

HL7 Drug Stability Reporting Release 2: (eStability)

Implementation Guide for FDA Stability Reporting

HL7 Informative Document

Sponsored by:
Regulated Clinical Research Information Management Technical Committee

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Introduction to Drug Stability Reporting (eStability)

Introduction

This Implementation Guide (IG) is for the use of the Health Level 7 (HL7) Stability Standard. The IG describes the basic requirements needed for using the standard and the requirements needed for submitting information to the Food and Drug Administration (FDA) using the standard. This standard is meant to be used for all regulated product (e.g., test kits, drugs, reagents, medicated feeds, etc.), excluding foods. The IG is based on the most up-to-date information from HL7.

The HL7 Stability Standard is for one way communication from a contractor to company, company to company, company to regulatory agency.

HL7 Basics

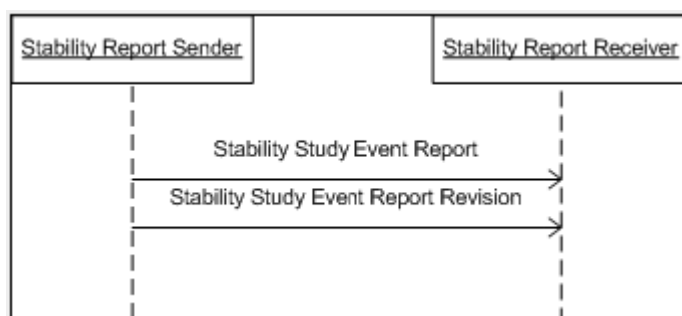
HL7 is defining data exchange standards with “focus on the electronic interchange of clinical, financial and administrative information among independent healthcare-oriented computer systems”.

Besides the definition of data standards, HL7 defines message wrappers that define how to exchange HL7-XML documents between computer systems. These “wrappers” will not be in the scope of this document. Please refer to HL7 “Version 3 Guide, HL7 Messaging Components, V3 message wrappers and Infrastructure” for more details about this.

The Extensible Markup Language (XML) examples given in this Implementation Guide are “fragments” which represent only a small section of the full message and are not valid XML documents or will skip these “control wrappers”. The Extensible Markup Language (XML) examples given in the appendix are full messages that are valid XML documents.

eStability Storyboard

The HL7 storyboard describes two scenarios when using this data standard when sending it from a “Stability Tester” (e.g. a pharmaceutical company) to a “Stability Test Receiver” (e.g. FDA).



Here are the textual examples given by the HL7 Ballot Site:

Interactions: Stability Report (PORT_IN090004UV02)

ChemCentric Drug Company has been working on a new product, CureAll. Development work on the product has been completed, as have many aspects of the regulatory process. One aspect of the regulatory process is to demonstrate the stability of the CureAll product by testing it against an established Testing Specification using an acceptable protocol. ChemCentric has carried out the necessary testing, and reports the test results to the applicable regulatory authority.

Interactions: Stability Report Revision (PORT_IN090005UV02)

Last month, ChemCentric Drug Company submitted a stability study for its new product, CureAll, to the FDA.

However, Dr. Reggie Review has been going over the results of the test. He has discovered a transcription error that could lead reviewers to get an unfair estimation of CureAll's efficacy even after lengthy storage. In order to correct this state of affairs, ChemCentric submits a revised Stability Study.

These two types of messages reference one schema definition:

PORT_MT090002UV02

The act of sending, revising and retracting a stability report will be managed within the context of the eCTD or the message wrapper.

Both schema definitions are identical, but to send a revised message the second schema has to be referenced.

For this reason, only the implementation of the PORT_MT090002UV02 schema will be in the scope of this document.

For further details on the full message Description (Transmission Wrapper and Control Act Wrapper) please refer to the HL7 Web site www.HL7.org, and search for Generic Message Transmission.

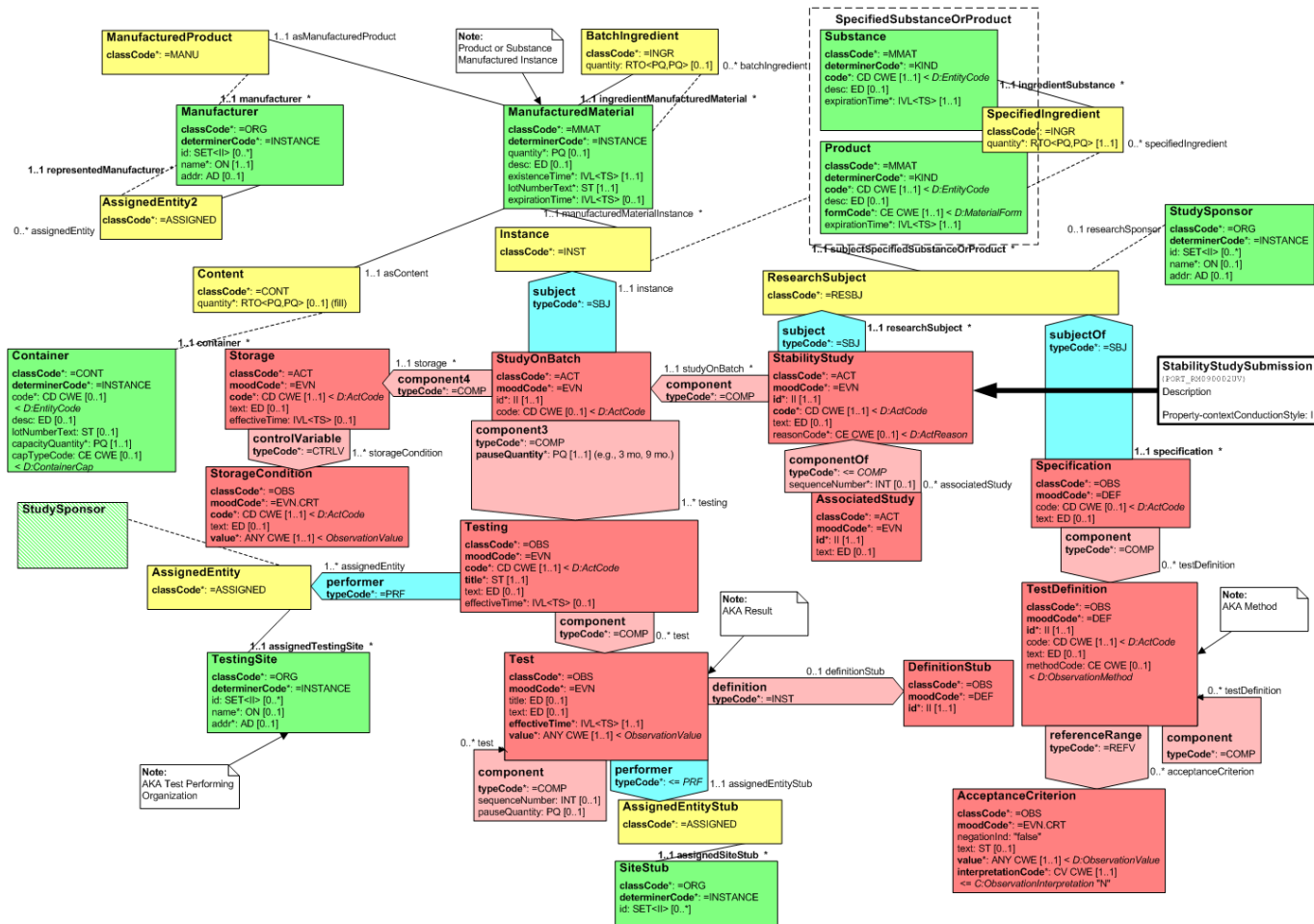
The role of the message when using RPS or eCTD

The eStability message may be used stand-alone or in conjunction with an eCTD or an HL7 "Regulated Product Submission" (RPS) message.

