Organization or the Health Level 7 (HL7) organization. The unique OID will be used to uniquely identify organizations when electronic submissions are received. This unique OID must be used in all electronic adverse event submissions to FDA/CVM. If your organization has obtained an OID for use with the *European Medicines Organization (EMA)* electronic

submissions system you may use the same OID for FDA/CVM ICSR Electronic submissions. For more information on OIDS and obtaining an Organizational OID see the *Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM.*

1.6 Assigned Organizational Identifiers

Organizational Identifiers (OIDs) have previously been assigned to facilitate the correct ownership of information and to allow for the seamless interchange of adverse event information. *Section 6.3 - Vocabulary Code System OIDs* details the organizations and the OIDs that have been assigned for ICSR data element encoding and processing.

1.7 Structure of HL7 ICSR Adverse Event Report Submission Message

The FDA/CVM electronic adverse event report submission structure is based on the HL7 ICSR version 3 standard. Each submission to CVM must follow this model. The complete set of adverse event reports is to be bounded by a single *Batch Submission* wrapper. Individual reports are then bounded by a *Transmission* and *Control Act* wrappers. CVM's adverse event processing system will allow up to a maximum of 65,535 individual reports (which consist of a *Transmission*, *Control Act*, and *ICSR Message*) within a single Batch submission. Please refer to the *Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM* that addresses the maximum size of a batch transmission. Each *Batch* submission must be for a single Veterinary Medical Product (VMP).

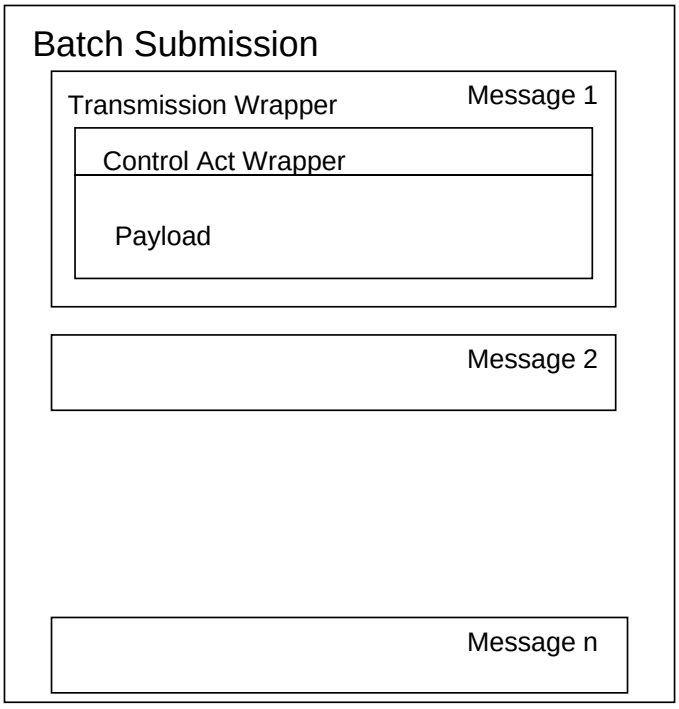

Figure 1-1 Sample ICSR Submission Format

The following figure depicts a sample valid XML Batch electronic submission using the HL7 ICSR version 3 data model.

```
<MCCI_IN200100UV 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
        MCCI_IN200100UV.xsd" ITSVersion="XML_1.0">
    <id/>
    ……..
    <message xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
        <id root="2.16.840.1.156.3.150" extension="Batch-155-392"/>
        <creationTime value="20100120"/>
        <versionCode code="V3200909"/>
        <interactionId/>
        <profileId root="2.16.840.1.113883.3.156"
                extension="AES.FDA.VICHGL42.M.V1.ACCOUNT.AE“/>
        ……..

        <controlActProcess moodCode="EVN" classCode="CACT">
            <id root="1.2.3.4" extension="USA-GAP-14973"/>
            <code code="TriggerEvent"/>
            ……..
            <subject typeCode="SUBJ">
                <investigationEvent moodCode="EVN” classCode="INVSTG">
                    ……..
                </investigationEvent>
            </subject>
        </controlActProcess >

    </message>

    <message xsi:type="PORR_IN049006UV.MCCI_MT000100UV01.Message">
        ……
    </message>
    ……
</MCCI_IN200100UV>
```

Figure 1-2 Sample XML ICSR Batch Submission

All adverse event electronic transmissions sent or forwarded to FDA/CVM of ICSRs must follow this structure to be accepted by CVM and forwarded for review. Not following this standard and structure will result in the submission being rejected and not being reviewed.

1.8 Exceptions to Be Noted

There are two data elements (A.5 and B.2.1.6) that are for FDA internal use only. These data elements are marked as "FDA Internal Only", and should be deleted before publishing for the general external public.

Please note that in this document, the XPath's are based on single ICSR instance example. For batch message instances, please replace //PORR_IN049006UV with //MCCI_IN200100UV/message.

1.9 Special Handling of Element Fields (Null Flavors)

This Implementation Guide applies to all three types of ICSR reports: Adverse Event Only Report (AE only), Product Problem Only Report (PP only), and Adverse Event plus Product Problem report (AE/PP report). Reporters should map every data element that is applicable to the specific type of report into the ICSR message, whether or not it is a required data element or an optional data element. However, reporters are advised that for any data element that is not applicable to a specific type of report, mapping such a data element into the ICSR message will result in a rejection of the message. For example, reporters should not send data about animal administration information in a Product Problem Only report.

For the data elements that are applicable to the specific type of report, all the data elements should be mapped into the ICSR message. For required fields, if the data are unknown, reporters should use the "NI – No Information" variety, as referenced in the example below. A sample showing a fully complaint data element is shown and then a fully compliant data element demonstrating a null flavor is shown.

Fully Compliant XML Snippet

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95010"
                                        displayName="Female Physiological  Status"/>
      <value xsi:type="CE" codeSystem="2.16.840.1.113883.13.49 " code="NPL"
      displayName="NONPREGNANT LACTATING"/>
  </observation>
</subjectOf2>
```

Fully Compliant Null Flavor XML Snippet

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <!– The following is Physiological Status. –>
    <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95010"
                                        displayName="Female Physiological Status"/>
      <value xsi:type="CE" nullFlavor="NI"/>
  </observation>
</subjectOf2>
```

Note that for the line

<value xsi:type="CE" nullFlavor="*NI*"/>,

a short format

<value nullFlavor="*NI*"/>

is also allowed. This is because HL7 Datatypes Release 2 allows this form, though it is considered a deviation from the HL7 standard, and it is not preferred.

If "Unknown" or a similar code is in an FDA Published Vocabulary list for that particular data element (mandatory or optional) the assigned code and the accompanying term together with the codeSystem OID should be used, instead of using the null flavor.

All mandatory and optional elements of the ICSR message must be coded with an actual value or a null flavor selection specific to the associated data element. See Section 7--List of Element Fields for a complete list of elements and the correct application of null flavors.

The process of selecting and employing a null flavor is controlled by two rules that have precedence. Rule one; is outlined in the table below and is the default set of rules for applying the null flavor to ICSR elements. Rule two; is contained in the individual validation business rules (See *Electronic Transmission Implementation Specifications [Validation Procedures)]* for the all elements. Rule two has precedence over Rule one. If the Validation Guide for the individual element does not definitively specify an element null flavor treatment then Rule one applies appropriately.

The following table documents the null flavor handling for each element type. It also indicates how CVM's ICSR processing systems will validate and process elements that are mandatory and/or optional and when a null value can be properly used as element data response.

Element Type	Null Flavor Rule
Mandatory Coded Element	Submitters must use a valid value from the vocabulary list. Must use the best selection possible 'Unknown' may be included in vocabulary lists.
Optional Coded Element	Must use the null flavor specified for the element when a valid value is not known. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Text Field Element	Submitters must use a valid value. Use of a null flavor is NOT permitted. Blank/empty fields (for this element type) are NOT permitted.
Optional Text Field Element	Must use null flavors when a valid value is not known. 'NI – No Information' is the default null flavor for this data type. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Numeric Field Element	Must contain a valid value. Null flavor use is NOT permitted. Zero may be a valid value (unless otherwise specified by specific business rules).
Optional Numeric Field Element	Must use a null flavor when a valid value is not known. 'NI – No Information' is the default null flavor for this data type. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Date Field Element	Must contain a valid date. Null flavor use is NOT permitted. Blank or empty fields are NOT permitted.
Optional Date Field Element	Must use a null flavor when a valid date is not known. 'NI – No Information' is the default null flavor for this data type. Blank or empty fields are NOT permitted unless used in conjunction with a null flavor attribute.
Mandatory Text Element Related to Mandatory Coded Element	Reporters must use a valid value from the list. 'Unknown' may be a value included in vocabulary lists.
Optional Text Element Related to Coded Element	Must use a null flavor when a valid value is not known. 'NI – No Information' is the default null flavor for this element type. Blank or empty

Element Type	Null Flavor Rule
	fields are NOT permitted unless used in conjunction with a null flavor attribute.
Boolean Field Elements – Mandatory or Optional	Boolean elements have a number of null flavor terms and conditions and when a null flavor can be used. *Appendix A.31 Boolean Information Table* documents the allowable null flavors ("NA", "NI", and "UNK") and the cases when the null flavor must/may be employed.

Table 1-2 Null Flavor Element Data Rules

1.10 Report Type Elements

The following table describes the FDA/CVM specific reporting types for which data elements is valid. Reporting Types can include the following: Adverse Events (AE only), Product Problems (PP only) or Adverse Events with Product Problems (AE+PP). For example, a data element may be valid for only those reports containing adverse event information, therefore, the data element would only be valid for reporting types AE and AE+PP. For further guidance on adverse events and product problems, please reference *#188 - Guidance for Industry - Data Elements for Submission of Veterinary Adverse Event Reports to the Center for Veterinary Medicine*.

Only fields designated for the specified report type should be included in the ICSR for that report type (i.e. if the report type equals AE only, then PP data should not be included in the AE only ICSR). The only exception to this rule is if the element is not valid for the specified report type, but is required by the HL7 ICSR schema. In this case, if the element is not valid for the specified report type and is required by the HL7 ICSR schema, then the element must be present in the ICSR, but contain a null flavor. The table below details the ICSR data sections, whether the specified information is required, optional, or should not be reported per the HL7 ICSR schema.

		Required Elements per ICSR Report		
GL 42 Section Title	**GL42 Section Number**	**Adverse Event (AE) Only**	**Product Problem (PP) Only**	**AE + PP**
Administrative and Identification Information – Section A				
Regulatory Authority (RA)	A.1	X	X	X
Marketing Authorization Holder (MAH) (Sender) -- Section A.2				
MAH Information	A.2.1	X	X	X
Person Acting on Behalf of MAH	A.2.2	*	*	*
Person(s) Involved in AER (Reporter) – Section A.3				
Primary Reporter Information	A.3.1	X	X	X
Other Reporter Information	A.3.2	*	*	*
AER Information (Sender Investigation/Report Information) – Section A.4				
Unique Adverse Event Identification Number	A.4.1	X	X	X
Original Receive Date	A.4.2	X	X	X
Date of Current Submission	A.4.3	X	X	X
Type of Report – Section A.4.4				
Type of Submission & Code	A.4.4.1	X	X	X
Reason for Nullification Report	A.4.4.2	*	*	*
Type of Information in Report & Code	A.4.4.3	*	*	*
Description of Animal Data Information – Section B				

GL 42 Section Title	GL42 Section Number	Required Elements per ICSR Report		
		Adverse Event (AE) Only	Product Problem (PP) Only	AE + PP
Animal Data – Section B.1				
Number of Animals Treated	B.1.1	*	#	*
Number of Animals Affected	B.1.2	X	#	X
Attending Veterinarian's Assessment of Animal Health Status Prior to VMP & Code	B.1.2.1	*	#	*
Species (Type of Species) & Code	B.1.3	X	#	X
Breed (Breed Group)	B.1.4	*	#	*
Gender & Code	B.1.5	*	#	*
Reproductive Status & Code	B.1.6	*	#	*
Female Physiological Status & Code	B.1.7	*	#	*
Animal Weight – Section B.1.8				
Weight Measured, Estimated or Unknown & Code	B.1.8.1	X	#	X
Minimum Weight	B.1.8.2	X	#	X
Maximum Weight	B.1.8.3	X	#	X
Animal Age – Section B.1.9				
Age Measured, Estimated or Unknown & Code	B.1.9.1	X	#	X
Minimum Age	B.1.9.2	X	#	X
Minimum Age Units	B.1.9.2.1	X	#	X
Maximum Age	B.1.9.3	X	#	X
Maximum Age Units	B.1.9.3.1	X	#	X
VMP Data and Usage – Section B.2				
Registered Name or Brand Name	B.2.1	X	X	X
Product Code (Product NDC Number or Unique ID)	B.2.1.1	*	*	*
Registration Identifier	B.2.1.2	X	X	X
Anatomical Therapeutic Chemical Vet (ATCvet) Code	B.2.1.3	X	X	X
Company or MAH	B.2.1.4	*	*	*
MAH Assessment	B.2.1.5	*	#	*
RA Assessment (FDA Internal Use Only)	B.2.1.6	-	-	-
Route of Exposure & Dosage Information – Section B.2.1.7 & Section B.2.2				
Route of Exposure (Route of Administration)	B.2.1.7	*	#	*
Dose Per Administration	B.2.1.7.1	*	#	*
Interval of Administration	B.2.1.7.1.2	*	#	*
Date of First Exposure	B.2.1.7.1.2.2	*	#	*
Date of Last Exposure	B.2.1.7.1.2.3	*	#	*
Active Ingredient(s) & Code(s)	B.2.2.1	X	X	X
Dosage Form & Code	B.2.2.2	*	*	*
Manufacturing/Product Defect Information – Section B.2.3 & B.2.3.6				
Lot Number(s)	B.2.3	*	*	*
Expiration Date	B.2.3.1	*	*	*
Manufacturer's Site Id Number	B.2.6.1	#	*	*

GL 42 Section Title	GL42 Section Number	Required Elements per ICSR Report		
		Adverse Event (AE) Only	Product Problem (PP) Only	AE + PP
Manufacturer's Identifier Type	B.2.6.1.1	#	*	*
Manufacturing Date	B.2.6.2	#	*	*
Number of Defective Units	B.2.6.3	#	*	*
Number of Units Returned	B.2.6.4	#	*	*
ORA District Field Office Where Product Quality Report was Filed and Code	B.2.6.5	#	X	X
Administration – Section B.2.4				
Who Administered the VMP & Code	B.2.4	*	#	*
Label Usage – Section B.2.5				
Use According to Label	B.2.5	*	#	*
Explanation for Off-Label Use & Code	B.2.5.1	*	#	*
Adverse Event Data – Section B.3				
Narrative of AE	B.3.1	X	X	X
Adverse Clinical Manifestations (AER Term Name(s) & Code(s))	B.3.2	X	X	X
Date of Onset of AE (AE Start Date)	B.3.3	X	#	X
Length of Time between Exposure to VMP & Onset of AE	B.3.4	*	#	*
AE Duration Time	B.3.5.1	*	#	*
AE Duration Time Units	B.3.5.1.1	*	#	*
Serious AER Reported	B.3.6	X	#	X
Treatment of AE	B.3.7	*	#	*
Outcome to Date	B.3.8	*	#	*
Previous Exposure to the VMP	B.3.9	*	#	*
Previous AE to VMP	B.3.10	*	#	*
Dechallenge - Rechallenge Information – Section B.4				
Did AE Abate After Stopping the VMP?	B.4.1	*	#	*
Did AE Reappear After Re-introduction of the VMP?	B.4.2	*	#	*
Veterinary Assessment of AE – Section B.5				
Attending Veterinarian's Assessment of AE	B.5.1	*	#	*
Supplemental Documents -- Section B.6				
Supplemental Document Filename	B.6.1	*	*	*
Supplemental Document Description	B.6.2	*	*	*
Supplemental Document Type	B.6.3	*	*	*
U.S. Specific Only – Section B.7				
Report Identifier	B.7.1	X	X	X
Domestic vs. Foreign Report Category	B.7.2	X	X	X
US Pharmacovigilance Contact Person for MAH	B.7.3	X	X	X
Key to Table:				

GL 42 Section Title	GL42 Section Number	Required Elements per ICSR Report		
		Adverse Event (AE) Only	Product Problem (PP) Only	AE + PP
X = Required Element – Must Be Present – Null Flavor Required If Data Is Not Known * = Optional Element – If Reported the Element Data Must Follow the Established Validation Rules # = Element MUST Not Be Reported - = FDA Usage Only Aug 5, 2009				

Table 1-3 Submitted Elements versus Report Type

If fields are included that are not valid for the specified report type (and not required by the HL7 ICSR schema), then the ICSR will be rejected. For example, if any of the elements under the Animal Data section (B.1) are included for the Product Problem Only Report type then the ICSR will be rejected.

1.11 Structure of This Document

This document is structured to follow the GL42 adverse event standard specification. We have attempted to track the GL42 element numbering system as close as possible. For elements that are not covered by the GL42 specification they are noted and the GL42 numbering system is extended.

Each required and optional ICSR data element is discussed with a description of the element along with its structure. XPath XML examples are included along with sample XML snippets. The sample XML snippets have a defined format that includes the following:

- Defined HL7 ICSR element names and element reference values
- CodeSystem OIDs that must be used
- Variable sample data (Indicated by the use of italics within the snippet)
- Specific element attribute typing

1.12 ICSR Schema Locator Codes

The HL7 ICSR XML format employs a set of coded "Observation XPath" values to locate specific parts of the ICSR message. FDA has extended this locator system with list of codes to locate their element extensions to the HL7 schema. ***Appendix A.23-Observation Locator Codes*** is a listing of these "Observation" locators.

1.13 Rules Concerning Handling Responses Within Elements

CVM's Adverse Events Processing system will validate and process all ICSR element responses using the following data format rules:

- Leading and trailing white space (blanks) *will* be trimmed for each element value
- White space within an element value *will* be considered part of the element value
- Case *will not* be significant *nor considered* when validating element values

1.14 Vocabulary Reference List of Values

Section 6—"Vocabulary Tables" lists the sample set of reference vocabularies used in coding HL7 ICSR messages. All FDA ICSR processing systems use these vocabularies to validate and confirm proper information within the ICSR message.

1.15 Disclaimer

For any HL7 ICSR version 3 messages that are submitted to FDA CVM for evaluation and review, please note that FDA CVM applications and systems will only capture and process the data elements that are explicitly described in this document. Any other data elements and/or information that are included within the submitted messages but are not explicitly described within this document will be ignored and not processed.