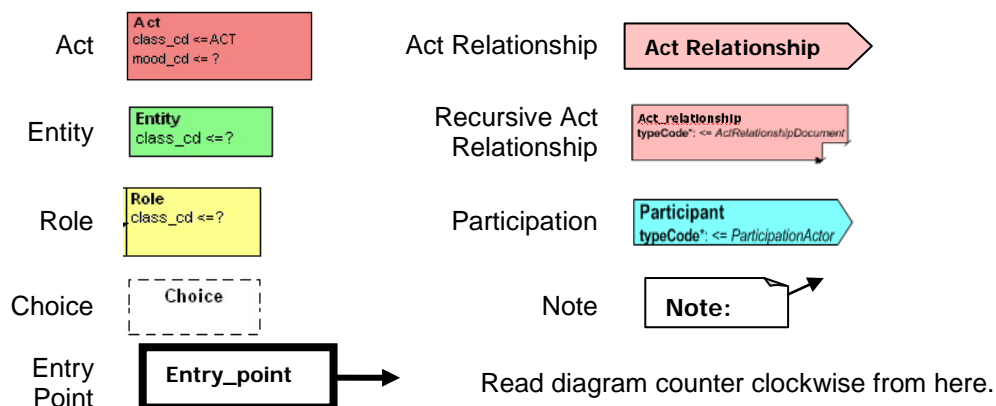
When using stand-alone, the participating parties have to decide which part of the HL7 protocol (i.e. which interactions) should be implemented to fulfill the needs of their communication and if the full scope of the message needs to be implemented (e.g. message header). To implement an HL7 compliant system, all interactions need to be implemented.

In conjunction with a regulated, electronic submission the intention is to only use PORT_IN090004UV02 since the status and purpose of the submission and the usage of the submitted file are already documented with the eCTD or RPS. All "protocol" specific lifecycle information is handled using the mechanism implemented within these standards.

The eStability Model (RMIM)



Legend



Cardinality is expressed in min .. max notation. * is unlimited. E.g.: 0..1 is zero or one.

Elements of an eStability Message

The Drug Stability Report RMIM captures information relevant for the drug stability testing process. This testing is required by regulatory agencies as a component of the drug regulatory process. It verifies the correctness of a manufacturer's claims related to the stability - the ability to be stored over time without losing its therapeutic effectiveness - of a product.

It is important to note that the material that can be reported as part of a Stability Study is not limited to the items explicitly listed as attributes within the RMIM. This is because the "text" attribute in Acts (shown in red on the diagram), and the "desc" attribute in Entities (shown in green on the diagram) can be valued with a Uniform Resource Locator (URL) which provides a link to additional documentation (i.e., you can add hyperlinks to other documents). This additional documentation would either be provided along with the stability report, or would be stored at the location indicated by the URL.

This discussion provides some discussion of the data structures within the model. The review of individual classes is ordered by reference to the messaging entry point. (The messaging entry point indicates the starting point for the message. When the model is serialized, the model contents are ordered, starting with the StabilityStudy class, for transmission as a message.)

The HL7 schema contains many elements, each having various associated attributes. Not all elements and attributes are used by eStability. The IG describes the critical elements, not all attributes are defined. It is recommended that implementers use an XML tool to explore the schema for a comprehensive list of elements and attributes.

Stability Study

The Stability Study serves as the high level defining information for the stability study, and as the entry point for messaging. It represents, in essence, the collection of all test results for a single formulation of a product stored in a single set of storage conditions. Note, in some cases, multiple stability studies may be carried out to provide the entire picture of a product's stability. This class captures information related to the study as a whole, notably the study type, study id, and the reason for the study.

At this point, the primary point of reference is current stability reporting within the United States. The scope of a single transaction or message in this specification has been restricted to only include studies with a single set of storage conditions. However, the stability studies that are filed with regulatory authorities are not simply a study with a single set of storage conditions - the studies include a number of storage conditions plus multiple orientations (upright and inverted). This is especially true for injectable/Parenteral products. These more complex situations, that is to say, studies that require multiple storage conditions and/or orientations (e.g. accelerated, room temperature, inverted, upright, etc.), will be handled through the submission of multiple linked reports, with each report covering a single storage condition and orientation (see AssociatedStudy.)

XML Code example:

```
<stabilityStudy>
  <id root="2.2.3.4.5.6.7.88.99.1.98721.1.3.2.4"/>
  <code code="C96085" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Standard" />
  <text>optional - this is either a text provided by the submitter or an URI to an external document with further
  annotations for this submission. Mandatory for style sheet - the eStability style sheet treats the information entered in
  the text tag as purpose of study.</text>
  <reasonCode code="C72899" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="New Drug Application" />
```

The associations of this class indicate:

researchSubject

A product or substance that participates as the subject of the study, (furthermore, the organization associated with the researchSubject indicates the organization sponsoring the study.)

studyOnBatch

A component study which includes the test results related to testing on a single batch.

Note that a stability study is associated with a single research subject, and one to one instance of StudyOnBatch.

AssociatedStudy

This element is a reference to other stability study messages that contain more data (e.g., for other storage conditions of the current researchSubject, studies for multiple researchSubjects supporting a manufacturing change (new facility), studies for multiple researchSubjects submitted in an annual report, etc.). There is no limit to the number of studies associated. These messages are defined to be associated to the current message in terms of completeness of information of a submission.

subjectSubstance Or subjectProduct

The role of research subject is played by either a drug substance or a drug product, for which the stability study was conducted. It is also possible to use the desc (Description) or text attribute to include a URL link that gives access to additional product information. All special characters used in a message should be coded appropriately for html display. If the product is approved the stylesheet will display the registration number and preferred name. Otherwise the text supplied in the desc element will be displayed. The organization (researchSponsor) that scopes the research subject role indicates the submitter of the study.

The associations of the role and playing entity classes indicate:

- a) the specification that documents the tests that were performed,
- b) the studyOnBatch is the actual batch that provides the samples on which tests are carried out.

Note that a research subject (and hence the stability study) is associated with a single specification.

XML Code example:

```
<researchSubject>
  <subjectProduct>
    <code code="N12345-679" codeSystem="2.16.840.1.113883.6.69" codeSystemName="Food and Drug Administration
Drug Registration and Listing System" displayName="Cure All" />
    <desc> Cure All </desc>
    <formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="TABLET" />
    <expirationTime>
      <width value="24" unit="Month"/>
    </expirationTime>
  </subjectProduct>
</researchSubject>

<researchSubject>
  <subjectSubstance classCode="MMAT" determinerCode="INSTANCE">
    <code code="WYQ7N0BPYC" codeSystem="2.16.840.1.113883.4.9" codeSystemName="Food and Drug Administration
Substance Registration System" displayName="ACETYLCYSTEINE" />
    <desc>
      <reference value="http://www.mycompany.com/example.htm"/>
    </desc>
    <expirationTime>
      <width value="12" unit="month"/>
    </expirationTime>
  </subjectSubstance>
</researchSubject>
```

Specification

This element defines the tests that will be performed to demonstrate stability. Information collected directly about the specification includes the specification type, and associated text or other documentation.

The association of the specification indicates:

- a) the research subject on which the tests are to be performed.
- b) the tests that are to be performed.

Note that a specification contains one to many tests.

XML Code example:

```
<specification>
  <code displayName="SPEC1112121-X12" />
  <text>Optional - Enter a URI for additional documentation.</text>
```

TestDefinition

This element defines the tests that are to be performed. Information collected for the test definition includes the test type, any relevant Description, and the test method. A test can contain multiple component tests. For example, a Physical Appearance test may contain component tests such as Color, Clarity, and Container/Closure Integrity which together characterize the Physical Appearance test. A component test carries the same type of information as the test that it is associated with.

The associations of this class indicate that:

- a) an observation may contain component observations,
- b) performed observations (test results) are evaluated by reference to defined acceptance criteria,
- c) a test definition is associated with each of the tests that are performed.