2 Administrative and Identification Information – GL-42 Section A

2.1 Regulatory Authority (RA) – GL-42 Section A1

FDA Requirement Number(s)
RA Name: 4017.1
RA Street Address: 4017.2
RA City: 4017.3
RA State: 4017.4
RA Mail / Zip Code: 4017.5
RA Country: 4017.6

Information: This is the Regulatory Authority (RA) to which this AER is to be initially submitted based on which RA has the authority to regulate the product. The ICSR reporter should enter the **"**RA Name", "RA Street Address", "RA City", "RA State/County", "RA Mail/Zip Code", and "RA Country" (3 character code ISO 3166). The codeSystem OID is "National Cancer Institute Thesaurus [1]", and the locator code to be used is "T95009".

The information required for this section is as follows:

Regulatory Authority (RA) Identifier	RA Name	RA Address	RA City	RA State	RA Zip Code	RA Country
USFDACVM	Food and Drug Administration, Center for Veterinary Medicine	7500 Standish Place (HFV-199), Room 403	Rockville	Maryland (MD)	20855	USA

Table 2-1 Regulatory Authority Information

GL-42 Section**:** A.1

ICSR Location: RA information is located in the ICSR message payload <receiver> section of an <investigationEvent> within the <controlActEvent> element.

XML Details: RA information is captured using <assignedOrganization> element as shown in the sample code below. Note that for "RA Address", data elements are captured in <addr> element.

Reporters should use the <code> element of <assignedEntity> to specify the role played by this receiver. In this case, set the code value to "T95009", and set the codeSystem value to the "National Cancer Institute Thesaurus".

Note that an OID is not required for address information. For "RA Country" data, an ISO 3166 3-letter country code shall be used, see ***Appendix–A.36-List of ISO 3-Digit Country Codes***. For US

[1] See Section 6.3 - Vocabulary Code System OIDs on page 6-0 for OID values

RA, users shall select the two letter state abbreviation for US States (***Appendix A.35–List of US States & Territory Codes***).

The XPath's to get the "RA Name" and the "RA Country Code" in an ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf/controlActEvent/receiver/assignedEntity[code/@code="T95009"]/assignedOrganization/name

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf/controlActEvent/receiver/assignedEntity[code/@code="T95009"]/addr/country

A sample XML snippet for "RA Name" in an ICSR message is shown below. Note that this example uses a US address (the actual address for FDA/CVM). For foreign addresses using province, simply map the province data into <state> element.

```
<controlActEvent classCode="CACT" moodCode="EVN">
    <receiver typeCode="RCV">
        <assignedEntity classCode="ASSIGNED">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95009"  displayName="RA"/>
            <addr use="WP">
                <streetAddressLine>7500 Standish Place (HFV-199), Room 403</streetAddressLine>
                <city>Rockville</city>
                <state>MD</state>
                <postalCode>20855</postalCode>
                <country>USA</country>
            </addr>
            <assignedOrganization determinerCode="INSTANCE" classCode="ORG">
                <name>Food and Drug Administration, Center for Veterinary Medicine</name>
            </assignedOrganization>
        </assignedEntity>
    </receiver>
</controlActEvent>
```

2.2 Marketing Authorization Holder (MAH) (Sender) – GL-42 Section A.2

FDA Requirement Number(s):
Sender Category: ??
Sender Organization: 48
Sender Street Address: 40
Sender City: 41
Sender State: 42
Sender Mail / Zip Code: 43
Sender Country: 45
Sender Title / Person Acting on Behalf of MAH: 4003.1
Sender First Name: 4003.2
Sender Last Name: 4003.3
Sender Telephone: 4003.4
Sender Fax: 4003.5
Sender Email: 4003.6

Information: This is the AER "Sender" information. Typically, this is the MAH responsible for sending the AE information to the RA who is responsible for regulating the VMP.

Sender information consists of three parts: "MAH Information", "Person Acting on Behalf of MAH" (optional), and "Sender Category".

***GL-42 Section*:** A.2

ICSR Location: MAH (Sender) information is located in the ICSR message payload <author> section of <investigationEvent> within the <controlActProcess> element.

XML Details: The MAH part of the "Sender Information" should provide the business name, street address, city, state/province, mail/zip code, and country of the submitting organization. As with the RA information, the MAH information is captured using <assignedOrganization> element. The "Person Acting on Behalf of MAH" is captured in <contactParty> child element. A NCI codeSystem shall be used to capture the "Sender Category" information. The codeSystem OID is "National Cancer Institute Thesaurus", and the code value should be one of the values in the code list shown in ***Appendix A.1 – Sender Category Vocabulary***.

The telecom values for email addresses, phone and fax numbers in ICSR messages should follow the following rules to be a valid:

Telecom Entry Rules
Each telecom value must include the type of telecom entry. The element type choices must be one of the following: "FAX:", "MAILTO:", and "TEL:" . Any other choice will result in the ICSR being rejected.
No spaces, bracket(s), and hyphens are allowed in phone number (*spaces are used in this table for clarification only*).
The phone number could be in either local format (e.g. 123 123 4567 or 2 1234 5678) or international format (e.g. +1 123 123 4567 or +61 2 1234 5678).
It also accepts an optional extension of up to five digits prefixed by "x" or "ext" (e.g. 123 123 4567 x89).
If the validation rules allow and all telecom entries are not known then the complete telecom entry can use a single "NI – No Information" nullFlavor. It is not required to list each telecom entry with a nullFlavor. Example: <telecom nullFlavor="NI"/>

Table 2-2 Telecom Entry Format Rules

The XPath's to locate the "MAH Information", "Sender Information", and "Sender Category" in an ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf/controlActEvent/author/assignedEntity/assignedOrganization/contactParty/contactPerson/name

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf/controlActEvent/author/assignedEntity/assignedOrganization/contactParty/contactPerson/telecom[starts-with(@value, "TEL")]/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/subjectOf/controlActEvent/author/assignedEntity/code/@code

A sample XML snippet for “Sender Category”, “MAH Information” and “Sender Information” in an ICSR message is:

```
<author typeCode="AUT">
   <assignedEntity classCode="ASSIGNED">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95001" displayName="MAH"/>
      <addr use="WP">
         <streetAddressLine>555 Prosperity Place</streetAddressLine>
         <city>Woodbury</city>
         <state>TN</state>
         <postalCode>37615</postalCode>
         <country>USA</country>
      </addr>
      <assignedOrganization classCode="ORG" determinerCode="INSTANCE">
         <name>GAP Industries</name>
         <contactParty classCode="CON">
            <contactPerson determinerCode="INSTANCE" classCode="PSN">
               <name>
                  <prefix>Mr.</prefix>
                  <given>Roger</given>
                  <family>Paterson</family>
               </name>
               <telecom value="TEL:6155551110x10"/>
               <telecom value="FAX:6165559090"/>
               <telecom value="MAILTO://someone@apple.com"/>
            </contactPerson>
         </contactParty>
      </assignedOrganization>
   </assignedEntity>
</author>
```

Note that the example above is for a “Sender” who is a “MAH”. If the “Sender” belongs to the “Other” category, the reporter should use the XML shown in the following snippet:

```
<author typeCode="AUT">
   <assignedEntity classCode="ASSIGNED">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C10616" displayName="Other"/>
   </assignedEntity>
</author>
```

2.3 Person(s) Involved in AER (Reporter) – GL-42 Section A.3

FDA Requirement Number(s):
Reporter Category: 49
Reporter First Name: 401
Reporter Last Name: 400

Reporter Organization: 403
Reporter Street Address: 407
Reporter City: 409
Reporter State: 410
Reporter Mail / Zip Code: 413
Reporter Country: 412
Reporter Telephone: 404
Reporter Fax: 417
Reporter Email: 406

Information: This section contains information on the Reporter(s) who originally reported the AE to the (sender). A required "Primary Reporter" and one optional "Other Reporter" should be entered in the ICSR message.

***GL-42 Section*:** A.3

ICSR Location: Reporter information is captured in the ICSR message payload using a list of <sourceOf> child elements of <investigationEvent>.

XML Details: Since the <sourceOf> element in ICSR message can be used for other information related to ICSR investigation event, when the "Reporter Information" element is selected, reporters should use the code for "sourceReport" to identify that this <sourceOf> element contains "Reporter Information". To differentiate "Primary Reporter" from "Other Reporter", a <priorityNumber> child element is used. For "Primary Reporter", its value is "1", for "Other Reporter", its value equals "2".

Unlike the RA and MAH information, reporters should use <assignedPerson>, not <representedOrganization>, to capture the "Reporter's Information". Use <assignedPerson>'s child element <asMember> to capture the "Business Name" information of the reporter if needed (as the value of <name> element under <groupOrganization>). If "Business Name" value is not available then use the null flavor "NI", as shown in the snippet below.

"Reporter Category" shall be selected using a NCI codeSystem in <code> element and the value as the displayName, with the codeSystem OID set to "National Cancer Institute Thesaurus", and code value set to one of the codes listed in ***Appendix A.2–List of Reporter Categories***. See Table 2-2 Telecom Entry Format Rules for telecom entry rules.

The XPath to get the "Primary Reporter's" "Last Name" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/sourceOf[priorityNumber/@value=1]/relatedInvestigation[code/@code="T95002"]/author/assignedEntity/assignedPerson/name/family
```

The XPath to get the "Reporter Fax" number of the "Primary Reporter" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/sourceOf[priorityNumber/@value=1]/relatedInvestigation[code/@code="T95002"]/author/assignedEntity/assignedPerson/telecom[starts-with(@value, "FAX")]/@value
```

The following is a sample XML snippet for “Primary Reporter” in an ICSR message. Note that the same snippet could be for “Other Reporter” if the second line in the snippet is replaced with <priorityNumber value="*2*"/>.

```
<sourceOf typeCode="SPRT">
   <priorityNumber value="1"/>
   <relatedInvestigation classCode="INVSTG" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95002" displayName="SourceReport"/>
      <author typeCode="AUT">
         <assignedEntity classCode="ASSIGNED">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C82468" displayName="Animal Owner"/>
            <addr use="WP">
                  <streetAddressLine>2nd Prosperity Place</streetAddressLine>
                  <city>Woodbury</city>
                  <state>TN</state>
                  <postalCode>37615</postalCode>
                  <country>USA</country>
            </addr>
            <assignedPerson classCode="PSN" determinerCode="INSTANCE">
               <name>
                  <family>Peter</family>
                  <given>Ken</given>
               </name>
               <telecom value="TEL:6155551112x3"/>
               <telecom value="FAX:8095559090"/>
               <telecom value="MAILTO://someone1@example.com"/>
               <asMember classCode="MBR">
                     <groupOrganization classCode="ORG" determinerCode="INSTANCE">
                        <name nullFlavor="NI"/>
                     </groupOrganization>
                </asMember>
            </assignedPerson>
         </assignedEntity>
      </author>
   </relatedInvestigation>
</sourceOf>
```

2.4 AER Information (Investigation/Report Information) – GL-42 Section A.4

FDA Requirement Number(s):
Unique Adverse Event Report Identification Number: 600.6
Original Receive Date: 88.1
Date of Current Submission: 88.1
Type of Report: 75
Individual Case Safety Report Number: N54
Profile ID: N75
Report Application Number: N41

Information: This section contains general information about the AER, including:

- A.4.1 Unique Adverse Event Report Identification Number
- A.4.2 Original Receive Date

- A.4.3 Date of Current Submission
- A.4.4 Type of Report
    - A.4.4.1 Type of Submission
    - A.4.4.2 Reason for Nullification
    - A.4.4.3 Type of Information in Report

2.4.1 Unique Adverse Event Report Identification Number – GL-42 Section A.4.1

The "Unique Adverse Event Report Identification Number" is Sender's (Case) Safety Report Unique Identifier. It contains the 3 digit ISO 3166 country code, the 8 character MAH identifier code, and a number that is unique within the Sender organization.

***GL-42 Section*:** A.4.1

ICSR Location: This information is located in the ICSR message payload <id> section of <investigationEvent> within the <controlActProcess> element. The "<id root>" attribute value is the Sender's OID. Senders should refer to the main "*CVM Electronic ICSR Submission Instructions*" in order to obtain a unique OID for their company's submissions. The "extension" attribute captures the identifier number. The format of the identifier is 3 distinct fields; the country of the "MAH", the name of the "MAH" and the unique ICSR number assigned by the "MAH". The three fields are separated by hyphens '-'.

XML Details: The XPath to get the "Unique Adverse Event Report Identification Number" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/id/@extension
```

A sample XML snippet for "Unique Adverse Event Report Identification Number" in an ICSR message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
    <id root="SendersAssignedOID" extension="USA-GAPINDSY-14973"/>
    ……
</investigationEvent>
```

2.4.2 Original Receive Date – GL-42 Section A.4.2

This is the date the initial report was received by the MAH.

***GL-42 Section*:** A.4.2

ICSR Location: This information is located in the ICSR message payload <sourceOf> section of <investigationEvent>, specifically inside the <relatedInvestigation> child element. Note that this <relatedInvestigation> element is located in the same <sourceOf> element where the "Primary Reporter" element is located.

XML Details: "YYYYMMDD" is the date format to be used for this data element, i.e. the HL7 "Point in Time" (TS) literal form, which is a simple calendar form. To get the day, month, and year data, the reporter needs to parse the date value.

The XPath to get the "Original Receive Date" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/sourceOf[priorityNumber/@value=1]/relatedInvestigation[code/@code="T95002"]/effectiveTime/@value
```

A sample XML snippet for "Original Receive Date" in an ICSR message is:

```
<sourceOf typeCode="SPRT">
   <priorityNumber value="1"/>
   <relatedInvestigation moodCode="EVN" classCode="INVSTG">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95002" displayName="SourceReport"/>
      <effectiveTime value="20080528"/>
      ……..
   </relatedReport>
</support>
```

2.4.3 Date of Current Submission – GL-42 Section A.4.3

This is the date that the current AER was submitted to the RA.

***GL-42 Section*:** A.4.3

ICSR Location: This information is located in the ICSR message payload <activityTime> element of <investigationEvent>.

XML Details: The XPath to get the "Date of Current Submission" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/activityTime/@value
```

A sample XML snippet for "Date of Current Submission" in an ICSR message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
      ……..
      <activityTime value="20090517"/>
      ……..
</investigationEvent>
```

2.4.4 Type of Report – GL-42 Section A.4.4

2.4.4.1 Type of Submission

This information contains "Type of Submission", and if this is a nullification report then this element contains, "Reason for Nullification Report". It also contains "Type of Information in Report".

***GL-42 Section*:** A.4.4

ICSR Location: "Type of Report" information is located in the ICSR message payload <component4> section of <investigationEvent> within a <investigationCharacteristic> tag.

XML Details: "Type of Submission" shall be set using an NCI code in <code> element and the value as the displayName, with the codeSystem OID set to "National Cancer Institute Thesaurus", and code value set to one of the codes listed in ***Appendix A.3–List of Type of Submission***.

2.4.4.2 Reason for Nullification

For the element "Reason of Nullification Report", the information is captured within a <reasonCode> element. The reporter can use the <originalText> element to enter text for the reason. "Reason of Nullification" shall be entered only when the code value for "Type of Submission" is "C68625", i.e. "NULLIFICATION".

The XPath to get "Type of Submission" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component4/investigationCharacteristic
[code/@code="T95003"]/value/@code
```

A sample XML snippet for the "Type of Submission" in an ICSR message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
  ……
  <component4 typeCode="COMP">
    <investigationCharacteristic classCode="CASE" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95003" displayName="Type of Submission"/>
      <reasonCode nullFlavor="NI"/>
      <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C68624"
                                                                    displayName="EXPEDITED"/>
    </investigationCharacteristic>
  </component4>
  ……
</investigationEvent>
```

The XPath to get to the "Reason for Nullification" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component4/investigationCharacteristic
[code/@code="T95003"]/reasonCode/originalText
```

A sample XML snippet for "Reason for Nullification" in an ICSR message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
  ……
  <component4 typeCode="COMP">
    <investigationCharacteristic  classCode="CASE" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95003"
                                                displayName="Type of Submission"/>
        <reasonCode>
```

```
            <originalText>Here is the reason of nullification</originalText>
          /reasonCode>
        <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C68625"
                                                displayName="NULLIFICATION"/>
    </investigationCharacteristic>
  </component4>
  ……
</investigationEvent>
```

2.4.4.3 Type of Information in Report

"Type of Information in Report" shall be set using a NCI codeSystem in the <code> element and the value as the displayName, with codeSystem OID set to "National Cancer Institute Thesaurus", and code value set to one of the codes listed in ***Appendix A.4–List of Type of Information in Report***.

The XPath to get "Type of Information in Report" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component4/investigationCharacteristic
[code/@code="T95004"]/value/@code
```

A sample XML snippet for "Type of Information in Report" in an ICSR message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
  ……
  <component4 typeCode="COMP">
    <investigationCharacteristic classCode="CASE" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95004"
                          displayName="Type of Information in  Report"/>
        <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C82452"
                          displayName="Both  Safety And Lack Of Expected Effectiveness"/>
    </investigationCharacteristic>
  </component4>
  ……
</investigationEvent>
```

2.5 Animal Data – GL-42 Section B.1

***Information*:** *Except for the element "Number of Animals Treated", data in this Section relates to the affected animals only.*

GL-42 Section: B.1

***ICSR Location*:** These data elements are provided in the appropriate sections and subsections of ICSR message payload, within the <associatedAnimal> node which is located within the <primaryRole> and <subject> element tags of the <adverseEventAssessment> parent element.

The Animal Data Elements are described below.

2.5.1 Number of Animals Treated – GL-42 Section B.1.1

FDA Requirement Number(s):
Number of Animals Treated: 2024

***Information*:** Optional. Number of Animals Treated With VMP

***GL-42 Section*:** B.1.1

***ICSR Location*:** This data is captured using a <quantity> element inside the <associatedAnimal> node. The <associatedAnimal> node is located inside the <primaryRole> and <subject> element tags.

***XML Details*:** The XPath to get "Number of Animals Treated" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/associatedAnimal/quantity/@value
```

A sample XML snippet for "Number of Animals Treated" in an ICSR message is:

```
<component1 typeCode="COMP">
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
      <subject typeCode="SBJ">
        <primaryRole classCode="SBJ">
          <associatedAnimal classCode="ANM" determinerCode="INSTANCE">
            ……
            <quantity xsi:type="PQ" value="9"/>
            ……
          </associatedAnimal>
        </primaryRole>
      </subject>
  </adverseEventAssessment>
</component1>
```

2.5.2 Number of Animals Affected – GL-42 Section B.1.2

FDA Requirement Number(s):
Number of Animals Affected: 2025

***Information*:** This is the number of animals adversely affected by the VMP(s). If the actual number is unknown, the MAH/reporter should estimate the number of animals affected. In addition, the MAH/reporter can optionally provide the information regarding how the counts of animals were obtained, for example, "ESTIMATE"; in the narrative section of the investigation event (refer to Section 3.3.1).

***GL-42 Section*:** B.1.2

***ICSR Location*:** This information is captured as an observation using a <observation> element inside a <subjectOf2> node.