Although a component test can contain component tests under the HL7 schema. For the purpose of eStability, only one level of component test is used. Continuing with the example above, this means that Color test, which itself a component test, cannot contain component tests.

XML Code example – Test that generates numerical data:

```
<component>
  <testDefinition>
    <id root="2.16.840.1.19927.1.12345.13.32.813" />
    <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
      displayName="Chemical" >
      <originalText>Assay</originalText>
    </code>
    <text>
      <reference value="..\m3\32-body-data\32p-drug-prod\865-acetate-300mg\32p5-analyt-meth\432.pdf"/>
    </text>
    <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
      displayName="Proprietary" >
      <originalText>NH432 Assay</originalText>
    </methodCode>
    <referenceRange>
      <acceptanceCriterion>
        <text></text>
        <value xsi:type="PQ" value="90" unit="%_LC" />
        <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
          displayName="NLT" />
      </acceptanceCriterion>
    </referenceRange>
    <referenceRange>
      <acceptanceCriterion>
        <text></text>
        <value xsi:type="PQ" value="110" unit="%_LC" />
        <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
          displayName="NMT" />
      </acceptanceCriterion>
    </referenceRange>
  </testDefinition>
```

```

    </referenceRange>
  </testDefinition>
</component>

```

XML Code example – Test that generates descriptive data:

```

<component>
  <testDefinition>
    <id root="2.16.840.1.19927.1.12345.9.25.14" />
    <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
    displayName="Physical" >
      <originalText>Appearance</originalText>
    </code>
    <text></text>
    <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
    displayName="Proprietary" >
      <originalText>NH401 General appearance method</originalText>
    </methodCode>
    <referenceRange>
      <acceptanceCriterion>
        <text>Pink round, film-coated tablet scored 99 0T9 one side and plain on the other</text>
        <value xsi:type="ST" nullFlavor="NA" />
        <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Passed" />
      </acceptanceCriterion>
    </referenceRange>
  </testDefinition>
</component>

```

The testDefinition identifiers in the examples above are OIDs. A UID listing would look like this:

```
<id root="f47ac10c-58cc-4372-a765-0e02b2c3d497"/>
```

The same UID must be associated with the test for the life of the dossier (product or substance).

AcceptanceCriterion

Defines the limits within which performed observations are interpreted. Information collected for the acceptance criterion includes the criterion type (quantity or descriptive information), the actual criterion value, an indicator (NMT, NLT, etc) showing whether the criterion or its inverse is to be applied, and descriptive text.

StudyOnBatch

This element represents the information submitted for one physical lot or batch of the researchSubject. It includes the collection of observations (results) that are performed on samples from a single batch. Information collected directly about the study on batch includes a study type and an identifier.

The associations of this class indicate:

- the stability study of which this study on batch is a component,
- the product instance from which samples are drawn,
- the collection of storage and testing time points that make up the study on batch.

XML Code example:

```

<studyOnBatch>
  <id root="2.2.3.4.5.6.7.88.99.1.8888.1.2"/>
  <code code="C96109" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Commercial" />
  <subject typeCode="SBJ">
    <instance classCode="INST" >
      <manufacturedMaterialInstance classCode="MMAT" determinerCode="INSTANCE" >
        <quantity xsi:type="PQ" value="10000" unit="tube" />
        <desc></desc>
        <existenceTime>
          <high value="20020630" />
        </existenceTime>
        <lotNumberText>FDS6758AA</lotNumberText>
        <expirationTime>
          <high value="20040630" />
        </expirationTime>
      </instance>
    </subject>
  </studyOnBatch>

```

```

</expirationTime>
<asManufacturedProduct>
  <manufacturer>
    <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
    <name>ABC Co.</name>
    <addr>
      <country>USA</country>
      <state>MO</state>
      <city>St. Louis</city>
      <postalCode>32142</postalCode>
      <streetAddressLine>100 North Blvd.</streetAddressLine>
    </addr>
    <assignedEntity>
      <representedManufacturer>
        <id root="D987654321" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
        <name>Watts and Sons</name>
        <addr>
          <country>US</country>
          <state></state>
          <city>Denver</city>
          <postalCode>12121</postalCode>
          <streetAddressLine>9876 Big Road</streetAddressLine>
        </addr>
      </representedManufacturer>
    </assignedEntity>
  </manufacturer>
</asManufacturedProduct>
<asContent>
  <quantity>
    <numerator xsi:type="PQ" value="8" unit="g" />
    <denominator xsi:type="PQ" value="1" unit="tube" />
  </quantity>
  <container>
    <code code="C43207" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="TUBE, WITH APPLICATOR" />
    <desc></desc>
    <lotNumberText>tube321</lotNumberText>
    <capacityQuantity xsi:type="PQ" value="10" unit="g" />
    <capTypeCode code="C96133" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Snap-on Cap, Plastic" />
  </container>
</asContent>
</manufacturedMaterialInstance>
</instance>
</subject>

```

Storage

This class collects the storage conditions that are applicable to the testing done on the samples drawn from a batch. Information collected about storage includes the storage type, descriptive text, and the effective date on which the sample was placed into storage.

The associations of the storage act indicate:

- a) the study on batch related to the storage,
- b) the storage conditions that define the way the sample is stored.

Note that a storage act is associated with a single study on batch, and with one to many storage conditions.

StorageCondition

A storage condition should be considered as an intervention applied to a collection of samples. Each condition indicates a single parameter of storage (e.g., temperature, humidity, the orientation of the product container). Information collected about the storage condition includes the condition type, the descriptive text, and the condition value.

XML Code example:

```

<component2>
  <storage>

```

```

code code="C96146" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="ICH"
/>
<text></text>
<effectiveTime value="20090727"/>
<controlVariable>
  <storageCondition>
    <code displayName="ICH25C60RH" />
    <text></text>
    value xsi:type="ST">25±176;C ± 2±176;C/60% RH ± 5% RH</value>
  </storageCondition>
</controlVariable>
</storage>
</component2>

```

Instance(Manufactured Material)

The role of instance is played by manufactured material. This is some amount of product or substance drawn from a specific manufactured or formulated batch. As with test definition, the same class is used to define the information captured about the material tested and ingredients of which it is made up. Information collected includes the amount of material provided for testing, descriptive text, the production date, expiration date, and batch lot number.

The associations of the role and playing entity indicate:

- the product or substance of which the batch is an instance,
- the study on batch that uses samples from this batch,
- the ingredients that the product contains (Note that the BatchIngredient role class creates a recursive association. Therefore, it is possible to value the same data and associations for an ingredient of a product as for the product itself.) An ingredient can be part of a product,
- the manufacturer of the batch,
- the container used to contain the product.

Note that the manufactured material instance, is an instance of a single product or substance, is used in a single study on batch, is produced by a single manufacturer, is stored in a single type of container, and contains one to many ingredients. A manufactured material in the role of ingredient is used in one and only one product (within the context of this model).

Manufacturer

This role and scoping organization indicates the manufacturer of the product. Information collected includes the manufacturer name, an identifier, and an address. The identifier (Object Identifier, or OID) should be entered as a stand alone number, if a D-U-N-S® Number from Dun and Bradstreet (DUNS) number or FEI number is used it should have a prefix of "D" or "F", respectively and the hyphens removed is present (e.g., 2.3.4.5.6.7.88.99 for OID, D123456789 for DUNS, and F1234567890 for FEI). More detailed discussion about the OID is available later in this document.

The association of the organization indicates that the manufacturing site for a product can be carrying out that work as an assignee of another organization - the scoping organization.

Note that the manufacturing site can be carrying out the work as the assignee of zero to many scoping organizations.