***XML Details*:** The XPath to get the "Number of Animals Affected" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95005"]/value/@value
```

A sample XML snippet for "Number of Animals Affected" in an ICSR message is:

```
<component1 typeCode="COMP">
   ……
   <subjectOf2 typeCode="SBJ">
      <observation classCode="OBS" moodCode="EVN">
      </observation>          <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95005"
                                    displayName="Number of Animals Affected"/>
         <value xsi:type="INT" value="235"/>

   </subjectOf2>
   ……
</component1>
```

2.5.2.1 Attending Veterinarian's Assessment of Health Status Prior to VMP – GL-42 Section B.1.2.1

FDA Requirement Number(s):
Attending Veterinarian's Assessment of Health Status Prior to VMP: 2009

Information: Optional. This is the attending Veterinarian's assessment of the health status of the animal(s) involved in the AE prior to their exposure to the VMP.

***GL-42 Section*:** B.1.2.1

***ICSR Location*:** This information is captured as an observation using a <observation> element inside a <subjectOf2> node.

XML Details: Users should use a proper code to ensure <subjectOf2> contains "Attending Veterinarian's Assessment". The reporter must also use a NCI coded value for the actual assessment value. The list of NCI codes and values are shown in ***Appendix A.6–List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use***.

The XPath to get the "Attending Veterinarian's Assessment" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95006" and
author/assignedEntity/code/@code="C82470"]/value/@code
```

A sample XML snippet for "Attending Veterinarian's Assessment" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
    <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95006"
                displayName="Assessment of Health Status Prior to the Exposure to Product"/>
    <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C82488"
                                                displayName="EXCELLENT"/>
    <author typeCode="AUT">
      <assignedEntity classCode="ASSIGNED">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C82470" displayName="Veterinarian"/>
      </assignedEntity>
    </author>
  </observation>
</subjectOf2>
```

2.5.3 Species (Type of Species) – GL-42 Section B.1.3

FDA Requirement Number(s):
Type of Species: 2010

***Information*:** The species is the species of the animal affected by the VMP. In the case of a human AE, the MAH should choose "human" as the species.

***GL-42 Section*:** B.1.3

***ICSR Location*:** Species data is captured in the <associatedAnimal> in <adverseEventAssessment>

XML Details*:** This data are provided in code attribute value in the <code> element of <associatedAnimal> element. The VICH codes and values are shown in ***Appendix A.7–List of Species. The codeSystem OID is "*VICH – Species OID*".

The XPath to get the "Type of Species" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/associatedAnimal/code/@code
```

A sample XML snippet for “Type of Species” in an ICSR message is:

```
<component1 typeCode="COMP">
  <adverseEventAssessment classCode="INVSTG" moodCode="EVN">
    <subject typeCode="SBJ">
      <primaryRole classCode="SBJ">
        <associatedAnimal classCode="ANM" determinerCode="INSTANCE">
          <code codeSystem="2.16.840.1.113883.4.341" code="PIG" displayName="Pig"/>
        </associatedAnimal>
      </primaryRole>
    </subject>
  </adverseEventAssessment>
</component1>
```

2.5.4 Breed (Breed Group) – GL-42 Section B.1.4

FDA Requirement Number(s):
Breed: N42, N32, 2011

Information*:** Optional. This is the breed(s) of the animal(s) associated with the species chosen in B.1.3. The VICH codes and values for breed are shown in ***Appendix A.8–List of Breeds. The codeSystem OID is “*VICH – Breed OID*”.

***GL-42 Section*:** B.1.4, B.1.4.1, B.1.4.1.1, B.1.4.2, and B.1.4.2.1

***ICSR Location*:** Breed information is captured as an observation(s) using <subjectOf2> node(s).

XML Details: Breed information in an ICSR message may be purebred and/or crossbred. Both cases are modeled similarly.

For purebred, the information is captured as one single observation. The observation type code indicates that this observation is about animal breed. The observation value is a Boolean value, with “True” indicating crossbred, and “False” that indicates purebred. See ***Appendix A.31 – Boolean Information*** for purebred and crossbred values.

The actual breed information for the purebred case is then captured in a single or multiple child observations. Up to ninety-nine pure bred data components can be recorded.

The XPath to get the purebred information in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95007" and
value/@value=false()]/sourceOf2/observation/value/@code
```

A sample XML snippet for capturing the purebred information with multiple purebred animals (2) in an ICSR message follows:

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
```

```
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95007"
                  displayName="Are Animals Crossbred"/>
      <value xsi:type="BL" value="false"/>

      <sourceOf2 typeCode="COMP" contextConductionInd="true">
        <observation classCode="OBS" moodCode="EVN">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95008"
                displayName="Breed Components"/>
          <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342"
                                code="Pig33" displayName="Duroc"/>
        </observation>
      </sourceOf2>

      <sourceOf2 typeCode="COMP" contextConductionInd="true">
        <observation classCode="OBS" moodCode="EVN">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95008"
                displayName="Breed Components"/>
                        <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342"
                                code="Pig115" displayName="Yorkshire"/>
        </observation>
      </sourceOf2>

    </observation>
</subjectOf2>
```

For crossbred, up to ninety-nine crossbred component data elements could be included. Similar to purebred, use the observation type <code> to indicate that this observation is for breed information, but in this case the Boolean value is set to 'True' to indicate that the observation is for crossbred.

Note that per VICH requirements, all the breed components from different crossbred kinds existing in a herd should be listed in same observation, i.e., there is only one crossbred observation node that should be used.

The XPath for crossbred information that will get the list of breeds' component is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95007" and
value/@value=true()]/sourceOf2/observation/value/@code
```

The breed components for the crossbred are captured using a list of nested observations inside the <sourceOf2> nodes. These observations are handled similar to pure breed observations.

A sample XML snippet for crossbred information including multiple animal breeds (3) in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
  <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95007"
                  displayName="Are Animals  Crossbred"/>
      <value xsi:type="BL" value="true"/>
```

```
    <sourceOf2 typeCode="COMP" contextConductionInd="true">
      <observation classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95008"
              displayName=”Breed Components”/>
              <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342" code="Pig33"
                                   displayName="Duroc"/>
      </observation>
    </sourceOf2>
    <sourceOf2 typeCode="COMP" contextConductionInd="true">
      <observation classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95008"
              displayName=”Breed Components”/>
              <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342" code="Pig115"
                                   displayName="Yorkshire"/>
      </observation>
    <sourceOf2 typeCode="COMP" contextConductionInd="true">
      <observation classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95008"
              displayName=”Breed Components”/>
              <value xsi:type="CE" codeSystem="2.16.840.1.113883.4.342" code="Pig88"
                                   displayName="Other"/>
      </observation>
    </sourceOf2>
  </observation>
</subjectOf2>
```

2.5.5 Gender, Reproductive Status, and Female Physiological Status – GL-42 Section B.1.5

FDA Requirement Number(s):
Animal Gender: 4.1
Reproductive Status: 2012
Female Physiological Status: 2013

***Information*: “**Gender” is an optional element in the message. It captures the gender data based on the animal reported. “Mixed” should be chosen for group reports where the group represents both male and female animals.

“Reproductive Status” is also optional. It captures the “Reproductive Status” based on the animal reported. Choose “Mixed” for group reports where the group represents both intact and neutered animals.

“Female Physiological Status” is optional as well. It captures the physiological status based on the animal reported. For cases where there are only male animal(s) and/or neutered female animal(s), “Not Applicable” should be chosen.

***GL-42 Section*:** B.1.5, B.1.6, B.1.7

***ICSR Location*: “**Gender” and “Reproductive Status” codes are both captured inside <associatedAnimal>. “Female Physiological Status” is captured using an observation event inside <subjectOf2>.

XML Details: "Gender" and "Reproductive Status" are both captured inside <associatedAnimal>. For gender status, the code value and displayNames are shown in ***Appendix A.9-List of Gender Categories***.

For "Reproductive Status", reporters should use the code value and displayNames that represent one of the values in ***Appendix A.10–List of Reproductive Status Categories***.

For "Female Physiological Status", an observation is used to capture this information. The allowed code values and displayNames are shown in ***Appendix A.11–List of Female Physiological Status Categories***.

The XPath to get the "Gender" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment /subject/primaryRole/associatedAnimal/administrativeGenderCode/@code

The XPath to get the "Reproductive Status" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment /subject/primaryRole/associatedAnimal/genderStatusCode/@code

The XPath to get the "Female Physiological Status" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment /subject/primaryRole/subjectOf2/observation[code/@code="T95010"]/value/@code

A sample XML snippet for "Gender", "Reproductive Status" and "Female Physiological Status" in an ICSR message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
    ……
    <associatedAnimal classCode="ANM" determinerCode="INSTANCE">
        ……
        <!– The following administrativeGenderCode is the Gender of the animals. –>
          <administrativeGenderCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C16576"
                                                                displayName="FEMALE"/>
        <!– The following genderStatusCode is the Reproductive Status of the animals. –>
          <genderStatusCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C62399"
                                                          displayName="INTACT"/>
    </associatedAnimal>

    <subjectOf2 typeCode="SBJ">
       <observation classCode="OBS" moodCode="EVN">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95010"
                                                              displayName="Female Physiological  Status"/>
                <value xsi:type="CE" codeSystem=" 2.16.840.1.113883.13.49 " code="NPL"
                                                              displayName="NONPREGNANT LACTATING"/>
       </observation>
     </subjectOf2>
     ……
<adverseEventAssessment>
```

Note that in the example above, if any data element is unknown, the user should use the vocabulary choice of "UNK – Unknown" to indicate this, for example, if "Female Physiological Status" is not known, use the following:

```
<subjectOf2 typeCode="SBJ">
    <observation classCode="OBS" moodCode="EVN">
        <!– The following is Physiological Status. –>
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95010"
                                                displayName="Female Physiological Status"/>
            <value xsi:type="CE" codeSystem=" 2.16.840.1.113883.13.49 " code="C10612"
                                                displayName="UNKNOWN"/>
    </observation>
</subjectOf2>
```

2.5.6 Weight & Age – GL-42 Section B.1.8 and B.1.9

FDA Requirement Number(s):
Subject Weight: 5.2
Minimum Weight: 5.2.1
Maximum Weight: 5.2.2
Subject Age: 2.2
Minimum Age: 2.3
Minimum Age Units: 2.3.1
Maximum Age: 2.4
Maximum Age Units: 2.4.1

Information: The reporter should enter the numerical minimum weight for the animal reported in B.1.2 "Number of Animals Affected" in kilograms (kg) extended to 2 decimals. Regardless of the species involved in the case, all weights should be entered in kilograms (kg). The reporter should enter the numerical minimum age for the animal reported in B.1.2 "Number of Animals Affected".

***GL-42 Section*:** B.1.8, B.1.8.1, B.1.8.2, B.1.8.3, B.1.9, B.1.9.1, B.1.9.2, B.1.9.2.1, B.1.9.3, and B.1.9.3.1

***ICSR Location*:** Weight and Age information are captured using two observations inside <subjectOf2> elements.

XML Details: For both the "Weight" and "Age" data elements, a method code needs to be set. The value should be one of the NCI codes and code values shown in ***Appendix A.12–List of Precision Categories for Weight and Age Data***. Both "Weight" and "Age" should use data type IVL_PQ, and use low for Minimum and high for Maximum.

For "Age" data, units of measurements are shown in ***Appendix A.13–List of Time Units***; use the values in the first column.

For both "Weight" and "Age" data, if there is only one value, use <low> element.

The XPath's to get the code and value of" Weight" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95011"]/methodCode/@code

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95011"]/value/low/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95011"]/value/low/@unit

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95011"]/value/high/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95011"]/value/high/@unit

The XPath's to get the code and value of "Age" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95012"]/methodCode/@code

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95012"]/value/low/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95012"]/value/low/@unit

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95012"]/value/high/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/observation[code/@code="T95012"]/value/high/@unit

A sample XML snippet for Weight and Age in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95011" displayName="Weight"/>
      <value xsi:type="IVL_PQ">
          <low value="125" unit="kg"/>
          <high value="225" unit="kg"/>
      </value>
      <methodCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C44473" displayName="MEASURED"/>
   </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95012" displayName="Age"/>
      <value xsi:type="IVL_PQ">
          <low value="7" unit="mo"/>
          <high value="3" unit="a"/>
      </value>
      <methodCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C25498" displayName="ESTIMATED "/>
   </observation>
```

</subjectOf2>

Note that for any of these data elements, if only one value is available, use <low> element of the IVL_PQ data type to capture the data.

2.6 VMP(s) Data and Usage – GL-42 Section B.2

Information: This section contains information about the VMP(s) that are indicated in the reported AE, and the usage of the VMP(s). If multiple VMP(s) are used, a separate report should be submitted, as all the VMP(s) used should be included in each AE report.

2.6.1 Registered or Brand Name – GL-42 Section B.2.1

FDA Requirement Number(s):
Registered or Brand Name: 2028

Information: The reporter should provide the complete "Registered or Brand Name" for their approved VMP(s) involved in the adverse event. For non-MAH VMP(s) (the reporting MAH does not own or is not responsible for the VMP), if the Registered Name(s) are not available, the MAH should provide Brand Name(s) in B.2.1 or the active ingredient(s) in B.2.2.1.

***GL-42 Section*:** B.2.1

***ICSR Location*: "**Registered or Brand Name" information is captured as product information within an observation, inside <substanceAdminstrationProcess>, uses a <kindOfProduct> node.

XML Details: "Registered or Brand Name" should be complete and entered as a text field. Since multiple VMP(s) could be used, in order to provide the needed references, a <substanceAdminstrationProcess> id is used. Note that this id is only expected to be used within the context of a single ICSR.

The XPath to get the "Registered or Brand Name" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/name
```

A sample XML snippet for Brand Name in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            ......
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
               ......
               <name xsi:type="TN">DEXABRAND</name>
```

```
            ......
          </kindOfProduct>
          ......
        </instanceOfKind2>
      </consumable>
      ......
    </substanceAdministration>
</subjectOf2>
```

2.6.1.1 Product Code (National Drug Code (NDC) Number or Unique ID) – GL-42 Section B.2.1.1

FDA Requirement Number(s):
Product NDC Number: 26

Information: Optional. VMP's Product Code.

***GL-42 Section*:** B.2.1.1

***ICSR Location*:** Product Code information is captured in same product information node as B.2.1 "Brand Name" within an observation.

XML Details: This is an optional field. Product code (the NDC code for US Products) is entered as the code value text inside the <consumable> element. Use the "*FDA Product Code OID*" for codeSystem.

The XPath to get the "Product Code" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/code/@code
```

A sample XML snippet for "Product Code" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            ......
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
               <code codeSystem="2.16.840.1.113883.6.69" code="01234-*444"/>
               ......
            </kindOfProduct>
            ......
         </instanceOfKind2>
      </consumable>
      ......
   </substanceAdministration>
</subjectOf2>
```

2.6.1.2 Registration Identifier – GL-42 Section B.2.1.2

FDA Requirement Number(s):

Registration Identifier: 2030

Information: This is the "Registration Identifier" (application number) of the VMP. The "Registration Identifier" consists of the (3 character "Country Code" from ISO 3166-1 for the country where the VMP is approved) – (8 character "RA Identifier") from Table 2-1 Regulatory Authority Information
and the VMP Registration Number. For US products, regulated by US FDA/CVM, the format of the registration number should be the one character application/file identifier followed by the 6 numbers assigned by CVM for that application/file. Leading zeros must preface the code to make the number exactly 6 digits. The registration number can consist of numbers, letters and special characters. Hyphens ***must*** be used to separate the "Country Code", "RA Identifier" code and the "Registration Number". A sample "Registration Identifier" follows:

USA-USFDACVM-N009999

Information: Mandatory, Registration Identifier.

***GL-42 Section*:** B.2.1.2

***ICSR Location*:** The manufactured product role played by a product that is referred to in an adverse event or product problem report, has an associated observation on the regulatory approval that has been applied or issued for the product. "Registration Identifier" is captured inside <asManufacturedProduct> element, using the "Approval Id", as <id> element's extension attribute.

XML Details: The XPath to get the "Registration Identifier" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/asManufacturedProduct/subjectOf/approval/id/@extension
```

A sample XML snippet for "Registration Identifier" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            ......
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
               ......
               <asManufacturedProduct classCode="MANU">
                  ......
                  <subjectOf typeCode="SBJ">
                     <approval classCode="CNTRCT" moodCode="EVN">
                        <id root="2.16.840.1.113883.3.156" extension="USA-USFDACVM-N123123"/>
                        <author typeCode="AUT">
```

```
                        <territorialAuthority classCode="TERR">
                           <governingAgency classCode="PUB" determinerCode="INSTANCE">
                              <name>FDA</name>
                           </governingAgency>
                        </territorialAuthority>
                     </author>
                  </approval>
               </subjectOf>
            </asManufacturedProduct>

            <asSpecializedKind classCode="GEN">
               ......
            </asSpecializedKind>
            ……
         </kindOfProduct>
         ......
      </instanceOfKind2>
   </consumable>
   ......
</substanceAdministration>
</subjectOf2>
```

2.6.1.3 Anatomical Therapeutic Chemical Vet (ATCvet) Code – GL-42 Section B.2.1.3

FDA Requirement Number(s):

Anatomical Therapeutic Chemical Vet (ATCvet) Code: 2031

Information: The MAH should provide the "ATCvet Code" for their VMP(s). If the "ATCvet Code" cannot be determined, the MAH should use the HL7 null flavor value of "UNK" Unknown).

***GL-42 Section*:** B.2.1.3

***ICSR Location*:** Sibling node of B.2.1.2 Registration Identifier, but inside a <asSpecializedKind> element.

XML Details: **"**ATCvet Code" is captured using the <name> element value inside the <asSpecializedKind> node. The <code> element should be used to indicate that this name value is for the ATCvet code.

The XPath to get the "ATCvet Code" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/asSpecializedKind/generalizedMaterialKind[code/@code="T95013"]/name
```

A sample XML snippet for "ATCvet Code" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
```

```
        <instanceOfKind2 classCode="INST">
          ......
          <kindOfProduct classCode="MMAT" determinerCode="KIND">
            ......
            <asManufacturedProduct classCode="MANU">
              ......
            </asManufacturedProduct>

            <asSpecializedKind classCode="GEN">
              <generalizedMaterialKind classCode="MMAT" determinerCode="KIND">
                <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95013"
                                                    displayName="ATCvet Code"/>
                <name xsi:type="TN">QH02AB02</name>
              </generalizedMaterialKind>
            </asSpecializedKind>
            ……
          </kindOfProduct>
          ......
        </instanceOfKind2>
      </consumable>
      ......
    </substanceAdministration>
</subjectOf2>
```

2.6.1.4 Company or MAH – GL-42 Section B.2.1.4

FDA Requirement Number(s):
Company or MAH: 84

Information: This is the name of the "Company or MAH" owning the VMP(s) involved in the AE. For VMP(s) that are being reported and the "MAH" does not own or is not responsible for, enter the name of the "Company" owning that VMP.