Container

This role and scoping entity indicate the container within which the product is to be delivered, and within which samples for study will be contained. Information collected about the container includes the container type, the descriptive text, the container lot number, the capacity of the container, and the cap (closure system) type. The actual quantity in the container is also captured as an attribute of the content role.

(TimePoint)Testing

This class indicates the particular time point at which a sample is drawn from storage so that tests may be performed on it or on portions of the sample. Information collected about the testing act include the testing type, a title that labels the collection of related tests, descriptive text, and the effectiveTime on which samples were drawn (i.e., scheduled sample pull date). Note, component pauseQuantity indicates the sampling time point (e.g., three months, associated with the testing)

The associations of the testing act indicate:

- a) the study on batch,(i.e., a particular lot) related to the testing,
- b) the collection of observations that are performed on the sample or samples drawn at a particular testing time point.

Note that a testing act is associated with a single study on batch, and with one to many tests.

XML Code example:

```
<component1>
  <pauseQuantity xsi:type="PQ" value="0" unit="day" />
  <testing>
    <code code="C96150" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="Immediate" />
    <title>Initial testing</title>
    <text></text>
    <effectiveTime value="20020724" />
    <performer>
      <assignedEntity>
        <assignedTestingSite>
          <id root="D987654321" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
          <name>Do All Labs</name>
          <addr>
            <country>USA</country>
            <state>CA</state>
            <city>Irvine</city>
            <postalCode>92680</postalCode>
            <streetAddressLine>1122 Green Blvd.</streetAddressLine>
          </addr>
        </assignedTestingSite>
      </assignedEntity>
    </performer>
    <performer>
      <assignedEntity>
        <assignedTestingSite>
          <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
          <name>XYZ Pharmaceuticals, Inc.</name>
          <addr>
            <country>USA</country>
            <state>CA</state>
            <city>Utopia</city>
            <postalCode>90021</postalCode>
            <streetAddressLine>84 Main Street</streetAddressLine>
          </addr>
        </assignedTestingSite>
      </assignedEntity>
    </performer>
  </testing>
  <component>
    <test classCode="OBS" moodCode="EVN">
      <text></text>
      <effectiveTime value="20020724" />
      <value xsi:type="PQ" value="100.1" unit="mg" />
      <performer typeCode="PRF">
        <assignedEntityStub>
          <assignedSiteStub>
            <id root="D987654321" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
          </assignedSiteStub>
        </assignedEntityStub>
      </performer>
    </test>
    <definition>
      <definitionStub>
        <id root="2.2.3.4.5.6.7.88.99.1.8888.1.2.5.1.1" />
      </definitionStub>
    </definition>
  </component>
</component1>
```

```
</definition>  
</test>  
</component>
```

Test

This class indicates the performance of a test on a sample drawn from storage at a particular time point. Information collected about the test includes descriptive text, the specific time at which the test was performed, and the test result (value).

The associations of observation indicate:

- a) the observation definition for the observation (test, result) being performed,
- b) the testing point in time at which the sample is drawn from storage,
- c) whether component test instances are performed at particular points in time - indicated by pause quantity - after being drawn from storage,
- d) the organization (testing site) performing the test.

Note that a test has a single definition, is performed on a sample drawn from storage at a single point in time, and is performed at a single test site. A test may have multiple test components.

AssignedEntity(TestingSite)

The testing site entity makes it possible to indicate the particular site at which the test took place.

Detailed Description of eStability Elements

Required XML Elements

XML Schema and Validation

The eStability file is defined in the PORT_HD090002UV02.xmd schema. However, this file contains only an abstract definition, and thus cannot be used directly for validation of the eStability file. By design, it is the “payload” of an HL7 message of the type PORT_IN090004UV02.

To correctly validate the eStability XML file, it is necessary to wrap it in a message header, though this may be completely empty, i.e. no real data has to be present inside the message header elements.

This is how the message header may look:

```
<?xml version="1.0" encoding="UTF-8"?>
<PORT_IN090004UV02
  xsi:schemaLocation="urn:hl7-org:v3 PORT_IN090004UV02.xsd"
  ITSVersion="XML_1.0" xmlns="urn:hl7-org:v3"
  xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance">
  <id/>
  <creationTime/>
  <interactionId/>
  <processingCode/>
  <processingModeCode/>
  <acceptAckCode/>
  <receiver typeCode="RCV">
    <device determinerCode="INSTANCE" classCode="DEV">
      <id/>
    </device>
  </receiver>
  <sender typeCode="SND">
    <device determinerCode="INSTANCE" classCode="DEV">
      <id/>
    </device>
  </sender>
  <controlActProcess moodCode="EVN">
    <subject>
      <!--eStability data begins here.-->
      <stabilityStudy>
        ...
      </stabilityStudy>
      <!--eStability data ends here.-->
    </subject>
  </controlActProcess>
</PORT_IN090004UV02>
```

The schema location as stated in the example above would require all referenced XML Schemas to reside in the same directory as the eStability file itself. As these are quite many, this is not very

preferable. Instead, a path to the XML Schema can be stated in the xsi:schemaLocation attribute of the PORT_IN090004UV02 element, like:

`xsi:schemaLocation="urn:hl7-org:v3`

`C:\HL7\3ballot\html\processable\multicacheschemas\PORT_IN090004UV02.xsd"`

Unique Identifiers (UID)

The same UID must be associated with the same entities for the life of the dossier (product or substance). The different types of UIDs used in the message are OIDs and GUIDs (see below).

Object Identifiers (OID)

Object Identifiers (OID) are used to uniquely identify an object. They are created by self-extending a private enterprise number that is acquired by an institution and are managed hierarchically.

OID's are intended to be globally unique. They are formed by taking a unique numeric string (e.g. 2.3.5.7.9.24.68) and adding additional digits in a unique fashion (e.g. 2.3.5.7.9.24.68.1, 1.3.5.7.9.24.68.2, 1.3.5.7.9.24.68.1.1, etc.) An institution will acquire an arc (e.g., 2.3.5.7.9.24.68) and then extend the arc (called subarcs) as indicated above to create additional OID's and arcs. There is no limit to the length of an OID, and virtually no computational burden to having a long OID.

OID's are only used for "equality-matching". That is, two objects (e.g. directory attributes or certificate policies) are considered to be the same if they have exactly the same OID. There are no implied navigational or hierarchical capabilities with OID's (unlike IP addresses, for example); given an OID it is not easily possible to deduce who owns the OID, related OID's, etc. OID's exist to provide a unique identifier, recognizing that in a decentralized world, organizations may pick the same identical names for objects that they manage.

Though acquiring and management of OID's are out of scope in this document, the HL7 Object Identifier Registry may be a good starting point for further investigations: <http://www.hl7.org/oid/>

Usage of OIDs within eStability (example)

The basis of the OID usage within eStability is a root or arc OID which is identifying the company. This root OID may be used as "id" attribute of the "Organization" element.

This root element is extended by one or more digits to uniquely identify a product – this OID could be used with the "code" attribute of the "Product" or "Substance" element (e.g. company's OID is 2.3.6.1.4.1.24263, the according product OID might be 2.3.6.1.4.1.24263.1.32 – for some internal reason there is a substructure in the added digits). This OID could be registered with the approving agency and could be used to uniquely identify the product throughout all submissions.

This OID is extended by a "1" to distinguish all subsequent stability related identifiers from identifiers of other HL7 schemas belonging to the same product or substance.

For each product one or many studies are performed, which could be indicated by one or many additional digits (e.g. the company decides to simply number all studies performed for the product. Thus the 6th study has the OID 2.3.6.1.4.1.24263.1.32.1.6). This OID could be used for the "id" element of "StudyOnBatch".

Each report created for this study could have at least one additional digit within this structure (e.g. the third report is identified by 2.3.6.1.4.1.24263.1.32.1.6.3. A company can decide to map its versioning to this numbering schema).

Since one Stability Data File covers only one storage condition, in some cases many files will be submitted (e.g. when providing additional accelerated data with normal conditions). Each data file is identified by an additional digit (e.g. the first data file for the 3rd report is identified by 2.3.6.1.4.1.24263.1.32.1.6.3.1). This identifier is used as "id" attribute of the "StabilityStudy" element.

All other "id" attributes could be created uniquely within a file, i.e. the OID of the file should be extended in an ambiguous but unique way for each identifier.

Full example of OIDs in one Stability Data File:

Company	2.3.6.1.4.1.24263
Product / Application	2.3.6.1.4.1.24263.1.32
Stability related branch	2.3.6.1.4.1.24263.1.32.1
Study	2.3.6.1.4.1.24263.1.32.1.6
Report	2.3.6.1.4.1.24263.1.32.1.6.3
File of a report	2.3.6.1.4.1.24263.1.32.1.6.3.1
5 th Testdefinition of the spec	2.3.6.1.4.1.24263.1.32.1.6.3.1.5
4 th parameter of this Testdefinition (i.e. the second level of Testdefinition)	2.3.6.1.4.1.24263.1.32.1.6.3.1.5.4

The company OID in the above example is not derived from a DUNs number.

Usage of GUID within eStability

The usage of GUIDs (Globally Unique Identifier, see <http://en.wikipedia.org/wiki/GUID> for definition and examples) (e.g., B60C66C7-C91A-43BC-A071-284BDA91EFA2) in the context of the eStability message is an alternative approach for unique identifying objects within this message. The nature of GUIDs does not allow any systematic mapping of a structure as discussed in the last chapter. The context of OIDs, the submitting organization has to ensure that the GUIDs used across multiple submissions are consistent and that the same entities can be referenced across multiple messages using the same GUID.

Notation

Each of the following tables describes a structural element of the eStability XML document. They are ordered in the way the HL7 HMD is presenting these elements (i.e. a walk through of the XML model element by element following the “right-hand” rule).

Graphical schema representations are added to give a first impression of the referenced elements XML elements.

For orientation purposes, an XPath is provided to locate the element described in the table. An XPath is comparable to the well known directory path of PC or UNIX systems:

For example:

“SpecifiedIngredient” is a child element of “Product” which is a child of “ResearchSubject” which is a child of “Subject2” which is a child of the root element “StabilityStudy”, written as

`/stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient`

(Note the difference between the Names of the element, and their actual representation in the XPath.)

All element tables have two additional columns to indicate HL7 Optionality (H), and FDA Optionality (F).

Valid values for these columns are:

M – Mandatory (the information has to be provided in any case)

R – Required (the information should be provided if available)

O – Optional (the information can be provided)

N – Not used

Common Elements

ACTCODE

ACTCODE elements describe code values such as:

Element	Attribute	Code List
StabilityStudy	Code	Type of Data File
Product	Code	Product Code
Product	formCode	Product Form Code
Substance	Code	Substance Code
Specification	Code	Internal specification code
Testdefinition	Code	Test Code
StudyOnBatch	Code	Study Type
Container	Code	Container Code
Storage	Code	Storage code
StorageCondition	Code	Storage Condition Code
Testing	Code	Pause Description Code

ACTCODE – Elements

For an ACTCODE in the FDA implementation, only the “displayName” is required.

The code attributes (when specified) define the originator of the term used in the displayName attribute. For consistency, eStability has established specific terminologies used for the displayName attribute. Please refer to the Code Lists section.

The code, codeSystem, and displayName attributes are mandatory when a code list has been defined (see [Code Lists section](#)).

Attributes:

Name	Description	H	F
code	The code value for the given code system.	R	M
codeSystem	The OID of the code system.	R	M
codeSystemName	The name of the code system.	R	R
codeSystemVersion	The version of the code system used.	R	R
displayName	A displayable name of the code system code. When used by testDefinition, the displayName attribute documents the Test Type (such as “Chemical”, “Physical”, or “Biological”).	R	M

Complex Children:

Name	Description	H	F
originalText	Mandatory when used by testDefinition to document the Test Name; otherwise, not used.	N	N
translation	Not used.	N	N

Sample Code

Suppose “code” being an ACTCODE:

Example when code, codeSystem, and codeSystemName are not required:

```
<storageCondition>
  <code displayName="ICH25C60RH" />
  <text></text>
  value xsi:type="ST">25&#176;C ± 2&#176;C/60% RH ± 5% RH</value>
</storageCondition>
```

Mandatory example:

```
<code code="C96085" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Standard" />
```

ACTREASON

ACTREASON elements in eStability describe code values such as:

Element	Attribute	Meaning
StabilityStudy	reasonCode	Reason for Data File
Testdefinition	methodCode	Method Type Code

ACTREASON – Elements

The code attributes (when specified) define the originator of the term used in the displayName attribute. For consistency, eStability has established specific terminologies used for the displayName attribute. Please refer to the Code Lists section.

The code, codeSystem, and displayName attributes are mandatory when a code list has been defined (see [Code Lists section](#)).

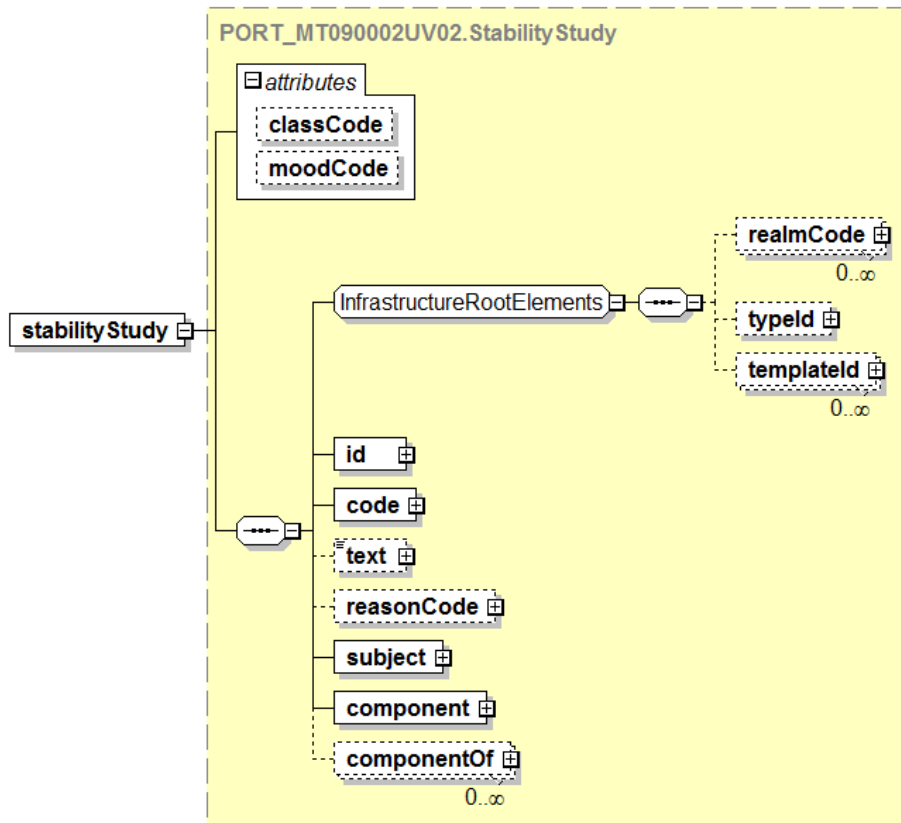
Attributes:

Name	Description	H	F
code	The code value for the given code system.	R	M
codeSystem	The OID of the code system.	R	M
codeSystemName	The name of the code system.	R	R
codeSystemVersion	The version of the code system used.	R	R
displayName	A displayable name of the code system code. When used by methodCode, the displayName attribute documents the Test Method Type (such as “Compendial” or “Proprietary”)	R	M

Complex Children:

Name	Description	H	F
originalText	Mandatory when used by methodCode to document the Test Method designation; otherwise, not used.	N	N
translation	Not used.	N	N

StabilityStudy – Type



StabilityStudy

/stabilityStudy

Description:

The root element of the document.