***GL-42 Section*:** B.2.1.4

***ICSR Location*:** This data is captured in <asManufacturedProduct> node, inside its <manufacturerOrganization> child.

XML Details: This information is captured as free text.

The XPath to get "Company" or "MAH" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/asManufacturedProduct/manufacturerOrganization/name
```

A sample XML snippet for "Company" or "MAH" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
  <substanceAdministration classCode="SBADM" moodCode="EVN">
    <id root="1.2.3.4" extension="1"/>
    ......
    <consumable typeCode="CSM">
```

```
        <instanceOfKind2 classCode="INST">
          ......
          <kindOfProduct classCode="MMAT" determinerCode="KIND">
            ......
            <asManufacturedProduct classCode="MANU">
              <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
                <name>ANIMAL HEALTH UNLIMITED</name>
              </manufacturerOrganization>
              ......
            </asManufacturedProduct>

            <asSpecializedKind classCode="GEN">
              ......
            </asSpecializedKind>
            …….
          </kindOfProduct>
          ......
        </instanceOfKind2>
      </consumable>
      ......
    </substanceAdministration>
</subjectOf2>
```

2.6.1.5 MAH Assessment – GL-42 Section B.2.1.5

FDA Requirement Number(s):

MAH Assessment: 4000

Information: Assessment by the MAH of the association between the use of the VMP and the AE, based on a hierarchical system. The assessment, codes and terms to be used are shown in ***Appendix A.14–List of Assessment Categories***.

GL-42 Section**:** B.2.1.5

ICSR Location**:** Located in a <causalityAssessment> element inside a <adverseEventAssessment> node.

XML Details: The XPath to get "MAH Assessment" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/component/causalityAssessment[author/assignedEntity/code/@code="T95001"]/value/@code
```

A sample XML snippet for "MAH Assessment" in an ICSR message is shown below. Note that since the causality assessment is for each VMP used, a <productUseReference> element is used to link the assessment to a particular VMP using the internal <id> to indicate the specific VMP. If multiple VMPs are used, multiple <causalityAssessment> nodes can be used with <author> being MAH, one for each VMP.

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
  ……
  <component typeCode="COMP">
    <causalityAssessment classCode="INVSTG" moodCode="EVN">
```

```
        <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C54154"
                                                                displayName="Probable"/>
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95001" displayName="MAH"/>
          </assignedEntity>
        </author>

        <subject1 typeCode="SUBJ">
          <productUseReference classCode="INFO" moodCode="EVN">
            <id extension="1"/>
          </productUseReference>
        </subject1>
      </causalityAssessment>
    </component>

    <component typeCode="COMP">
      <causalityAssessment classCode="INVSTG" moodCode="EVN">
        <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C82490"
                                                                displayName="Possible"/>
        <author typeCode="AUT">
          <assignedEntity classCode="ASSIGNED">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95001" displayName="MAH"/>
          </assignedEntity>
        </author>

        <subject1 typeCode="SUBJ">
          <productUseReference classCode="INFO" moodCode="EVN">
            <id extension="2"/>
          </productUseReference>
        </subject1>
      </causalityAssessment>
    </component>

    ……
</adverseEventAssessment>
```

2.6.1.6 RA Assessment (FDA Internal Only) – GL-42 Section B.2.1.6

FDA Requirement Number(s):

RA Assessment: 4001

Information: Assessment by the RA of the association between the use of the VMP and the AE, based on a hierarchical system. Also an optional explanation relating to assessment can be provided.

***GL-42*:** B.2.1.6, B.2.1.6.1

***ICSR Location*:** Same as "MAH Assessment", but in another <causalityAssessment> element.

XML Details: Same as "MAH Assessment", except that the <author> assignedEntity has a code value for "RA", instead of "MAH". For the explanation text element use the <text> child element. The assessment, codes and values to be used are shown in ***Appendix A.14–List of Assessment Categories***.

Note that, same as “MAH Assessment”, “RA Assessment” is tied to VMP. In the case of multiple products used, multiple <causalityAssessment> nodes should be used, one for each product.

The XPath to get “RA Assessment” in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/component/causalityAssessment[author/assignedEntity/code/@code="T95009"]/value/@code
```

A sample XML snippet for “RA Assessment” in an ICSR message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
  ……
  <component typeCode="COMP">
    <causalityAssessment classCode="INVSTG" moodCode="EVN">
      <text>The reason for RA's causality assessment can put here. </text>
      <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C54154"
                                                    displayName="Probable"/>
      <author typeCode="AUT">
        <assignedEntity classCode="ASSIGNED">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95009" displayName="RA"/>
        </assignedEntity>
      </author>

      <subject1 typeCode="SUBJ">
        <productUseReference classCode="INFO" moodCode="EVN">
          <id extension="1"/>
        </productUseReference>
      </subject1>

    </causalityAssessment>
  </component>
  ……
</adverseEventAssessment>
```

2.6.1.7 Route of Exposure (Route of Administration) – GL-42 Section B.2.1.7

FDA Requirement Number(s):
Route of Administration: 19.3

Information: Optional. NCI codes and values should be used; the codeSystem OID is National Cancer Institute Thesaurus. The codes and values for “Route of Exposure” are shown in ***Appendix A.15–List of Routes of Exposure***. Note, that for “Route of Exposure”, a <translation> element should be used to capture the “VICH Route of Exposure” code. The OID to use for the <translation> element is the “*VICH – Route of Exposure OID*”.

***GL-42 Section*:** B.2.1.7

***ICSR Location*:** Located in an observation of substance administration instance. For repeated route of exposure to same VMP, use the recursive <sourceOf2> element in substance administration process to provide further information.

XML Details: Optional, but multiple route of exposure information could be provided.

The XPath to get "Route of Exposure" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/routeCode/@code

For repeated "Route of Exposure" observations, the XPath for "Route of Exposure code" is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/substanceAdministration/routeCode/@code

A sample XML snippet for "Route of Exposure" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
         <translation codeSystem="2.16.840.1.113883.4.345" code="18" displayName="In Feed"/>
      </routeCode>
      ......
      <!--For repeated route of exposure, use multiple sourceOf2 -->
      <sourceOf2 typeCode="SEQL" contextConductionInd="true">
         <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="1.2.3.4" extension="1"/>
            ……
            <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
               <translation codeSystem="2.16.840.1.113883.4.345" code="18" displayName="In Feed"/>
            </routeCode>
            ……
         </substanceAdministration>
      </sourceOf2>
      ……
   </substanceAdministration>
</subjectOf2>
```

2.6.1.7.1 Dose per Administration – GL-42 Section B.2.1.7.1

FDA Requirement Number(s):
Dose per Administration: 19.1, 621.7

Information: This data element collects the actual dose administered, not the indicated labeled dose. If the actual dose is unknown, use the code = "C10612", displayName = "Unknown".

***GL-42 Section*:** B.2.1.7.1, B.2.1.7.1.1, B.2.1.7.1.1.1

***ICSR Location*:** This information is captured right next to "Route of Exposure".

XML Details: The "Dose per Administration (doseQuantity)" element consists of two parts; the "Dosage Amount (Dose Value); and the "Dosage Units of Measurement (Dose Unit)" code and

value. The "Dosage Units of Measurement", code and value, are extracted from one of two source vocabularies. Source one is found in ***Appendix A.24–List of Units of Measurements*** using codeSystem OID = "2.16.840.1.113883.6.8", source two can be found in vocabulary ***Appendix A.25–List of Units of Presentation*** using codeSystem OID = 2.16.840.1.113883.3.26.1.1. Depending on what vocabulary was used to report the "Dose Unit" the matching codeSystem OID must be also reported.

The XPath to get "Dose per Administration" in the ICSR message is:

For "Dose Value":

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/doseQuantity/@value

The XPath to get the "Dose Unit" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/doseQuantity/translation/@code

The XPath to get the "Repeated Exposure" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/substanceAdministration/doseQuantity/@value

A sample XML snippet for "Dose per Administration" that references the (***Appendix A.25–List of Units of Presentation*** codeSystem OID = National Cancer Institute Thesaurus) is shown first then a sample XML snippet for "Dose per Administration" that references the (***Appendix A.24–List of Units of Measurements*** (codeSystem OID = "2.16.840.1.113883.6.8") is shown next.

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
         <translation codeSystem="2.16.840.1.113883.4.345" code="18" displayName="In Feed"/>
      </routeCode>
      <doseQuantity value="2">
          <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C48542" displayName="Tablet"/>
       </doseQuantity>
      ......
      <!--For repeated route of exposure, use multiple sourceOf2 -->
       <sourceOf2 typeCode="SEQL" contextConductionInd="true">
         <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="1.2.3.4" extension="1"/>
            ……
            <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
               <translation codeSystem="2.16.840.1.113883.4.345" code="18" displayName="In Feed"/>
            </routeCode>
           <doseQuantity value="10">
```

```
            <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="Milliliter"/>
          </doseQuantity>
          ……
        </substanceAdministration>
      </sourceOf2>
      ……
    </substanceAdministration>
</subjectOf2>
```

2.6.1.7.2 Interval of Administration – GL-42 Section B.2.1.7.1.2

FDA Requirement Number(s):
Interval of Administration: 20.2, 20.3
Date of First Exposure: 5001
Date of Last Exposure: 5002

Information: This is the frequency of administration of the VMP(s) involved in the AE. For example, a tablet given "once per day" from August 1, 2006 to February 10, 2007

***GL-42 Section*:** B.2.1.7.1.2, including B.2.1.7.1.2.1, B.2.1.7.1.2.1.1, B.2.1.7.1.2.2, B.2.1.7.1.2.3

***ICSR Location*:** They are located next to "Route of Exposure" and "Dose per Administration"

XML Details: "Interval of Administration" is captured using an <effectiveTime> node, use the <low> element for "Date of First Exposure", and the <high> element for "Date of Last Exposure". The <period> element is used for the "Interval of Administration". Repeated exposures are handled the same way as "Route of Administration", using multiple <sourceOf2> nodes.

The XPath's to locate the "Interval of Administration" value and unit in the ICSR message are:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/period/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/period/@unit

The XPath's to locate the "Date of First Exposure" and the "Date of Last Exposure" in the ICSR message are:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/low/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/effectiveTime/comp/high/@value

For “Interval of Administration”, the units of measurements are shown in ***Appendix A.13-List of Time Units***.

A sample XML snippet for “Interval of Administration”, “Date of First Exposure” and “Date of Last Exposure” in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      <effectiveTime xsi:type="SXPR_TS">
            <comp xsi:type="IVL_TS">
               <low value="20060601"/>
               <high value="20060602"/>
            </comp>
            <comp xsi:type="PIVL_TS" operator="A">
               <period value="8" unit="h"/>
            </comp>
      </effectiveTime>
      <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
         <translation codeSystem="2.16.840.1.113883.4.345" code="18" displayName="In Feed"/>
      </routeCode>
      ......
      <!--For repeated route of exposure, use multiple sourceOf2 -->
      <sourceOf2 typeCode="SEQL" contextConductionInd="true">
         <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="1.2.3.4" extension="1"/>
            <effectiveTime xsi:type="SXPR_TS">
               <comp xsi:type="IVL_TS">
                  <low value="20060602"/>
                  <high value="20060603"/>
               </comp>
               <comp xsi:type="PIVL_TS" operator="A">
                  <period value="1" unit="d"/>
               </comp>
            </effectiveTime>
            <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
               <translation codeSystem="2.16.840.1.113883.4.345" code="18" displayName="In Feed"/>
            </routeCode>
            ……
         </substanceAdministration>
      </sourceOf2>
      ……
   </substanceAdministration>
</subjectOf2>
```

2.6.1.8 Dosage Form – GL-42 Section B.2.2.2

FDA Requirement Number(s):

Dosage Form: 2036

Information: Dosage Forms of the VMP(s) that is involved in the AER.

***GL-42 Section*:** B.2.2.2

***ICSR Location*:** This information is captured in ICSR message next to "Brand Name", in element <formCode> of <kindOfProduct> within <consumable> element.

XML Details: Use codeSystem National Cancer Institute Thesaurus, and the code and value for the dosage form as shown in ***Appendix A.33–List of Dosage Forms***. Note that a <translation> element must be used to capture the corresponding VICH dosage form code and the OID to code this element is *VICH – Dosage Form OID*.

The XPath to get the "Dosage Form" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/formCode/@code
```

A sample XML snippet for "Dosage Form" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            ......
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
               ......
               <name xsi:type="TN">DEXABRAND</name>
               <formCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C42998" displayName="TABLET">
                  <translation codeSystem="2.16.840.1.113883.4.343" code="C42998" displayName="tablet"/>
               </formCode>
               ......
            </kindOfProduct>
            ......
         </instanceOfKind2>
      </consumable>
      ......
   </substanceAdministration>
</subjectOf2>
```

The following section is a complete example that demonstrates VMP usages that involve two drugs; each drug has multiple values in "Route of Administration", "Dosage Levels", multiple "Intervals of Administration", and "Date of First Exposure" and "Date of Last Exposure".

Example: A data mapping of multiple drugs involved in the AER into the HL7 message. The examples of drug usages are illustrated below:

Drug#1: CP-200 (ATCvet Code: CHLORPEN; Dosage Form: TABLET, EXTENDED RELEASE)

Route	Dosage	Interval of Admin	Date of Exposures
Oral	5 KG	12 Hours	05/30/2006-06/05/2006
Oral	5 KG	1 Day	06/06/2006-06/15/2006

Table 2-3 Dosage Form Example -- Sample Drug 1

Drug#2: DEXABRAND (ATCvet Code: DEXSOL; Dosage Form: SOLUTION)

Route	Dosage	Interval of Admin	Date of Exposures
Oral	10 ml	8 Hours	06/01/2006-06/01/2006
Oral	30 ml	1 Day	06/02/2006-06/02/2006
Oral	30 ml	18 Hours	06/03/2006-06/05/2006
Intramuscular	5 ml	1 Day	06/06/2006-06/10/2006

Table 2-4 Dosage Form Example -- Sample Drug 2

A sample XML snippet for the drug usage examples shown above:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
  <subject typeCode="SBJ">
    <primaryRole classCode="SBJ">
      ......
      <!-- First Drug -->
      <subjectOf2 typeCode="SBJ">
        <substanceAdministration classCode="SBADM" moodCode="EVN">
          <id root="1.2.3.4" extension="1"/>
          <effectiveTime xsi:type="SXPR_TS">
            <comp xsi:type="IVL_TS">
              <low value="20060605"/>
              <high value="20060605"/>
            </comp>
            <comp xsi:type="PIVL_TS">
              <period value="12" unit="h"/>
            </comp>
          </effectiveTime>
          <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288"
                                                    displayName="Oral">
            <translation codeSystem="2.16.840.1.113883.4.345" code="18"
                                                    displayName="in feed"/>
          </routeCode>
          <doseQuantity value="5">
            <translation codeSystem="2.16.840.1.113883.6.8" code="kg" displayName="Kilogram"/>
          </doseQuantity>
          <consumable typeCode="CSM">
            <instanceOfKind2 classCode="INST">
              ......
              <kindOfProduct classCode="MMAT" determinerCode="KIND">
                <code codeSystem="2.16.840.1.113883.6.69" code="01234-*444"/>
                <name xsi:type="TN">CP-200</name>
                <formCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C42947"
                                                displayName="TABLET, EXTENDED RELEASE">
                  <translation codeSystem="2.16.840.1.113883.4.343" code="312"
                                                displayName="PROLONGED-RELEASE TABLET">
                </formCode>
                <asManufacturedProduct classCode="MANU">
                  <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
                    <name>The Company Name</name>
                  </manufacturerOrganization>
```

```
                <subjectOf typeCode="SBJ">
                  <approval classCode="CNTRCT" moodCode="EVN">
                    ……
                  </approval>
                </subjectOf>
              </asManufacturedProduct>
              <asSpecializedKind classCode="GEN">
                <generalizedMaterialKind classCode="MMAT" determinerCode="KIND">
                  <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95013"
                                                displayName="ATCvet Code"/>
                  <name xsi:type="TN">CHLORPEN</name>
                </generalizedMaterialKind>
              </asSpecializedKind>
              ......
            </kindOfProduct>
            ......
          </instanceOfKind2>
        </consumable>

        <sourceOf2 typeCode="SEQL" contextConductionInd="true">
          <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="1.2.3.4" extension="1"/>
            <effectiveTime xsi:type="SXPR_TS">
              <comp xsi:type="IVL_TS">
                <low value="20060606"/>
                <high value="20060615"/>
              </comp>
              <comp xsi:type="PIVL_TS">
                <period value="1" unit="d"/>
              </comp>
            </effectiveTime>
            <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288"
                                                displayName="Oral">
                  <translation codeSystem="2.16.840.1.113883.4.345" code="18"
                                                displayName="in feed"/>
            </routeCode>
            <doseQuantity value="5">
              <translation codeSystem="2.16.840.1.113883.6.8" code="kg" displayName="Kilogram"/>
            </doseQuantity>
          </substanceAdministration>
        </sourceOf2>
        ......
      </substanceAdministration>
    </subjectOf2>

    <!-- Second Drug -->
    <subjectOf2 typeCode="SBJ">
      <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="1.2.3.4" extension="2"/>
        <effectiveTime xsi:type="SXPR_TS">
          <comp xsi:type="IVL_TS">
            <low value="20060601"/>
            <high value="20060601"/>
          </comp>
          <comp xsi:type="PIVL_TS">
            <period value="8" unit="h"/>
```

```
    </comp>
</effectiveTime>
<routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
    <translation codeSystem="2.16.840.1.113883.4.345" code="18"  displayName="in feed"/>
</routeCode>
<doseQuantity value="10">
    <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="Milliliter"/>
</doseQuantity>
<consumable typeCode="CSM">
    <instanceOfKind2 classCode="INST">
        .....
        <kindOfProduct classCode="MMAT" determinerCode="KIND">
            <code codeSystem="2.16.840.1.113883.3.156" code="01234-*555"/>
            <name xsi:type="TN">DEXABRAND</name>
            <formCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C42986"
                                                displayName="SOLUTION">
                <translation codeSystem="2.16.840.1.113883.4.343" code="232"
                                                displayName="ORAL SOLUTION"/>
            </formCode>
            <asManufacturedProduct classCode="MANU">
                <manufacturerOrganization classCode="ORG" determinerCode="INSTANCE">
                    <name>The Company Name</name>
                </manufacturerOrganization>
                <subjectOf typeCode="SBJ">
                    <approval classCode="CNTRCT" moodCode="EVN">
                        ……
                    </approval>
                </subjectOf>
            </asManufacturedProduct>
            <asSpecializedKind classCode="GEN">
                <generalizedMaterialKind classCode="MMAT" determinerCode="KIND">
                    <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95013"
                                                displayName="ATCvet Code"/>
                <name xsi:type="TN">DEXSOL</name>
                </generalizedMaterialKind>
            </asSpecializedKind>
            ......
        </kindOfProduct>
        ......
    </instanceOfKind2>
</consumable>

<sourceOf2 typeCode="SEQL" contextConductionInd="true">
    <substanceAdministration classCode="SBADM" moodCode="EVN">
        <id root="1.2.3.4" extension="2"/>
        <effectiveTime xsi:type="SXPR_TS">
            <comp xsi:type="IVL_TS">
                <low value="20060602"/>
                <high value="20060602"/>
            </comp>
            <comp xsi:type="PIVL_TS">
                <period value="1" unit="d"/>
            </comp>
        </effectiveTime>
        <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
                    <translation codeSystem="2.16.840.1.113883.4.345" code="18"
```

```
                                                displayName="in feed"/>
            </routeCode>

            <doseQuantity value="30">
               <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="Milliliter"/>
            </doseQuantity>
         </substanceAdministration>
      </sourceOf2>

      <sourceOf2 typeCode="SEQL" contextConductionInd="true">
         <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="1.2.3.4" extension="2"/>
            <effectiveTime xsi:type="SXPR_TS">
               <comp xsi:type="IVL_TS">
                  <low value="20060603"/>
                  <high value="20060605"/>
               </comp>
               <comp xsi:type="PIVL_TS">
                  <period value="18" unit="h"/>
               </comp>
            </effectiveTime>
            <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C38288" displayName="Oral">
                     <translation codeSystem="2.16.840.1.113883.4.345" code="18"
                                                displayName="in feed"/>
            </routeCode>
            <doseQuantity value="30">
               <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="Milliliter"/>
            </doseQuantity>
         </substanceAdministration>
      </sourceOf2>

      <sourceOf2 typeCode="SEQL" contextConductionInd="true">
         <substanceAdministration classCode="SBADM" moodCode="EVN">
            <id root="1.2.3.4" extension="2"/>
            <effectiveTime xsi:type="SXPR_TS">
               <comp xsi:type="IVL_TS">
                  <low value="20060606"/>
                  <high value="20060610"/>
               </comp>
               <comp xsi:type="PIVL_TS">
                  <period value="1" unit="d"/>
               </comp>
            </effectiveTime>
            <routeCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C28161"
                                                displayName="INTRAMUSCULAR">
               <translation codeSystem="2.16.840.1.113883.4.345" code="41"
                                                displayName="INTRAMUSCULAR"/>
            </routeCode>
            <doseQuantity value="5">
               <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="Milliliter"/>
            </doseQuantity>
         </substanceAdministration>
      </sourceOf2>
      .....
   </substanceAdministration>
</subjectOf2>
```

```
        .....
      </primaryRole>
    </subject>
</adverseEventAssessment>
```

2.6.2 Active Ingredient(s) – GL-42 Section B.2.2

This section captures the active ingredients, the strength of the active ingredient and the dosage form of the reported VMP.