Simple Children:

Name	Type	Description	H	F	
Id	II	The global unique identifier for the document.	M	M	
		Attributes			
		Root			ID for this document
code	CE	An ACTCODE which describes the type of document sent. (See page 71).	M	M	
text	ED	The submitter can either provide text or an URI to an external document with further annotations for this submission. If you want to track an internal number (e.g., study number) enter it in this field. The eStability stylesheet displays this information as “Study Purpose”.	O	O	
reasonCode	CE	An ACTREASON which describes the reason for this document. (See page 72).	R	M	

StabilityStudy /stabilityStudy				
Complex Children:				
Name	Type	Description	H	F
subject	Subject1	A complex structure to describe the researchsubject of the study (exactly one provided).	M	M
component	Component5	A complex structure to describe a batch and the studies performed on this batch and reported in this document (one or many provided).	M	M
componentOf	Component	A complex structure that can occur multiple times and that contains a reference to another eStability message.	O	O

Sample Code

```

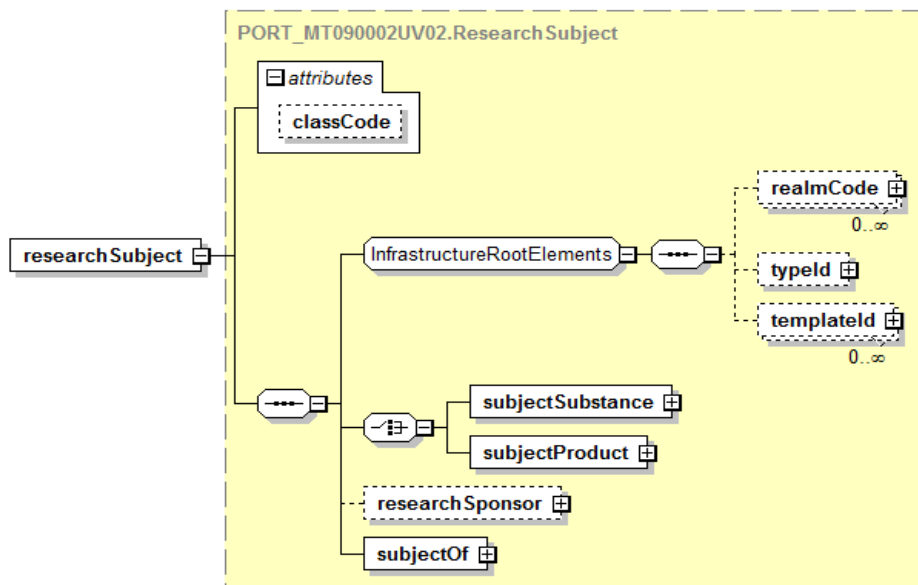
<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.1.1"/>
  <code code="C96085" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Standard" />
  <text>JBE1000-7196</text>
  <reasonCode code="C82667" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Investigational Device Exemption" />
  <subject>
    <researchSubject>
      ...
    </researchSubject>
  </subject>
  <component>
    <studyOnBatch>
      ...
    </studyOnBatch>
  </component>
  < componentOf >
    <associatedStudy>
      ...
    </associatedStudy>
  </ componentOf >
</stabilityStudy>

```

Subject1 – Type

Subject1 /stabilityStudy/subject				
Description:				
Intermediate element				
Complex Children:				
Name	Type	Description	H	F
researchSubject	ResearchSubject	A complex structure to describe the researchsubject (exactly one provided).	M	M

Research Subject – Type



ResearchSubject

/stabilityStudy/subject/researchSubject

Description:

This is the subject of this study. This can either be a “Product” or a “Substance” – only one has to be provided – so the “M” is exclusive on one of the elements.

Information about the included “Substances” of a “Product” can be provided.

Complex Children:

Name	Type	Description	H	F
subjectSubstance	Substance	Active ingredient (exactly one).	M	M
subjectProduct	Product	Finished dosage form (exactly one).	M	M
researchSponsor	StudySponsor	Research Sponsor.	O	R
subjectOf	Subject3	Reference to the specification used in this study.	M	M

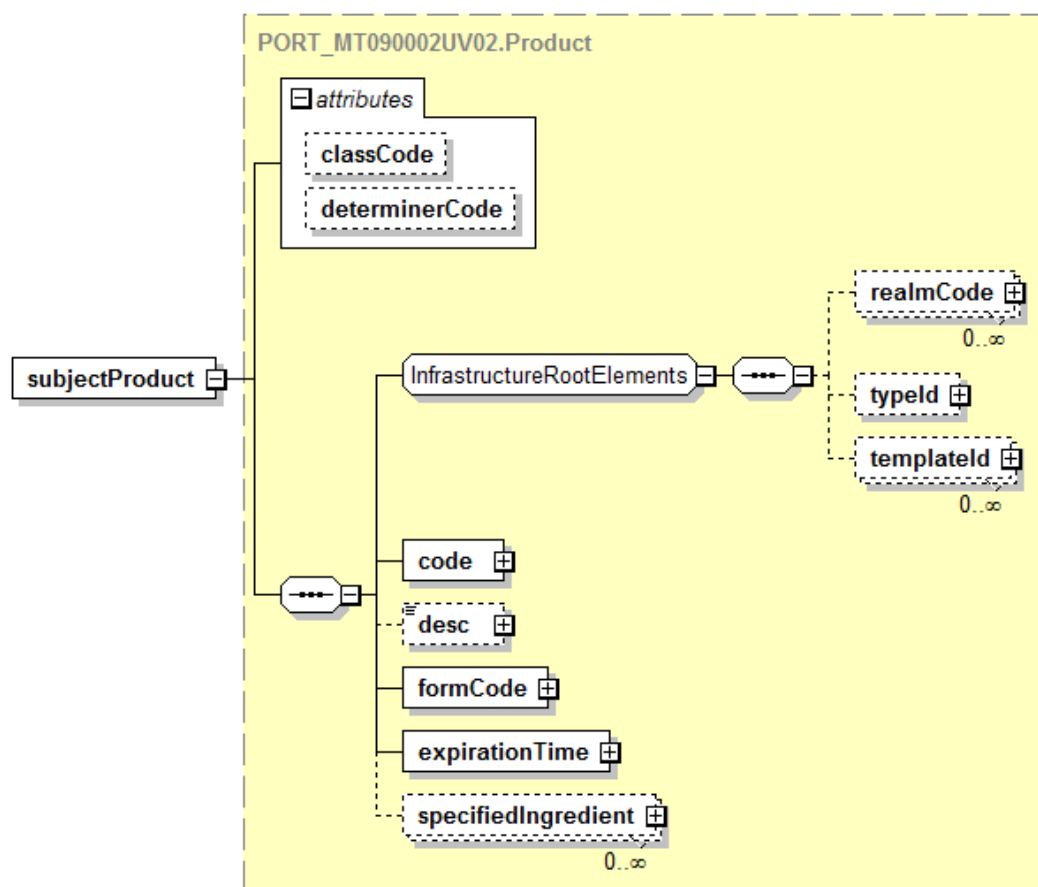
Sample Code

```

<researchSubject>
  <subjectProduct>
    <code code="N12345-678" codeSystem="2.16.840.1.113883.6.69" codeSystemName=" Food and Drug
Administration Drug Registration and Listing System" displayName="JBE1000"/>
    <desc>Gummi Bears 100g Bag</desc>
    <formCode displayName="Not provided"/>
    <expirationTime/>
  </subjectProduct>
  <researchSponsor>
    ...
  </researchSponsor>
  <subjectOf>
    <specification>
      ...
    </specification>
  </subjectOf>
</researchSubject>

```


Product – Type



Product

/stabilityStudy/subject/researchSubject/subjectProduct

Description:

Complex structure to describe a finished dosage form. This is for the product as a whole as it is at the time of this submission, not the specific lot of product contained in this report.

Simple Children:

Name	Type	Description	H	F
code	CE	<p>An ACTCODE: ProductCode (i.e. a unique identifier of the product). (See page 73).</p> <p>For FDA implementation, only the "displayName" (i.e. the product name) is mandatory. If the NDC number exist for the product, it should be entered and prefix with "N".</p> <p>For NDA this is a new identifier.</p> <p>For ongoing studies the identifier must be identical to the already submitted code.</p>	M	M
desc	ED	<p>The product name must be put here and should be listed first. A description of the product provided by the submitter or an URI for additional external documentation. This is where the expirationTime can be specified as an expiration date and/or a dating period.</p>	O	M

Product /stabilityStudy/subject/researchSubject/subjectProduct				
formCode	CE	An ACTCODE: Form type of this product. (See page 73).	M	M
expirationTime	IVL_TS	The “approved” or “proposed” expiration period (e.g. 24 Months expressed using the width tag, see example code below) for NDA, or the existing expiration period for ongoing studies. This value works in conjunction with the “expirationTime” in “ManufacturedMaterial”.	R	M
Complex Children:				
Name	Type	Description	H	F
specifiedIngredient	SpecifiedIngredient	The formulation of this product (many, if necessary).	O	R

Sample Code

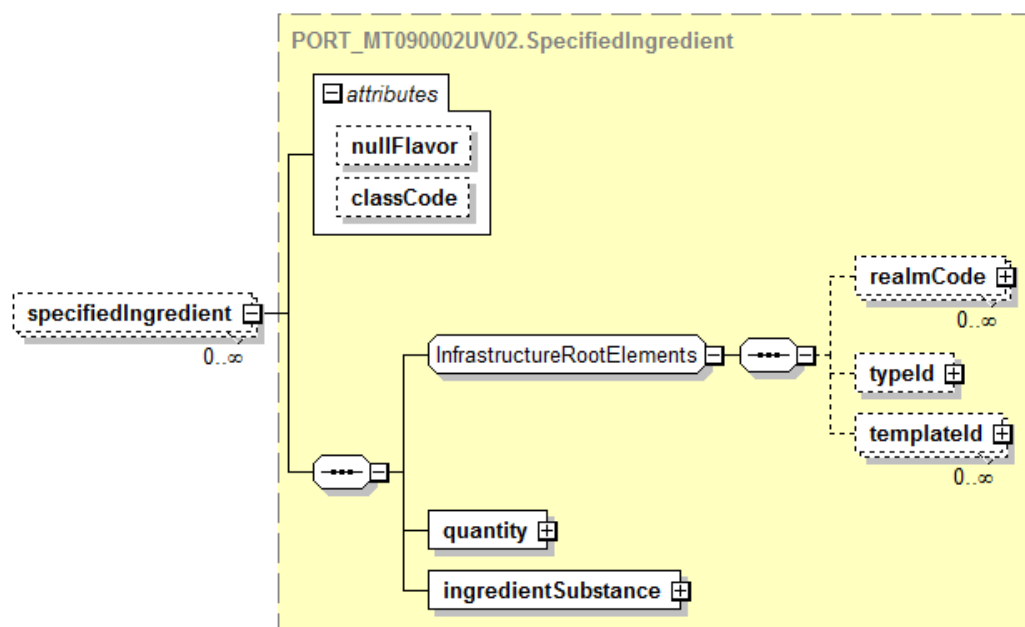
```

<researchSubject>
  <subjectProduct>
    <code code="N12345-679" codeSystem="2.16.840.1.113883.6.69" codeSystemName=" Food and Drug
Administration Drug Registration and Listing System" displayName="Cure All"/>
    <desc>Cure All</desc>
    <formCode code="C42998" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="TABLET" />
    <expirationTime>
      <width value="24" unit="Month"/>
    </expirationTime>
    <specifiedIngredient>
      <quantity>
        <numerator xsi:type="PQ" value="500" unit="mg"/>
        <denominator xsi:type="PQ" value="1" unit="tablet"/>
      </quantity>
      <ingredientSubstance determinerCode="INSTANCE">
        <code code="WYQ7N0BPYC" codeSystem="2.16.840.1.113883.4.9" codeSystemName="Food and Drug
Administration Substance Registration System" displayName="ACETYLCYSTEINE" />
        <desc></desc>
        <expirationTime/>
      </ingredientSubstance>
    </specifiedIngredient>
    <specifiedIngredient>
      <quantity>
        <numerator xsi:type="PQ" value="200" unit="mg"/>
        <denominator xsi:type="PQ" value="1" unit="tablet"/>
      </quantity>
      <ingredientSubstance determinerCode="INSTANCE">
        <code code="J2B2A4N98G" codeSystem="2.16.840.1.113883.4.9" codeSystemName="Food and Drug
Administration Substance Registration System" displayName="LACTOSE" />
        <desc></desc>
        <expirationTime/>
      </ingredientSubstance>
    </specifiedIngredient>
  </subjectProduct>

```

The codeSystemName is required. Note that in the above example for Substance, the codeSystemName matches the codeSystem.

SpecifiedIngredient – Type



SpecifiedIngredient

/stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient

Description:

With this element one can map the formulation of the product by referencing substances and providing information on the quantity of the substance used in the product.

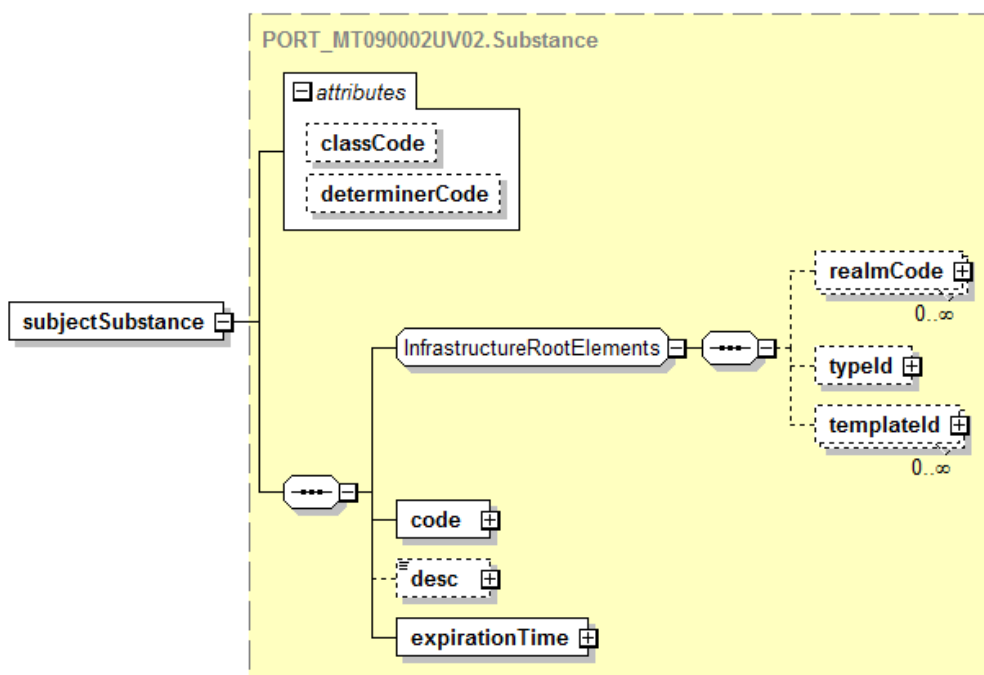
Simple Children:

Name	Type	Description	H	F
quantity	RTO_PQ_PQ	The quantity of the referenced substance in the product.	R	R

Complex Children:

Name	Type	Description	H	F
ingredientSubstance	Substance	Reference to substance, i.e. active ingredient.	M	M

Substance – Type (ingredientSubstance and subjectSubstance)



Substance

/stabilityStudy/subject/researchSubject/subjectSubstance

Description:

When used as a child of “ResearchSubject” this element describes the substance on which the study is performed. This is for the substance as a whole as it is at the time of this submission, not the specific lot of substance contained in this report. The Preferred Substance Name must be used as listed at the FDA Substance Registration System - Unique Ingredient Identifier (UNII) web page, <http://fdasis.nlm.nih.gov>.