2.6.2.1 Active Ingredient(s) – GL-42 Section B.2.2.1

FDA Requirement Number(s):
Active Ingredients: 2032
Strength Numerator: 2033
Strength Units Numerator: 2034, 2035
Strength Denominator: 2033.1
Strength Units Denominator: 2034.1

Information: Mandatory for MAH product(s). For all other non-MAH products, this is optional.

***GL-42 Section*:** B.2.2.1, including B.2.2.1.2, B.2.2.1.1, B.2.2.1.1.1

***ICSR Location*:** This information is captured in ICSR message next to "Brand Name", in element <ingredient> inside <kindOfProduct> within a <consumable> node.

XML Details: If more than one active ingredient needs to be included, use a list of <ingredient> elements. Ingredient strength is reported as a ratio of the two quantities. Both the numerator and denominator information needs to be included. Use *Appendix A24 – Units of Measurements* for numerator and denominator code and term values. The data element "Active Ingredients" code is selected from ***Appendix A.38–Substance Registration System Active Ingredient Codes*** using a codeSystem OID of "2.16.840.1.113883.4.9".

The XPath to get the "Active Ingredients Name" is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/ingredient/ingredient/name
```

The XPath to get the "Strength" (value and unit), the numerator part in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/ingredient/quantity/numerator/@value
```

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
kindOfProduct/ingredient/quantity/numerator/translation/@code
```

Substitute “numerator” with “denominator” in the above XPath’s for the denominator part of the “Strength” data.

The XPath to get the “Active Ingredients” code in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/kindOfProduct/ingredient/ingredient/code/@code

A sample XML snippet for “Active Ingredients” in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      .....
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            .....
            <kindOfProduct classCode="MMAT" determinerCode="KIND">
               .....
               <ingredient classCode="INGR">
                  <quantity>
                     <numerator xsi:type="PQ" value="5">
                        <translation codeSystem="2.16.840.1.113883.6.8" code="mL" displayName="milliliter"/>
                     </numerator>
                     <denominator xsi:type="PQ" value="1">
                        <translation codeSystem="2.16.840.1.113883.6.8" code="L" displayName="Liter"/>
                     </denominator>
                  </quantity>
                  <ingredient determinerCode="KIND" classCode="MMAT">
                     <code codeSystem="2.16.840.1.113883.4.9" code="7S5I7G3JQL"
                                                codeSystemVersion="UNIIS For 12December2009 Release"/>
                     <name xsi:type="TN">DEXAMETHASONE</name>
                  </ingredient>
               </ingredient>
               .....
            </kindOfProduct>
            .....
         </instanceOfKind2>
      </consumable>
      .....
   </substanceAdministration>
</subjectOf2>
```

2.6.3 Lot Number – GL-42 Section B.2.3

For information relating to the Lot Number data element see Section 3.2.6.

2.6.4 Who Administered the VMP (Administered or Performed by) – GL-42 Section B.2.4

FDA Requirement Number(s):
Administered or Performed By: 2020

Information: Optional. The Category of the person who administered the VMP involved in the AE. An agent acting for the owner will be entered as the owner.

***GL-42 Section*:** B.2.4

***ICSR Location*:** Captured using a <performer> element, inside a substance administration class.

XML Details: Use ***Appendix A.19–List of Administrators of VMP(s)*** for the code vocabulary.

The XPath to get the "Who Administered the VMP" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/performer/assignedEntity/cod
e/@code
```

A sample XML snippet for "Who Administered the VMP" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <performer typeCode="PRF">
         <assignedEntity classCode="ASSIGNED">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C42704" displayName="ANIMAL OWNER"/>
         </assignedEntity>
      </performer>
      ......
   </substanceAdministration>
</subjectOf2>
```

2.6.5 Use According to Label – GL-42 Section B.2.5

FDA Requirement Number(s):
Use According to Label: 2022
Explanation for Off Label Use: 2023

Information: Information on whether the VMP was used according to its label recommendations. If off-label use was employed then provide an explanation.

***GL-42 Section*:** B.2.5 and B.2.5.1

***ICSR Location*:** Next to the data element for "Who Administered the VMP", but captured using an observation class inside of <sourceOf2> elements where the reporter can provide additional related information.

XML Details: Two <sourceOf2> nodes should be used for label use information. One node is used to capture if the VMP was used according to the label, and the other node is used to capture the explanation if it was indeed off label use – i.e. if "False (no)" is chosen for "Use According to Label" see ***Appendix A.31 – Boolean Information Table*** then the reporter must provide an explanation by selecting the appropriate VICH label use code. The values for explanation of VICH label use are shown in ***Appendix A.30-List of Explanation for Off-Label Use – Coding System Table***. Note that this is an integer value.

The XPath to get "Use According To Label" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/observation[code/@code="T95015"]/value/@value

The XPath to get "Explanation for Label Use" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/observation[code/@code="T95016"]/value

A sample XML snippet for" Use According to Label" and "VICH Label Use" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <sourceOf2 typeCode="PERT" contextConductionInd="true">
         <observation classCode="OBS" moodCode="EVN">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95015"
                                                        displayName="Use According to Label"/>
            <value xsi:type="BL" value="false"/>
         </observation>
      </sourceOf2>
      <sourceOf2 typeCode="PERT" contextConductionInd="true">
         <observation classCode="OBS" moodCode="EVN">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95016"
                                                        displayName="VICH Label Use"/>
            <value xsi:type="CE" codeSystem="2.16.840.1.113883.13.41" code="1"
                                              codeSystemVersion="VICHLabelUseVersion1" />
         </observation>
      </sourceOf2>
      ......
   </substanceAdministration>
</subjectOf2>
```

2.6.6 Manufacturing/Product Defect Information – GL-42 Section B.2.6

Lot Number – Section B.2.3
FDA Requirement Number(s):
Lot Number: 2037
Expiration Date: 2038
Manufacturing Date: 1701

Information: This section includes information about the Lot Number, Expiration Date, and Manufacturing Date of the reported VMP

***GL-42 Section*:** B.2.3, B.2.3.1, B.2.6.2

***ICSR Location*:** Inside a particular product instance of a product, next to B.2.6.1 Manufacturing Site Identifier Number.

XML Details: These data elements are captured inside the <instanceOfKind2> element of the <consumable> element that represents the drug product. Reporters should use the <low> element of <existenceTime> for a product instance to capture the "Manufacturing Date". "Expiration Date" is captured in <expirationTime>. Currently "Lot Number" is captured within the text element <lotNumberText>.

The XPath to get the "Lot Number" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
productInstanceInstance/lotNumberText
```

The XPath to get the "Expiration Date" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
productInstanceInstance/expirationTime/@value
```

The XPath to get the "Manufacturing Date" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
productInstanceInstance/existenceTime/low/@value
```

A sample XML snippet for "Lot Number", "Expiration Date" and "Manufacturing Date" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      .....
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
```

```
            <id extension="1"/>
            <existenceTime xsi:type="IVL_TS">
               <low value="20051208"/>
            </existenceTime>
            <lotNumberText mediaType="text/plain">GAP3487 FOR USA-123479</lotNumberText>
            <expirationTime value="20060405"/>
         </productInstanceInstance>
         ......
      </instanceOfKind2>
   </consumable>
   ......
</substanceAdministration>
</subjectOf2>
```

For multiple lots of one drug product, use multiple <member> elements of <productInstanceInstance> element, one for each lot. Following is an example of two lots for one drug product.

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
               <id extension="1"/>
               <existenceTime xsi:type="IVL_TS">
                  <low value="20051208"/>
               </existenceTime>
               <lotNumberText mediaType="text/plain">GAP3487 FOR USA-123479</lotNumberText>
               <expirationTime value="20060405"/>

               <member classCode="MBR">
                  <memberProductInstance classCode="MMAT" determinerCode="INSTANCE">
                     <id extension="2"/>
                     <existenceTime xsi:type="IVL_TS">
                        <low value="20051218"/>
                     </existenceTime>
                     <lotNumberText mediaType="text/plain">GAP3488 FOR USA-123479</lotNumberText>
                     <expirationTime value="20060415"/>
                  </memberProductInstance>
               </member>

            </productInstanceInstance>
            ......
         </instanceOfKind2>
      </consumable>
      ......
   </substanceAdministration>
</subjectOf2>
```

This section is only to be used when reporting manufacturing and/or product defect reports.

The sub-sections within this section are:

- B.2.6.1 Manufacturing Site Identifier Number
- B.2.6.1.1 Manufacturer's Identifier Type
- B.2.6.2 Manufacturing Date
- B.2.6.3 Number of Defective Units
- B.2.6.4 Number of Units Returned
- B.2.6.5 ORA District Field Office Reported

2.6.6.1 Manufacturer's Site Identifier Number – GL-42 Section B.2.6.1

FDA Requirement Number(s):
Manufacturing Site Identifier Number: 1700

Information: This section of data elements captures the Manufacturing site identification information. This identifier can either be a 7 to 10 digit "FDA Establishment Identifier"(FEI Number) or the nine digit "D-U-N-S® Number" (Dun and Bradstreet).

2.6.6.1.1 Manufacturer's Identifier Type – GL-42 Section B.2.6.1.1

FDA Requirement Number(s):
Manufacturer's Identifier Type: 1700.1

Information: The "Manufacturer's Site Identifier Type" element is used to declare the type of "Manufacturing Site Identifier Number" being reported.

***GL-42 Section*:** B.2.6.1 and B.2.6.1.1

***ICSR Location*:** Located in the product instance of a product in <instanceOfKind2> element, captured inside its child <productEvent> element.

XML Details: Note that "FEI/D-U-N-S Number" and "Manufacturer's Identifier Type" are both tied to a "Lot Number", not the product itself. "Manufacturer's Site Identifier Type" will be determined by the codeSystem OID.

The code and value for the "Manufacturer's Site Identifier" are shown in ***Appendix A.18–List of Manufacturer Site Identifiers***.

The XPath to get the "FEI" or "D-U-N-S" number in the ICSR message is:
Note: The value here could either be an FEI or DUNS number; it depends on the "Manufacturer's Identifier Type"

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/subjectOf/productEvent/performer/assignedEntity/assignedOrganization/id/@extension

The XPath to get the "Manufacturer's Identifier Type" in the ICSR message is:
Note: If the attribute code value used here is a "FDA FEI OID", use 2.16.840.1.113883.4.82 as the OID or if it is a DUNS identifer use 1.3.6.1.4.1.519.1.

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/subjectOf/productEvent/performer/assignedEntity/assignedOrganization/id/@root

A sample XML snippet for "Manufacturing Site Identifier Number" and "Manufacturer's Identifier Type" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      .....
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            .....
            <subjectOf typeCode="SBJ">
               <productEvent classCode="ACT" moodCode="EVN">
                  <performer typeCode="PRF">
                     <assignedEntity classCode="ASSIGNED">
                        <assignedOrganization classCode="ORG" determinerCode="INSTANCE">
                                          <id root="2.16.840.1.113883.4.82" extension="F123454"/>
                        </assignedOrganization>
                     </assignedEntity>
                  </performer>
               </productEvent>
            </subjectOf>
            .....
         </instanceOfKind2>
      </consumable>
      .....
   </substanceAdministration>
</subjectOf2>
```

2.6.6.2 Manufacturing Date – Section B.2.6.2 & Expiration Date – Section B.2.3.1

See Section 3.2.6 for usage of Manufacturing Date and Expiration Date

Information: Indicates the manufacturing date of the product involved in the product quality issue. For Product Problem and AE plus Product Problem reports only

2.6.6.3 Number of Defective Units – Section B.2.6.3

Number of Defective Units: 1702

Information: Indicates the number of defective units involved in the product quality issue. For Product Problem and AE plus Product Problem reports only

2.6.6.4 Number of Units Returned – Section B.2.6.4

FDA Requirement Number(s):

Number of Units Returned: 1703

Information: Indicates the number and types of units returned for the product quality issue. For Product Problem and AE plus Product Problem reports only

***GL-42 Section*:** B.2.6.3, B.2.6.4

***ICSR Location*:** Each data element is captured inside a manufactured product observation of a product instance.

XML Details: HL7 data type PQ is used for these data elements. Use an integer for the value, and use <translation> child element to capture the unit. To differentiate between these two observations items, use the proper vocabulary for the code. Use ***Appendix A.29–List of Package Types*** to code the type of "Number of Defective Units" and the "Number of Defective Units Returned".
Note: that the both "Number of Defective Units" and "Number of Units Returned" are tied to a "Lot Number", not the product itself.

The XPath to get the "Number of Defective Units" and the "Package Type" in the ICSR message are shown below. Note that because this number is linked to a specific "Lot Number" of a product, a pre-determined "Lot Number" needs to be used in the predicate:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/subjectOf/observationEvent[code/@code="T95017"]/value/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/subjectOf/observationEvent[code/@code=" T95017"]/value/translation/@code

The XPath to get the "Number of Units Returned" and the "Package Type" of the units returned is similar; the only difference is that the code value used in the predicate is for the "Number of Units Returned":

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/subjectOf/observationEvent[code/@code=" T95018"]/value/@value

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/subjectOf/observationEvent[code/@code=" T95018"]/value/translation/@code

A sample XML snippet for "Number of Defective Units" and "Number of Units Returned" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            ......
            <subjectOf typeCode="SBJ">
               <observationEvent classCode="OBS" moodCode="EVN">
                  <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95017"
                                                                  displayName="Number of Defective Units"/>
```

```
                <value xsi:type="PQ" value="2">
                  <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C43178" displayName="Box"/>
                </value>
              </observationEvent>
            </subjectOf>
            <subjectOf typeCode="SBJ">
              <observationEvent classCode="OBS" moodCode="EVN">
                <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95018"
                                                              displayName="Number of Units Returned"/>
                <value xsi:type="PQ" value="1">
                  <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C43178" displayName="Box"/>
                </value>
              </observationEvent>
            </subjectOf>
            ......
          </instanceOfKind2>
      </consumable>
      ......
   </substanceAdministration>
</subjectOf2>
```

The following example accumulates all of the previous discussion of “Lot Number” into one example. In this example, what is documented demonstrates how to capture these data elements for a product that has three lots. Note that “Manufacturer FEI” is for the manufacturing site, not for the MAH who owns the product.

Sample data information used in the example:

FEI/DUNS #	Lot #	Expiration Date	Manufacturing Date	# of Defective Units	# of Units returned
DUNS-123	LOT-1234	03/01/2008	02/01/2008	10	5
DUNS-123	LOT-2345	04/01/2008	03/02/2008	9	4
FEI-456	LOT-6789	05/01/2008	04/03/2008	8	3

Table 2-5 Product Problem -- Sample Lot Number

An XML snippet for the example data above:

```
<consumable typeCode="CSM">
   <instanceOfKind2 classCode="INST">
      <productInstanceInstance classCode="MMAT" determinerCode="INSTANCE">
         <id extension="1"/>
         <existenceTime xsi:type="IVL_TS">
            <low value="20080201"/>
         </existenceTime>
         <lotNumberText mediaType="text/plain">LOT-1234</lotNumberText>
         <expirationTime value="20080301"/>

         <!-- multiple lot# -->
         <member classCode="MBR">
            <memberProductInstance classCode="MMAT" determinerCode="INSTANCE">
               <id extension="2"/>
```

```
      <existenceTime xsi:type="IVL_TS">
        <low value="20080302"/>
      </existenceTime>
      <lotNumberText mediaType="text/plain">LOT-2345</lotNumberText>
      <expirationTime value="20080401"/>
    </memberProductInstance>
    <subjectOf typeCode="SBJ">
      <productEvent classCode="ACT" moodCode="EVN">
        <performer typeCode="PRF">
          <assignedEntity classCode="ASSIGNED">
            <assignedOrganization classCode="ORG" determinerCode="INSTANCE">
              <id root="1.3.6.1.4.1.519.1" extension="DUNS-123"/>
            </assignedOrganization>
          </assignedEntity>
        </performer>
      </productEvent>
    </subjectOf>
    <subjectOf typeCode="SBJ">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95017"
                                                    displayName="Number of Defective Units"/>
        <value xsi:type="PQ" value="9">
          <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C43178" displayName="Box"/>
        </value>
      </observationEvent>
    </subjectOf>
    <subjectOf typeCode="SBJ">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95018"
                                                    displayName="Number of Units Returned"/>
        <value xsi:type="PQ" value="4">
          <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C43178" displayName="Box"/>
        </value>
      </observationEvent>
    </subjectOf>
  </member>

  <member classCode="MBR">
    <memberProductInstance classCode="MMAT" determinerCode="INSTANCE">
      <id extension="3"/>
      <existenceTime xsi:type="IVL_TS">
        <low value="20080403"/>
      </existenceTime>
      <lotNumberText mediaType="text/plain">LOT-6789</lotNumberText>
      <expirationTime value="20080501"/>
    </memberProductInstance>
    <subjectOf typeCode="SBJ">
      <productEvent classCode="ACT" moodCode="EVN">
        <performer typeCode="PRF">
          <assignedEntity classCode="ASSIGNED">
            <assignedOrganization classCode="ORG" determinerCode="INSTANCE">
              <id root="2.16.840.1.113883.4.82" extension="FEI-456"/>
            </assignedOrganization>
          </assignedEntity>
        </performer>
      </productEvent>
```

```
        </subjectOf>
        <subjectOf typeCode="SBJ">
          <observationEvent classCode="OBS" moodCode="EVN">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95017"
                                                displayName="Number of Defective Units"/>
            <value xsi:type="INT" value="8"/>
          </observationEvent>
        </subjectOf>
        <subjectOf typeCode="SBJ">
          <observationEvent classCode="OBS" moodCode="EVN">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95018"
                                                displayName="Number of Units Returned"/>
            <value xsi:type="INT" value="3"/>
          </observationEvent>
        </subjectOf>
      </member>
      <!-- end of multiple lot# -->

    </productInstanceInstance>

    <kindOfProduct classCode="MMAT" determinerCode="KIND">
      <code codeSystem="2.16.840.1.113883.6.69" code="01234-*555"/>
      <name xsi:type="TN">DEXABRAND</name>
      <formCode codeSystem="2.16.840.1.113883.3.26.1.1" code="C42986" displayName="Solution">
        <translation codeSystem="2.16.840.1.113883.4.343" code="59" displayName="dip solution"/>
      </formCode>
      ……
    </kindOfProduct>

    <subjectOf typeCode="SBJ">
      <productEvent classCode="ACT" moodCode="EVN">
        <performer typeCode="PRF">
          <assignedEntity classCode="ASSIGNED">
            <assignedOrganization classCode="ORG" determinerCode="INSTANCE">
              <id root="1.3.6.1.4.1.519.1" extension="DUNS-123"/>
            </assignedOrganization>
          </assignedEntity>
        </performer>
      </productEvent>
    </subjectOf>
    <subjectOf typeCode="SBJ">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95017"
                                                displayName="Number of Defective Units"/>
        <value xsi:type="PQ" value="10">
              <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C43178" displayName="Box"/>
        </value>
      </observationEvent>
    </subjectOf>
    <subjectOf typeCode="SBJ">
      <observationEvent classCode="OBS" moodCode="EVN">
        <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95018"
                                                displayName="Number of Units Returned"/>
        <value xsi:type="PQ" value="5">
              <translation codeSystem="2.16.840.1.113883.3.26.1.1" code="C43178" displayName="Box"/>
        </value>
```

```
        </observationEvent>
      </subjectOf>
   </instanceOfKind2>
</consumable>
```

2.6.6.5 ORA District Field Office Reported – GL-42 Section B.2.6.5

FDA Requirement Number(s):
ORA District Field Office Reported: N37

Information: This data element contains information about the "FDA ORA District Field Office" that the Product Quality report was filed with. This data element is required for "Product Problem Reports" only.

***GL-42 Section*:** B.2.6.5

ICSR Location: This data element is located in the ICSR message payload, using an observation event class of <consumable> element to capture the data.

XML Details:
For "ORA District Field Office Reported", the reporter should use the coded value shown in ***Appendix A.28–List of ORA District Field Offices*** and the System OID is FDA Regulatory Compliance Service.

The XPath to get "ORA District Field Office Reported" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/consumable/instanceOfKind2/
subjectOf/observationEvent[code/@code="T95019"]/value/@code
```

A sample XML snippet for "ORA District Field Office Reported" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <consumable typeCode="CSM">
         <instanceOfKind2 classCode="INST">
            ......
            <subjectOf typeCode="SBJ">
               <observationEvent classCode="OBS" moodCode="EVN">
                  <code codeSystem="2.16.840.1.113883.3.26.1.1" code= "T95019"
                                                displayName="ORA District Field Office Reported"/>
                  <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.153" code="ATL-DO"
                                                displayName="Atlanta District"/>
               </observationEvent>
            </subjectOf>
            ......
         </instanceOfKind2>
      </consumable>
      ......
```

```
  </substanceAdministration>
</subjectOf2>
```

2.7 Adverse Event Data – GL-42 Section B.3

This section contains information about the adverse event being reported.

2.7.1 Narrative of AE/PP – GL-42 Section B.3.1

FDA Requirement Number(s):
AE/PP as Reported (Narrative of AE/PP): 14

Information: Free Text. This data element captures the narrative description of the sequence of the adverse event and (or) product problem. The user is also required to provide a brief description of all "Supplemental Documents" that are covered in Section B.6.

***GL-42 Section*:** B.3.1

***ICSR Location*:** It is captured inside the <text> element of the investigative event.

XML Details: Required.

The XPath to get "Narrative of AE/PP" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/text
```

A sample XML snippet for "Narrative of AE/PP" in an ICSR message is:

```
<investigationEvent moodCode="EVN" classCode="INVSTG">
   ……
   <text mediaType="text/plain">
         The sows and gilts were given the two medications. Two days after receiving the
         chloratetracycline penicillin combination in the feed the sows and gilts started going
         off feed. A closer inspection of GAP7777 FOR USA-124578 indicated some kind
         of foreign contaminant in the Type A medicated article bag.
         SUPPLEMENTAL:document number one was supplied by attending vet.
         Document number two was supplied by ABC Labs, Inc. at the request of the attending vet.
   </text>
   ……
</investigationEvent>
```

2.7.2 Adverse Clinical Manifestations (AER Term Name) – GL-42 Section B.3.2

FDA Requirement Number(s):
Adverse Event Reaction Term Name (Adverse Clinical Manifestations): 92
Number of Affected Animals Per Clinical Manifestation: ??

Information: Mandatory. Adverse clinical manifestations observed in the AE.

***GL-42 Section*:** B.3.2

***ICSR Location*:** It is captured in the reaction that triggers the investigation event.

XML Details: The VeDDRA medical terminology code shall be used for this data element. The list as well as the full explanation and the Guidance Notes on the "Use of VeDDRA Terminology" for "Reporting Adverse Events in Animals" can be located at the EMEA Website: http://www.emea.europa.eu/home.htm. The "code" and the associated "displayName" will be the lowest level key value (LLT Key) entry. The reporter is also required to indicate the version of the VeDDRA table used by storing the version number in the "codeSystemVersion" element attribute.

The XPath to get "Adverse Clinical Manifestations" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95020"]/value/@code
```

The number of animals affected is mapped using a reference observation inside clinical manifestation observation. The XPath to get "Number of Animals Affected per Adverse Clinical Manifestations" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95020"]/referenceRange/observationRange/va
lue/@value
```

A sample XML snippet for "Adverse Clinical Manifestations" in an ICSR message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
   <subject typeCode="SBJ">
      <primaryRole classCode="SBJ">
         .....
         <subjectOf2 typeCode="SBJ">
            <observation classCode="OBS" moodCode="EVN">
               <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95020" displayName="Reaction"/>
               ……
               <value xsi:type="CE" codeSystem="2.16.840.1.113883.13.40"
                           codeSystemVersion="AdoptionByCVMP11February2009" code="984"
                                 displayName="Death"/>
               <referenceRange>
                  <observationRange classCode="OBS" moodCode="EVN.CRT">
                     <value xsi:type="INT" value="10" />
                     <interpretationCode/>
                  </observationRange>
               </referenceRange>
            </observation>
         </subjectOf2>
         .....
      </primaryRole>
   </subject>
</adverseEventAssessment>
```

2.7.3 Date of Onset of AE (AE Start Date) – GL-42 Section B.3.3

FDA Requirement Number(s):
Date of Onset of AE: 960
AE Duration (Numeric Value): 118
AE Duration (Units): 118.1

Information: This is the date of the first clinical manifestation of the AE along with the "AE Duration" in the actual or approximate length of time the AE lasted.

***GL-42 Section*:** B.3.3, B.3.5, B.3.5.1, B.3.5.1.1

***ICSR Location*:** The element is located in the adverse event assessment class, mapped as an observation.

XML Details: The information is captured using a <effectiveTime> element. The <low> value is the date of onset of the AE, and the <width> is the duration of AE. For the "AE Duration Time Units" element, the <unit> of measurement is shown in ***Appendix A.13–List of Time Units***.

The XPath to get "Date of Onset of AE" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95020"]/effectiveTime/low/@value
```

The XPath to get the "AE Duration – value" in an ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95020"]/effectiveTime/width/@value
```

The XPath to get the "AE Duration Time Units" in an ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95020"]/effectiveTime/width/@unit
```

A sample XML snippet for "Date of Onset of AE" in an ICSR message is:

```
<adverseEventAssessment classCode="INVSTG" moodCode="EVN">
  <subject typeCode="SBJ">
    <primaryRole classCode="SBJ">
      ......
      <subjectOf2 typeCode="SBJ">
        <observation classCode="OBS" moodCode="EVN">
          <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95020" displayName="Reaction"/>
          <effectiveTime xsi:type="IVL_TS">
            <low value="20060608"/>
            <width value="5" unit="d"/>
          </effectiveTime>
          <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1"
                        codeSystemVersion="AdoptionByCVMP11February2009" code="984"
                        displayName="Death"/>
        </observation>
      </subjectOf2>
```

```
        .....
      </primaryRole>
   </subject>
</adverseEventAssessment>
```

2.7.4 Length of Time between Exposure to VMP and Onset of AE – GL-42 Section B.3.4

FDA Requirement Number(s):
Length of Time between Exposure to VMP and Onset of AE: 119

Information: Optional. Length of time refers to the time difference between the exposure to VMP and onset of AE.

***GL-42 Section*:** B.3.4

***ICSR Location*:** This data element is captured in an observation of the investigative subject, inside a <subjectOf2> element.

XML Details: A NCI code value should be used for "Length of Time between Exposure to VMP and Onset of AE". The code should correspond to one of the length of time contained in ***Appendix A.22–List of Length of Time Between Exposure and Onset of AE***.

The XPath to get "Length of Time Between Exposure to VMP and Onset of AE" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95021"]/value/@code
```

A sample XML snippet for" Length of Time Between Exposure to VMP and Onset of AE" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95021"
            displayName="Length of Time Between Exposure to VMP and Onset of AE"/>
      <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C82440"
            displayName="<12 hours"/>
   </observation>
</subjectOf2>
```

2.7.5 Duration of AE – GL-42 Section 3.5

See Section 2.7.3 - Date of Onset of AE (AE Start Date) – GL-42 Section B.3.3 for "AE Duration" and "AE Duration Time Units" elements discussion.

2.7.5.1 AE Duration – GL-42 Section 3.5.1

{Placeholder}

2.7.5.1.1 AE Duration Time Units – GL-42 Section 3.5.1.1

{Placeholder}

2.7.6 Serious AER (Serious AE as Reported) – GL-42 Section B.3.6

FDA Requirement Number(s):
Serious AE as Reported: 12.2

Information: This data element indicates whether the AE is being reported as a serious AE.

***GL-42 Section*:** B.3.6

***ICSR Location*:** This data element is captured as an observation, inside an <investigationCharacteristic> > class, as a reference of the investigation event.

XML Details: HL7 Boolean values will be used. A list of values has been provided in ***Appendix A.31 – Boolean Information Table*** for addressing the seriousness of the case in the column labeled "B.3.6 (Serious AE)".

The XPath to get "Seriousness of AE" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component4/investigationCharacteristic
[code/@code="T95022"]/value/@value
```

A sample XML snippet for "Seriousness of AE" in an ICSR message is:

```
<component4 typeCode="COMP">
   <investigationCharacteristic classCode="CASE" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95022" displayName="Serious AE"/>
      <value xsi:type="BL" value="true"/>
   </investigationCharacteristic>
</component4>
```

2.7.7 Treatment of AE – GL-42 Section B.3.7

FDA Requirement Number(s):
Treatment of AE: 14.2

Information: This data element indicates whether the human or animal involved in the AE was treated for the AE.

***GL-42 Section*:** B.3.7

***ICSR Location*:** This data element is located inside a <subjectOf2> observation of the adverse event assessment subject class.

XML Details: "Treatment of AE" is captured as an observation, using <code> node for observation type, and using the <value> node for the actual observation value. HL7 Boolean values and the HL7 null flavor will be used. A list of values has been provided in ***Appendix A.31***

– Boolean Information Table for addressing the "Treatment of AE" in the column labeled "B.3.7 (Treatment of AE)".

The XPath to get "Treatment of AE" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="T95023"]/value/@value
```

A sample XML snippet for "Treatment of AE" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <observation classCode="OBS" moodCode="EVN">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95023" displayName="Treatment of AE"/>
      <value xsi:type="BL" value="true"/>
   </observation>
</subjectOf2>
```

2.7.8 Outcomes to Date – GL-42 Section B.3.8

FDA Requirement Number(s):
Outcomes to Date
Ongoing: 1704
Recovered / Normal: 1705
Recovered with Sequela: 1706
Died: 1707
Euthanized: 1708
Outcome Unknown: 1709

Information: Optional. This provides a number of possible outcome categories for the animal(s) affected in the adverse event. These categories are: Ongoing, Recovered/Normal, Recovered with Sequela, Died, Euthanized, Unknown (Outcome Unknown).

GL-42 Section**:** B.3.8.1, B.3.8.2, B.3.8.3, B.3.8.4, B.3.8.5, B.3.8.6

ICSR Location**:** These data elements are captured using a list of observations of investigative subject.

XML Details: Six observation nodes are used, one for each category, to capture this information. Users should reference *Section 1.12 - ICSR Schema Locator Codes on page 1-10* to identify each observation.

The XPath to get "Ongoing" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/observation[code/@code="C53279"]/value/@value
```

Use the same XPath for other "Outcomes to Date" data elements ("Recovered/Normal", "Recovered with Sequela", "Died", "Euthanized" and "Outcome Unknown") by simply replacing the code value in XPath predicate.

A sample XML snippet for “Outcomes to Date” data elements (“Recovered/Normal”, “Recovered with Sequela”, “Died”, “Euthanized” and “Outcome Unknown”) in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C53279"
                                        displayName="Ongoing"/>
      <value xsi:type="INT" value="2"/>
   </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C82467"
                                        displayName="Recovered/Normal"/>
      <value xsi:type="INT" value="2"/>
   </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C49495"
                                        displayName="Recovered with Sequela"/>
      <value xsi:type="INT" value="1"/>
   </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C28554"
                                        displayName="Died"/>
      <value xsi:type="INT" value="3"/>
   </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C21115"
                                        displayName="Euthanized"/>
      <value xsi:type="INT" value="1"/>
   </observation>
</subjectOf2>

<subjectOf2 typeCode="SBJ">
   <observation moodCode="EVN" classCode="OBS">
      <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C17998"
                                        displayName="Outcome Unknown"/>
      <value xsi:type="INT" value="0"/>
   </observation>
</subjectOf2>
```

2.7.9 Previous Exposure to the VMP – GL-42 Section B.3.9

FDA Requirement Number(s):
Previous Exposure to VMP: 2024.1

Information: For exposures before the reported "Date of First Exposure" for this report.

***GL-42 Section*:** B.3.9

***ICSR Location*:** Located in an observation of investigative subject, inside the substance administration process node.

XML Details: Using <code> to identify that the observation is for this data element, use <value> to provide the actual data. HL7 Boolean values and the HL7 null flavor will be used. A list of values has been provided in ***Appendix A.31 – Boolean Information Table*** for addressing previous exposure to VMP in the column labeled "B.3.9 (Previous Exposure to VMP)".

The XPath to get "Previous Exposure to VMP" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/observation[code/
@code="T95024"]/value/@value
```

A sample XML snippet for "Previous Exposure to VMP" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      .....
      <sourceOf2 typeCode="PERT" contextConductionInd="true">
         <observation moodCode="EVN" classCode="OBS">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95024"
                                    displayName="Previous Exposure to the VMP"/>
            <value xsi:type="BL" value="true"/>
         </observation>
      </sourceOf2>
      .....
   </substanceAdministration>
</subjectOf2>
```

2.7.10 Previous AE to VMP – GL-42 Section B.3.10

FDA Requirement Number(s):
Previous AE to VMP: 2025.1

Information: Optional. This field refers only to clinical manifestations that occurred during the previous exposure mentioned in B.3.9 above.

***GL-42 Section*:** B.3.10

***ICSR Location*:** Same as B.3.9, except that this data element is in another observation element.

XML Details: Same as B.3.9, except that in the observation type <code> node, the code attribute value should be the code that indentifies this data element. HL7 Boolean values and the HL7 null flavor will be used. A list of values has been provided in ***Appendix -- A.31 – Boolean Information Table*** for addressing previous AE to VMP in the column labeled "B.3.10 (Previous AE to VMP)".

The XPath to get "Previous AE to VMP" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/observation[code/
@code="T95025"]/value/@value
```

A sample XML snippet for "Previous AE to VMP" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      .....
      <sourceOf2 typeCode="PERT" contextConductionInd="true">
         <observation moodCode="EVN" classCode="OBS">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95025"
                  displayName="Previous AE to the VMP"/>
            <value xsi:type="BL" value="false"/>
         </observation>
      </sourceOf2>
      .....
   </substanceAdministration>
</subjectOf2>
```

2.8 Dechallenge - Rechallenge Information – GL-42 Section B.4

Information: The information in this section relates to affected animal(s). This set of fields will be used for cases where dechallenge or rechallenges occur in single VMP events.

If the VMP is neither stopped nor re-introduced, the MAH should choose "NA" "Not Applicable".

2.8.1 Did AE Abate After Stopping the VMP – GL-42 Section B.4.1

FDA Requirement Number(s):
Did AE Abate After Stopping VMP: 2026

2.8.2 Did AE Reappear After Re-introduction of the VMP – GL-42 Section B.4.2

FDA Requirement Number(s):
Did AE Reappear After Re-introducing the VMP: 2027

***GL-42 Section*:** B.4.1, B.4.2

ICSR Location*:** Same as B.3.10, data elements in B.4.1 and B.4.2 are captured in observations, one for each data element, except that the code value in <code> that identifies the observation type is different. HL7 Boolean values and the HL7 null flavor will be used. A list of values has been provided in ***Appendix A.31 – Boolean Information Table for addressing these two data element in the column labeled "*B.4.1 (Did AE Abate)*" and "*B.4.2 (Did AE Reappear)*".

XML Details: Same as B.3.10. Note the difference in code value in the predicates.

The XPath to get "Did AE Abate After Stopping the VMP" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/observation[code/
@code="T95026"]/value/@value
```

The XPath to get "Did AE Reappear After Re-introduction of the VMP" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/subject/primaryRole/subjectOf2/substanceAdministration[id/@extension="1"]/sourceOf2/observation[code/
@code="T95027"]/value/@value
```

A sample XML snippet for "Did AE Abate After Stopping the VMP" and "Did AE Reappear After Re-introduction of the VMP" in an ICSR message is:

```
<subjectOf2 typeCode="SBJ">
   <substanceAdministration classCode="SBADM" moodCode="EVN">
      <id root="1.2.3.4" extension="1"/>
      ......
      <sourceOf2 typeCode="PERT" contextConductionInd="true">
         <observation moodCode="EVN" classCode="OBS">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95026"
                  displayName="Did AE Abate After Stopping the VMP "/>
            <value xsi:type="BL" value="false"/>
         </observation>
      </sourceOf2>

      <sourceOf2 typeCode="PERT" contextConductionInd="true">
         <observation moodCode="EVN" classCode="OBS">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="T95027"
                  displayName="Did AE Reappear After Re-introducing the VMP"/>
            <value xsi:type="BL" nullFlavor="NA"/>
         </observation>
      </sourceOf2>
      ......
   </substanceAdministration>
</subjectOf2>
```

2.9 Assessment of AE – GL-42 Section B.5

FDA Requirement Number(s):
Attending Veterinarian's Assessment: 2019

Information: This is the assessment of the attending veterinarian regarding the association between the VMP and the AE.

***GL-42 Section*:** B.5.1

***ICSR Location*:** Located in a causality assessment class instance that is associated with the adverse event assessment that triggers the investigation event.

XML Details: This data element must use the NCI code. A list of values is shown in ***Appendix A.27–List of Attending Veterinarian's Causality Assessment.***

The XPath to get the "Assessment of AE" in the ICSR message is:

```
//PORR_IN049006UV/controlActProcess/subject/investigationEvent/component1/adverseEventAssessment
/component/causalityAssessment[author/assignedEntity/code/@code="C82470"]/value/@code
```

A sample XML snippet for "Assessment of AE" in an ICSR message is:

```
<component typeCode="COMP">
   <causalityAssessment classCode="INVSTG" moodCode="EVN">
      <value xsi:type="CE" codeSystem="2.16.840.1.113883.3.26.1.1" code="C82490" displayName="Possible"/>
      <author typeCode="AUT">
         <assignedEntity classCode="ASSIGNED">
            <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C82470" displayName="Veterinarian"/>
         </assignedEntity>
      </author>
   </causalityAssessment>
</component>
```

2.10 Supplemental Documents – Section GL-42 B.6

Information: This section lists the "Supplemental Documents" information on a specific AER to be submitted to the RA. Please note that "Supplemental Documents" should be embedded in the ICSR XML file, and binary "Supplemental Document" should be embedded as Base-64 encoded data. Each "Supplemental Document" shall be mapped into a single <document> node. The following table lists the acceptable file kinds that FDA/CVM will accept as "Supplemental Documents".

Extension	Kind	Description
doc	MSWORD	Microsoft's word processing program
pdf	PDF	The Portable Document Format (PDF) as defined by Adobe
bmp	BMP Image	BMP is a bitmap image format
gif	GIF Image	The Graphics Interchange Format (GIF) is a bitmap image format
jpg	JPEG Image	JPEG is a photographic image format defined by the Joint Photographic Experts Group
png	PNG Image	The Portable Network Graphics (PNG) is a bitmapped image format standard to replace BMP.

tif	TIFF Image	TIFF (Tag Image File Format) for faxed and scanned images of paper based documents.
xls	MS Excel	Microsoft's spreadsheet processing program
txt	Plain Text	For any plain text
rtf	RTF Text	The Rich Text Format word-processor documents

Table 2-6 Accepted Supplemental Document Kinds

A "Supplemental Document" is mapped into the <document> node inside the <reference> element that is associated with the investigation event. In the case that multiple "Supplemental Documents" need to be attached, reporters can use multiple <reference> nodes in the ICSR message, one for each "Supplemental Document". Reporters should use a unique <id> element to specify each document.

Each "Supplemental Document" requires the following four data elements:

- The "Supplemental Document" filename
- The "Supplemental Document" description
- The "Supplemental Document" type
- The "Supplemental Document" data

2.10.1 Supplemental Document Filename – GL-42 Section B.6.1

FDA Requirement Number(s):
Supplemental Document Filename: N51

Information: This is the proper name of the "Supplemental Document". The filename must contain the 3-character file extension of the acceptable file kind.

***GL-42 Section*:** B.6.1

***ICSR Location*:** This element is located within the <title> element within the <document> node.

XML Details: The XPath to get to the "Supplemental Document Filename" in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document/title

2.10.2 Supplemental Document Description – GL-42 Section B.6.2

FDA Requirement Number(s):
Supplemental Document Description: N52

Information: This is the narrative description of the "Supplemental Document".

***GL-42 Section*:** B.6.2

***ICSR Location*:** It is captured inside the <text> element of the investigative event, as part of the narrative text of AE. The "Supplemental Document Description" should be appended to any existing text previously stored in the <text> element. The "Supplemental Document Description"

should be prefaced with the tag “SUPPLEMENTAL:” to distinguish between the narrative description and the “Supplemental Document Description”.

XML Details: The XPath to get the “Supplemental Document Description” in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/text

2.10.3 Supplemental Document Type – GL-42 Section B.6.3

FDA Requirement Number(s):
Supplemental Document Type: N53

Information: FDA/CVM has defined the types of “Supplemental Document(s)” that it will accept. ***Appendix A.32–List of Attached Document Type*** defines the document types that FDA/CVM has approved to be incorporated within an ICSR document. Please note that this is not the “Supplemental File Kind” as described in *Table 2-6 Accepted Supplemental Document Kinds* above.

***GL-42 Section*:** B.6.2

***ICSR Location*:** This element is located within the <code> element of the <document> node; codeSystem National Cancer Institute Thesaurus should be used for this data element.

XML Details: The XPath to get the “Supplemental Document Type” in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document/code/@code

2.10.4 Supplemental Document Data – GL-42 Section B.6.4

FDA Requirement Number(s):
Supplemental Document: ????

Information: The “Supplemental Document” itself should be embedded inside the <text> element of the <document> node. Binary “Supplemental Documents”, for example a graphic GIF file, should be Base-64 encoded.

***GL-42 Section*:** B.6.4

***ICSR Location*:** This element is located within the <text> element of the <document> node; "B64" should be used as the attribute value.

XML Details: The XPath to get to the “Supplemental Document Data” in the ICSR message is:

//PORR_IN049006UV/controlActProcess/subject/investigationEvent/reference/document/text

A sample XML snippet for a “Supplemental Document”, including a “Supplemental Document Filename”, “Supplemental Document Type”, and a “Supplemental Document Data” is shown in

the following XML snippet. To view a snippet depicting a “Supplemental Document Description” please see the example in *Section 2.7.1 page 2-50*.

```
<investigationEvent classCode="INVSTG" moodCode="EVN">
   ......
   <reference typeCode="REFR">
      <document classCode="DOC" moodCode="EVN">
         <id extension="1"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C68623"
                                                displayName="Necropsy (Autopsy)"/>
         <title>nec-picture.gif</title>
         <text mediaType="text/plain" representation="B64">
           R0lGODlhZABqALMAAFrMYr/BvlKOVJKOg2xZUKmenMfDw8tgWJpVUbaxsPb19v///+bm5tfX1wAAAAAA
           ACwAAAAAZABqAAAE/3DJSau9mCrGWhkFIopF2TSMkq1s674rk4x0TRB1ETQq7P/AS6gmOhiPRxuu0Ag6
           nyzGCEmtVmkFqHa7MByK1rCV8OWagwUjTsw2FhG9s5ylQCRxtIF+gNjTvmtfDHOEGQ12
           ….… more Base-64 data …...
         <text>
         </document>
   </reference>

   <reference typeCode="REFR">
      <document classCode="DOC" moodCode="EVN">
         <id extension="2"/>
         <code codeSystem="2.16.840.1.113883.3.26.1.1" code="C36292"
                                                displayName="Laboratory Report"/>
         <title>lab-report.pdf</title>
         <text mediaType="text/plain" representation="B64">
           JVBERi0xLjQNJeLjz9MNCjYgMCBvYmo8PC9IWzQ3NiAxMzNdL0xpbmVhcml6ZWQgMS9FIDE3OTAvTCA
           1Njg5L04gMS9PIDkvVCA1NTIzPj4NZW5kb2JqDSAgICAgICAgICAgICAgICAgICAgICAgICAgICAgDQp4cmVm
           DQo2IDkNCjAwMDAwMDAwMTYgMDAwMDAgbg0KMDAwMDAwMDYwOSAwMDA
           ..... more Base-64 data .....
         <text>
      </document>
   </reference>
   ......
</investigationEvent>
```

3 ICSR Wrapper Information

This group of data elements contains information that is captured in one of the HL7 wrappers.
~~Information in this section does not correspond to GL-42 standard.~~

3.1 U.S. Specific Only – Section B.7

This information is not included in the VICH GL-42 Adverse Event data element standard.

3.1.1 Report Identifier – Section B.7.1

FDA Requirement Number(s): N/A
Information: This information indicates the application/file number that this message is reporting to.

***GL-42 Section*:** B.7.1

***ICSR Location*:** This information is located in the ICSR message Transmission Wrapper. It is captured in an <attentionLine> node.

XML Details: Note that since multiple <attentionLine> nodes are used for different information, User shall use an identification code in <keyWordText> element to identify this date element.

The XPath to get "Report Identifier" in the ICSR message is:

```
//PORR_IN049006UV/attentionLine[keyWordText="Report Identifier"]/value
```

A sample XML snippet for "Report Identifier" in an ICSR message is:

```
<attentionLine>
        <keyWordText>Report Identifier</keyWordText>
        <value xsi:type="ST">N123123</value>
</attentionLine>
```

3.1.2 Domestic vs. Foreign Report Category – Section B.7.2

FDA Requirement Number(s): N76

Information: This information indicates if this message is a domestic or foreign report.

***GL-42 Section*:** B.7.2

***ICSR Location*:** This information is located in the ICSR message Transmission Wrapper. It is captured in an <attentionLine> node.

XML Details: Note that since multiple <attentionLine> nodes are used for different information, a code must be used in <keyWordText> node to identify this data element. Users should use

published vocabulary for the value as shown in ***Appendix A.5–List of Domestic vs. Foreign Report Categories***.

The XPath to get "Third Country Report Indicator" in the ICSR message is:

```
//PORR_IN049006UV/attentionLine[keyWordText="Domestic vs Foreign Report Category"]/value/@code
```

A sample XML snippet for "Third Country Report Indicator" in an ICSR message is:

```
<attentionLine>
        <keyWordText>Domestic vs Foreign Report Category</keyWordText>
        <value xsi:type="SC" codeSystem="2.16.840.1.113883.3.26.1.1" code="C82450"
                                                displayName="FOREIGN - SAME"/>
</attentionLine>
```

3.1.3 U.S. Pharmacovigilance Contact Person for the MAH – Section B.7.3

FDA Requirement Number(s):

Information: This is the person within the U.S. MAH that acts on the behalf of and is responsible for the case, and is the contact person for the US FDA/CVM.

***GL-42 Section*:** B.7.3

***ICSR Location*:** This information is located in the HL7 Transmission Wrapper. It is captured in the transmission wrapper sender class.

XML Details: The reporter should provide the person's title, first name, last name, telephone number, optional fax number, and e-mail address.

The XPath to get the "U.S. Pharmacovigilance Contact Person for the MAH" in the ICSR message is:

```
//PORR_IN049006UV/sender/device/asAgent/representedOrganization/notificationParty/contactPerson/*
```

A sample XML snippet for U.S. Pharmacovigilance Contact Person for the MAH is:

```
<PORR_IN049006UV ......>
   ........
    <sender>
      <device classCode="DEV" determinerCode="INSTANCE">
         <id/>
         <asAgent classCode="AGNT">
            <representedOrganization classCode="ORG" determinerCode="INSTANCE">
               <id/>
               <notificationParty>
                  <id/>
                  <contactPerson>
                     <id/>
                     <name>
                        <prefix>Dr</prefix>
                        <given>John</given>
```

```
                    <family>Doe</family>
                  </name>
                  <telecom value="TEL:6155531112"/>
                  <telecom value="FAX:8093459090"/>
                  <telecom value="MAILTO://someone@example.com"/>
                </contactPerson>
            </notificationParty>
          </representedOrganization>
        </asAgent>
        </device>
    </sender>
    ........
</PORR_IN049006UV>
```

3.2 Data Elements Not Defined in GL-42

The following data elements are not included in the GL42 definitions. They have been added by FDA/CVM for required information and to satisfy HL7 ICSR XML standards.

3.2.1 Individual Case Safety Report Identifier (ICSR ID)

FDA Requirement Number(s):

Information: This field contains the assigned Unique ICSR identification number. Each submitted report must have a unique number assigned regardless if the report is an "ORIGINAL", "FOLLOW UP" or "NULLIFICATION". This field format is up to the creator of the ICSR. The ICSR creator must ensure that this uniquely assigned number will never be used in another ICSR.

***GL-42 Section*:** N/A

ICSR Location: This information is located in the ICSR message Transmission Wrapper. It is captured in an <attentionLine> node. Note that since multiple <attentionLine> nodes are used for different information, a code should be used in <keyWordText> node to identify this node. Currently the name of the data element is used as the key word.

XML Details: Use "ICSR" in the <keyWordText> to identify this <attentionLine> element.

The XPath to get the "Individual Case Safety Report Number" in an ICSR message is:

```
//PORR_IN049006UV/attentionLine[keyWordText="ICSR"]/value
```

A sample XML snippet for "Individual Case Safety Report Number" in an ICSR message is:

```
<PORR_IN049006UV ……>
    ……..
    <attentionLine>
        <keyWordText>ICSR</keyWordText>
        <value xsi:type="ST">GAPINDSY-SUB1-14973</value>
    </attentionLine>
    ……..
</ PORR_IN049006UV>
```

3.2.2 Message Sender Identifier

FDA Requirement Number(s): 38.2, 38.4, 46, 48, 51, 69

Information: This information identifies the sender who is responsible for any corresponding communications regarding the complete batch transmission of ICSRs.

***GL-42 Section*:** N/A

***ICSR Location*:** This information is located in the HL7 Batch Wrapper. It is captured in the batch sender class.

XML Details: The sender could provide an ID and contact information inside <sender> node. See *Table 2-2 Telecom Entry Format Rules* for telecom entry rules.

The XPath to get the "Message Sender Identifier Telecom" information in the ICSR message is:

```
//MCCI_IN200100UV/sender/device/as Agent/representedOrganization/notificationParty/telecom
```

A sample XML snippet for "Message Sender Identifier" in an ICSR message is:

```
< MCCI_IN200100UV ……>
  <sender>
    <device>
      <id/>
      <asAgent classCode="AGNT">
        <representedOrganization classCode="ORG">
          <id></id>
          <notificationParty classCode="CON">
            <id></id>
            <addr use="WP">
              <streetAddressLine>2nd Maple Place</streetAddressLine>
              <city>Woodbury</city>
              <state>TN</state>
              <postalCode>37615</postalCode>
              <country>USA</country>
            </addr>
            <telecom value="TEL:6155531112"/>
            <telecom value="FAX:8093459090"/>
            <telecom value="MAILTO://someone@example.com"/>
            <contactPerson>
              <id/>
              <name>
                <given>Jane The Sender</given>
                <family>Doe</family>
              </name>
            </contactPerson>
          </notificationParty>
        </representedOrganization>
      </asAgent>
    </device>
  </sender>
</ MCCI_IN200100UV >
```

3.2.3 Profile Identifier Code

FDA Requirement Number(s):

Information: The "Profile Identifier (Profile ID) Code" contains details about the type of report contained in this message payload. Currently three types of mandatory ICSR reports are accepted: AE (adverse drug event), PP (product problem), and AEPP (combination of AE and PP)

For system harmonization purposes, other information is included in the full "Profile ID" element. The full "Profile ID" consists of the following components, as shown in the following table, with sample values:

Component	Sample Values	
Application	• FPSR • AES*[2]	
Agency	• FDA*	
	• NIH	
Reporting Situation / Questionnaire	• RFR • PETF • VICHGL42* • GEM	
Regulatory Status	• M*	Mandatory
	• V	Voluntary
Version	• V1*	
Data Entry Pathway	• GUEST (Guest User Pathway)	
	• ACCOUNT* (Account User Pathway)	
	• PROXY (Proxy User Pathway)	
Report Type	• AE (Adverse Event Report) • PP (Product Problem Report) • AEPP (Adverse Event & Product Problem Report)	

Table 3-1 Profile ID Data Components

What follows is an example of a complete and valid Profile ID in a VICH GL42 ICSR message:

AES.FDA.VICHGL42.M.V1.ACCOUNT.PP

Description and breakdown of the above example:

- "AES" is the generic application name that creates the ICSR message. Always use "AES" for the application name.
- "FDA" is the regulatory agency to which the reports are being sent.
- "M" denotes that the report is submitted under regulations that require the MAH to make the report.

[2] Elements that are noted by an "*" are default items to be included with GL42 ICSR messages.

- "V1" is for version 1 of the Profile ID (as this changes, guidance will be updated explaining different values along with a schedule for implementing them).
- "ACCOUNT" indicates that the submitter has a valid account with the receiving agency (every MAH that submits using the FDA Electronic Submission Gateway (ESG) has an 'account' for this purpose).
- "PP' indicates that the ICSR is for a Product Problem. Your actual "Profile ID" could vary; for example, if it were describing an adverse event, it would have a report type of "AE" instead of "PP" in the example above.

The ***Appendix A.26 – Profile Identifier Code Vocabulary*** is a reference list of the values for VICH GL42 ICSR reports for this data element,

***GL-42 Section*:** N/A

***ICSR Location*:** This information is located in the ICSR message Transmission Wrapper. It is captured in the <profileId> node. The actual value is set in its extension attribute. The OID to use is the "FDA ICSR Processing System".

XML Details:

The XPath to get the "Profile ID" element within the ICSR message is:

```
//PORR_IN049006UV/profileId/@extension
```

A sample XML snippet for "Profile ID" in an ICSR message is:

```
<PORR_IN049006UV ……>
      ……..
      <profileId root="2.16.840.1.113883.3.156"
          extension="AES.FDA.VICHGL42.M.V1.ACCOUNT.AEPP"/>
     …….
</ PORR_IN049006UV>
```

3.2.4 Batch Identifier

FDA Requirement Number(s):

Information: The "Batch Identifier" information identifies the collection of reports in this batch as a complete submission message. This identifier should uniquely identify each batch of reports. It is the sender's responsibility to define and assign this identifier as each batch submission must have a unique identifier. A "Batch Identifier" must be supplied even if only one case report is within the batch. The format and content of the identifier is within the complete control of the creator. FDA/CVM will use the "Batch Identifier" in all communications with the submitter.

***GL-42 Section*:** B.7.3

***ICSR Location*:** This information is located in the HL7 Batch Wrapper. It is captured in the <id> element.

XML Details: The "Batch Identifier" of this batch transmission of ICSR reports is captured in the extension attribute of <id> element. The <id root> attribute should be populated with company's assigned HL7 OID (*See section 1.5.2 - Unique Organizational OID*
{Note for the Initial System Release this requirement has been relaxed. A unique system OID is NOT required. A substitute OID of "1.2.3.4" must be used in lieu of an assigned OID.}

Formatted: Bullets and Numbering

This unique organizational identifier can be obtained from either the International Standards Organization or the Health Level 7 (HL7) organization. The unique OID will be used to uniquely identify organizations when electronic submissions are received. This unique OID must be used in all electronic adverse event submissions to FDA/CVM. If your organization has obtained an OID for use with the *European Medicines Organization (EMA)* electronic submissions system you may use the same OID for FDA/CVM ICSR Electronic submissions. For more information on OIDS and obtaining an Organizational OID see the *Instructions for Submitting Mandatory Electronic Adverse Event Reports to FDA CVM.*
.) The "Batch ID" format is up to the MAH submitter to encode and keep track of. Batch IDs should be unique within the sender organization.

The XPath to get "Batch ID" in the ICSR message is:

```
//MCCI_IN200100UV/id/@extension
```

A sample XML snippet for "Batch ID" in the ICSR message is:

```
< MCCI_IN200100UV ……>
        <id root="SubmittingOrganizationOID" extension="ABCDrug-20100328-batch-12345"/>
</ MCCI_IN200100UV >
```

3.2.5 Message Date

FDA Requirement Number(s):

Information: This information indicates the date this batch of ICSRs was created.

***GL-42 Section*:** B.7.8

***ICSR Location*:** This information is located in the HL7 Batch Wrapper. It is captured in the <creationTime> element.

XML Details: The "Message Date" is captured using a simple TS data format.

The XPath to get "Message Date" in the ISCR message is:

```
//MCCI_IN200100UV/creationTime/@value
```

A sample XML snippet for "Message Date" in an ICSR message is:

```
< MCCI_IN200100UV ……>
    ……..
    <creationTime value="20071016"/>
    ……..
</ MCCI_IN200100UV >
```

3.2.6 Message Version Number & Release Number

FDA Requirement Number(s):

Information: This information indicates the HL7 "Message Version" and "Release Number" on which this batch report submission is based.

***GL-42 Section*:** B.7.10, B.7.11

***ICSR Location*:** This information is located in the HL7 Batch Wrapper. It is captured in the <versionCode> element.

XML Details: Submitters should use the HL7 standard version code. This is the domain of HL7 version codes for the Version 3 standards. Values are to be determined by HL7 and added with each new version of the HL7 Standard.

The XPath to get "Version Information" in the ICSR message is:

```
//MCCI_IN200100UV/versionCode/@code
```

A sample XML snippet for "Version Information" in an ICSR message is:

```
< MCCI_IN200100UV ……>
    ……..
    <versionCode code="V320090914"/>
    ……..
</ MCCI_IN200100UV >
```

4 Sample Reports and Sample XML Submissions

This section of the Step-By-Step Implementation Guide contains sample adverse event reports and the associated sample HL7 ICSR XML message submissions. There are four samples each with a mocked up FDA Form to collect AE data closely following the <FDA/CVM Adverse Event Guidelines Document>. In addition, there is an HL7 XML ICSR message for each sample.

The examples are as follows:

- Two Adverse Event reports for a single VMP
- One Product Quality Report
- One Product Quality Report and one associated Adverse Event Report

4.1 Two Adverse Events Reports for a Single VMP

4.2 One Product Quality Report

4.3 One Product Quality Product Report with Associated Adverse Event Report

5 List of Abbreviations

Abbreviation	Description
AE	Adverse Event
AER	Adverse Event Report
ATC Vet Code	Anatomical Therapeutic Chemical classification system for veterinary medicinal products
CVM	Center for Veterinary Medicine
DUNS	A unique nine digit number assigned to a organizational facility by Dun & Bradstreet
Element	XML Field Name
EMEA	European Medicines Agency
ESG	FDA's Electronic Submissions Gateway
FDA	US Food and Drug Administration
GL42	A VICH standard for defining elements of data to be collected for an Animal adverse event
HL7	Health Level 7 Organization
ICSR	HL7 Individual Case Safety Report format
ISO	International Standards Organization
MAH	Marketing Authorized Holder
NCI	US National Cancer Institute
NDC	US National Drug Code
OID	Organizational Identifier
Payload	The HL7 ICSR message organizational structure that contains the AER
PP	Product Quality Problem Report
RA	Regulatory Authority who regulates the VMP
UCUM	Unified Codes of Measurement
VICH	International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products
VMP	Veterinary Medical Product
WHO	World Health Organization
Wrapper	XML code structure that encompasses another code structure
XML	Extensible Markup Language
XPath	An XML method to locate specific elements within an XML document

6 Vocabulary Tables

6.1 Introduction

This section documents the individual samples of the vocabulary tables that are to be used to select codes, values and terms in order to construct a valid adverse event in the HL7 ICSR form. The valid code tables can be found on either the FDA's Data Council's ICSR website or CVM's Electronic Submissions website below:

FDA Data Standards Council:

CVM Electronic Submissions:

Comment [HC1]: Need Web URL addresses

6.2 The Unified Code for Units of Measure (UCUM)

All reporting of measurements of time and amounts must use the "Unified Code for Units of Measure (UCUM)" as defined by the UCUM Organization, Indianapolis, IN. Their web site address is: http://unitsofmeasure.org/. Whenever the "***Unified Code for Units of Measure***" OID is required it is 2.16.840.1.113883.6.8.

6.3 Vocabulary Code System OIDs

Each defined vocabulary has a codeSystem Organizational Identifier (OID) that identifies the source of information and the owning organization of the vocabulary. The following table lists the OIDS in use within FDA/CVM's AE ICSR system. Note that the items shaded in blue are temporary and will change in the future.

Comment [HC2]: Update OIDS as received from FDA Data Council

Code System	Code System OID
Dun and Bradstreet D-U-N-S Number	1.3.6.1.4.1.519.1
FDA CVM ICSR Processing System	2.16.840.1.113883.3.156
FDA NDC Product Code	2.16.840.1.113883.6.69
FDA Regulatory Compliance Service	2.16.840.1.113883.4.82
FDA Submission Tracking System	2.16.840.1.113883.3.150
FDA Substance Registration System (SRS) (UNII)	2.16.840.1.113883.4.9
GL42 – Female Animal Physiological Status	2.16.840.1.113883.13.49
National Cancer Institute Thesaurus	2.16.840.1.113883.3.26.1.1
Unified Code for Units of Measure (UCUM)	2.16.840.1.113883.6.8
VeDDRA - Animal Clinical Terminology	2.16.840.1.113883.4.358
VICH -- Animal Breed	2.16.840.1.113883.4.342
VICH – Animal Species	2.16.840.1.113883.4.341
VICH -- Dosage Form	2.16.840.1.113883.4.343
VICH – Exposure Time Intervals	2.16.840.1.113883.13.50
VICH – Off-Label Use	2.16.840.1.113883.13.51
VICH – Regulatory Agency Identifier Code	2.16.840.1.113883.4.344
VICH -- Route of Exposure	2.16.840.1.113883.4.345

Table 6-1 ICSR Organizational Identifier Codes (OIDS)

6.4 List of Vocabulary Tables

ICSR Vocabulary
A.1-Sender Category Vocabulary
A.2-List of Reporter Categories
A.3-List of Type of Submission
A.4-List of Type of Information in Report
A.5-List of Domestic and Foreign Report Categories
A.6-List of Attending Veterinarian's Assessment of Health Status Prior to VMP Use
A.7-List of Species
A.8-List of Breeds
A.9-List of Gender Categories
A.10-List of Reproductive Status Categories
A.11-List of Female Physiological Status Categories
A.12-List of Precision Categories for Weight and Age Data
A.13-List of Time Units
A.14-List of Assessment Categories
A.15-List of Routes of Exposure
A.16-Interval of Administration Vocabulary {**To Be Deleted – Use A.13 List of Time Units**}
A.17-Duration Vocabulary {**To Be Deleted – Use A.13 List of Time Units**}
A.18-List of Manufacturer Site Identifiers
A.19-List of Administrators of VMP(s)
A.20-ATCvet Code -- Information Only
A.21-VeDDRA Vocabulary
A.22-List of Length of Time Between Exposure and Onset of AE
A.23-ICSR Observation Locator Codes (Not a vocabulary)
A.24-List of Units of Measurement
A.25-List of Units of Presentation
A.26-Profile Identifier Code Vocabulary
A.27-List of Attending Veterinarian's Causality Assessment
A.28-List of ORA District Field Offices
A.29-List of Package Types
A.30-List of Explanation for Off-Label Use – Coding System
A.31-Boolean -- Information Only
A.32-List of Attached Document Types
A.33-List of Dosage Forms
A.34-{Deleted}
A.35-List of US States & Territory Codes
A.36-List of ISO 3-Digit Country Codes
A.37-{Deleted}
A.38-Substance Registration System Active Ingredient Codes

7 List of Element Fields

The following is a complete table of ICSR data elements. Each entry contain the type of element, the mandatory/optional status of the element, whether a null flavor can be used and what type of null flavor is expected. The column cells that contain "SC" are special conditions that require the reader to reference the *Electronic Transmission Implementation Specifications [Validation Procedures]* for directions on how and when a null flavor can be used. The legend to the table follows.

Color	Comment
	Section Header – No Data
	Null Flavor Not Allowed
SC	Special Case – See Element Description in Validation Guide

Table 7-1 Legend to Element Table

GL 42 Section Title	GL42 Number	Element Type	Mand / Option	Null Ok	Null Type Required
Regulatory Authority (RA)	A.1				
RA Name		Text	M	N	
RA Street Address		Text	M	N	
RA City		Text	M	N	
RA State		List	M	N	
RA Mail / Zip code		Text	M	N	
RA Country		List	M	N	
MAH Information	A.2				
Sender Category		List	M	N	
Sender Organization		Text	M	N	
Sender Street Address		Text	M	N	
Sender City		Text	M	N	
Sender State		List	M	N	
Sender Mail/ Zip Code		Text	M	N	
Sender Country		List	M	N	
Person Acting on Behalf of MAH	A.2.2				
Sender Title		Text	O	Y	NI
Sender First Name		Text	O	Y	NI
Sender Last Name		Text	O	Y	NI
Sender Telephone		Tel #	O	Y	NI
Sender Fax		Tel #	O	Y	NI
Sender Email		Text	O	Y	NI
Reporter Information (Primary or Other)	A.3.1 & A.3.2				
Primary Reporter Category		List	M	N	
Other Reporter Category		List	SC	Y	NI
Reporter First Name		Text	O	Y	NI
Primary Reporter Last Name		Text	M	N	
Other Reporter Last Name		Text	O	Y	NI
Reporter Organization		Text	O	Y	NI
Reporter Street Address		Text	O	Y	NI
Reporter City		Text	O	Y	NI
Reporter State		List	O	Y	NI
Reporter Mail/ Zip Code		Text	O	Y	NI

GL 42 Section Title	GL42 Number	Element Type	Mand / Option	Null Ok	Null Type Required
Reporter Country		List	O	N	NI
Reporter Telephone		Tel #	O	Y	NI
Reporter Fax		Tel #	O	Y	NI
Reporter Email		Text	O	Y	NI
AER Information	A.4				
Unique Adverse Event Identification Number	A.4.1	Text	M	N	
Original Receive Date	A.4.2	Date	M	N	
Date of Current Submission	A.4.3	Date	M	N	
Type of Report	A.4.4				
Type of Submission & Code	A.4.4.1	List	M	N	
Reason for Nullification Report	A.4.4.2	Text	O	Y	NI
Type of Information in Report & Code	A.4.4.3	List	O	Y	NI
Animal Data B.1	B.1				
Number of Animals Treated	B.1.1	Integer	O	Y	NI
Number of Animals Affected	B.1.2	Integer	M	N	
Attending Veterinarian's Assessment of Health Status Prior to VMP & Code	B.1.2.1	List	O	Y	NI
Species (Type of Species) & Code	B.1.3	List	M	N	
Are Animals Crossbred	B.1.4	Boolean	M	SC	
Breed (Breed Group)	B.1.4.1	List	SC	Y	NI
Gender & Code	B.1.5	List	O	Y	NI
Reproductive Status & Code	B.1.6	List	O	Y	NI
Female Physiological Status & Code	B.1.7	List	O	Y	NI
Weight & Age Data B.1.8	B.1.8				
Weight Measured, Estimated or Unknown & Code	B.1.8.1	List	O	Y	NI
Minimum Weight	B.1.8.2	Integer	SC	Y	NI
Maximum Weight	B.1.8.3	Integer	SC	Y	NI
Age Measured, Estimated or Unknown & Code	B.1.9.1	List	M	N	
Minimum Age	B.1.9.2	Integer	SC	Y	NI
Minimum Age Units	B.1.9.2.1	List	SC	Y	NI
Maximum Age	B.1.9.3	Integer	SC	Y	NI
Maximum Age Units	B.1.9.3.1	List	SC	Y	NI
VMP Data & Usage B.2	B.2				
Registered Name or Brand Name	B.2.1	Text	SC	Y	Y
Product Code (Product NDC Number or Unique ID)	B.2.1.1	Text	O	Y	NI
Registration Identifier	B.2.1.2	Text	O	Y	NI
Anatomical Therapeutic Chemical Vet (ATCvet) Code	B.2.1.3	List	O	Y	NI
Company or MAH	B.2.1.4	Text	O	Y	NI
MAH Assessment	B.2.1.5	Text	O	Y	NI
Route of Exposure (Route of Administration)	B.2.1.7	List	M	N	
Dose Per Administration	B.2.1.7.1				
Dose Value		Number	O	Y	NI
Dose Unit of Measurement		List	SC	Y	List
Interval of Administration	B.2.1.7.1.2	Integer - List	SC	Y	NI
Date of First Exposure	B.2.1.7.1.2.2	Date	O	Y	NI
Date of Last Exposure	B.2.1.7.1.2.3	Date	O	Y	NI
Active Ingredient	B.2.2				

GL 42 Section Title	GL42 Number	Element Type	Mand / Option	Null Ok	Null Type Required
Active Ingredient(s) Name	B.2.2.1	Text	SC	Y	SC
Active Ingredient Code(s)		Text	SC	SC	SC
Strength Numerator		Integer	SC	SC	SC
Strength Units Numerator		List	SC	SC	SC
Strength Denominator		Integer	SC	SC	SC
Strength Units Denominator		List	SC	SC	SC
Dosage Form & Code	B.2.2.2	List	O	Y	NI
Lot Number(s)	B.2.3	Text	O	Y	NI
Manufacturing Date		Date	O	Y	NI
Expiration Date	B.2.3.1	Date	O	Y	NI
Manufacturer's Site Id Number	B.2.6.1	Text	O	Y	NI
Manufacturer's Identifier Type	B.2.6.1.1	List	O	Y	NI
Manufacturing Date	B.2.6.2	Date	O	Y	NI
Number of Defective Units	B.2.6.3	Integer & List	O	Y	NI
Number of Units Returned	B.2.6.4	Integer & List	O	Y	NI
ORA District Field Office Where Product Quality Report was Filed and Code	B.2.6.5	List	SC	Y	NI
Who Administered the VMP & Code	B.2.4	List	O	Y	NI
Use According to Label	B.2.5	Boolean	O	SC	NI
Explanation for Off-Label Use & Code	B.2.5.1	Integer	O	Y	NI
Adverse Event Data	B.3				
Narrative of AE	B.3.1	Text	M	N	
Adverse Clinical Manifestations (AER Term Name(s) & Code(s))	B.3.2	List	SC	SC	SC
Number of Animals Affected		Integer	O	Y	SC
Date of Onset of AE (AE Start Date)	B.3.3	Date	M	N	
Duration Time	B.3.5.1	Integer	O	Y	NI
Duration Time Units	B.3.5.1.1	List	SC	SC	NI
Length of Time between Exposure to VMP & Onset of AE	B.3.4	List	O	Y	NI
Serious AER Reported	B.3.6	Boolean	M	N	
Treatment of AE	B.3.7	Boolean	O	Y	SC
Outcomes to Date	B.3.8				
Ongoing		Integer	O	Y	NI
Recovered/Normal		Integer	O	Y	NI
Recovered with Sequela		Integer	O	Y	NI
Died		Integer	O	Y	NI
Euthanized		Integer	O	Y	NI
Outcome Unknown		Integer	O	Y	NI
Previous Exposure to the VMP	B.3.9	Boolean	O	Y	SC
Previous AE to VMP	B.3.10	Boolean	O	Y	SC
Did AE Abate After Stopping the VMP?	B.4.1	Boolean	O	Y	SC
Did AE Reappear After Re-introduction of the VMP?	B.4.2	Boolean	O	Y	SC
Attending Veterinarian's Assessment of AE	B.5.1	List	O	Y	NI
Supplemental Documents	B.6				
Supplemental Document Filename	B.6.1	Text	O	Y	SC
Supplemental Document Description	B.6.2	Text	O	N	SC
Supplemental Document Type	B.6.3	List	O	Y	SC

GL 42 Section Title	GL42 Number	Element Type	Mand / Option	Null Ok	Null Type Required
US Specific Section	B.7				
Report Identifier	B.7.1	Text	M	N	
Domestic vs. Foreign Report Category	B.7.2	List	M	N	
US Pharmacovigilance Contact Person for MAH	B.7.3				
Title	B.7.3.1	Text	M	N	
First Name	B.7.3.2	Text	M	N	
Last Name	B.7.3.3	Text	M	N	
Telephone	B.7.3.4	Tel #	M	N	
Fax	B.7.3.5	Tel #	M	N	
Email	B.7.3.6	Text	M	N	
Data Elements Outside of GL-42					
ICSR Number		Text	M	N	
Message Sender Identifier					
Contact First Name		Text	M	N	
Contact Last Name		Text	M	N	
Contact Organization		Text	M	N	
Contact Street Address		Text	M	N	
Contact City		Text	M	N	
Contact State		List	M	N	
Contact Mail/ Zip Code		Text	M	N	
Contact Country		List	M	N	
Contact Telephone		Tel #	M	N	
Contact Fax		Tel #	M	N	
Contact Email		Text	M	N	
Wrapper Elements					
Profile Identifier Code		Text	M	N	
Batch Identifier Code		Text	M	N	
Message Date		Date	M	N	
Message Version & Release Number		Text	M	N	

Table 7-2 Element Fields Listing

8 Index of Element Names