Simple Children:

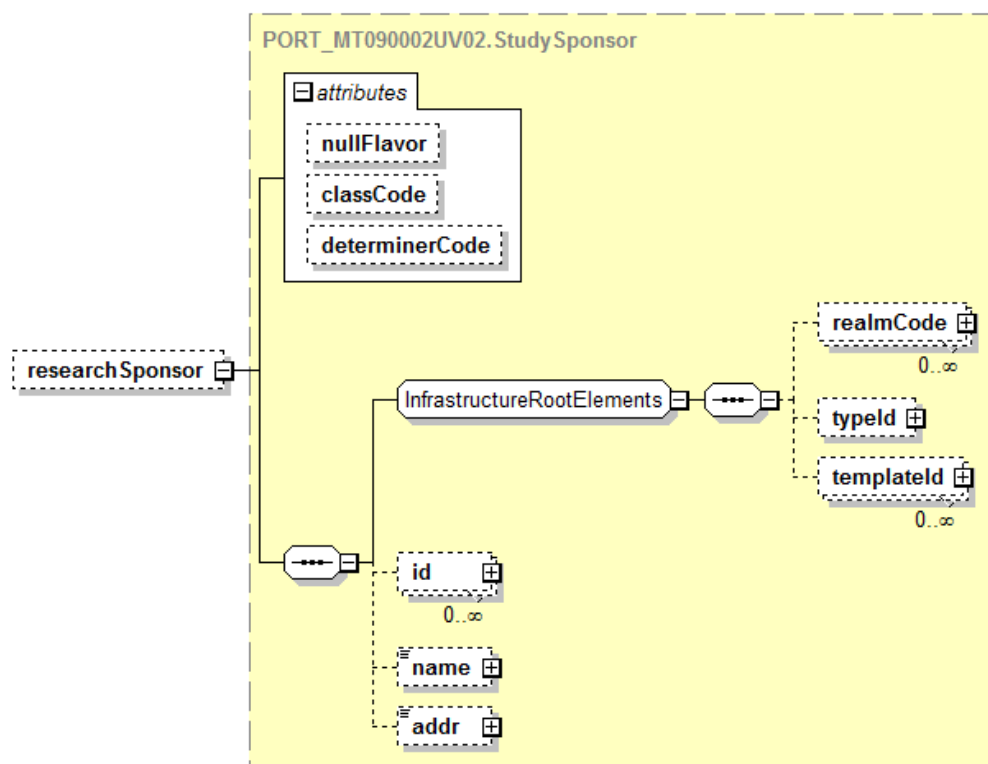
Name	Type	Description	H	F
code	CE	An ACTCODE: code of the substance. (See page 74).	M	M
desc	ED	URI for additional documentation. This is where the expirationTime can be specified as a retest date, an expiration date and/or a dating period.	O	O
expirationTime	IVL_TS	The “approved” or “proposed” expiration period (e.g. 24 Months expressed using the width tag, see example code below) for the substance, or the existing expiration period for ongoing studies. This value works in conjunction with the “expirationTime” in “ManufacturedMaterial”.	R	M

Sample Code

```
<researchSubject>
  <subjectSubstance classCode="MMAT" determinerCode="INSTANCE">
    <code code="WYQ7N0BPYC" codeSystem="2.16.840.1.113883.4.9" codeSystemName="Food and Drug
Administration Substance Registration System" displayName="ACETYLCYSTEINE" />
    <desc>
      <reference value="http://www.mycompany.com/example.htm"/>
    </desc>
    <expirationTime>
      <width value="12" unit="month"/>
    </expirationTime>
  </subjectSubstance>
</researchSubject>
```

The codeSystemName is required. Note that in the above example for Substance, the codeSystemName matches the codeSystem.

StudySponsor – Type



StudySponsor

/stabilityStudy/subject/researchSubject/researchSponsor

Description:

The research sponsor for the study.

Simple Children:

Name	Type	Description	H	F												
id	II	<p>A set of identifiers used to uniquely identify the study sponsor.</p> <p>Use the DUNS number as the primary identifier. Other examples can be FEI number or a global unique identifier for the sponsoring organization assigned by IANA. For DUNS number, remove hyphens if present and prefix with "D" and if an FEI number prefix with an "F". Note: The assigningAuthorityName for a DUNS number is "Dun and Bradstreet D-U-N-S Number" and for a FEI number is "FDA FEI OID". A DUNS number and FEI number example are shown here. The assigning authority name is mandatory for all OIDs for organizations. Always list the DUNS number first if listing multiple numbers. It is the submitter's responsibility to ensure that the DUNS number id along with the firm's postal code (if any) and country match the DUNS number, postal code and country in the Dun and Bradstreet database.</p> <p><id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <id root="F1234567890" assigningAuthorityName="FDA FEI OID"/>.</p> <table><tr><th colspan="4">Attributes</th></tr><tr><td>Root</td><td>Identifier</td><td>M</td><td>M</td></tr><tr><td>assigningAuthorityName</td><td></td><td>N</td><td>M</td></tr></table> <p>This identifier should be the same for one organization within all submissions of one company. .The provided identifiers should be chosen in a way, that if a company has more than one location (e.g., with different addresses), the identifier is specific for this location (same address – same number).</p>	Attributes				Root	Identifier	M	M	assigningAuthorityName		N	M	O	M
Attributes																
Root	Identifier	M	M													
assigningAuthorityName		N	M													
name	ON	Name of the organization sponsoring the study.	R	M												
addr	AD	Address of the organization.	O	M												

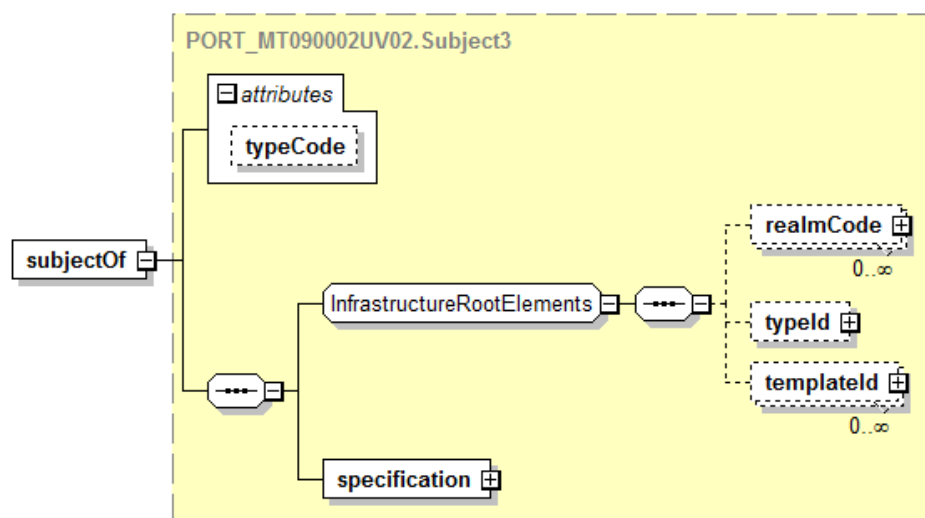
Sample Code

```

<researchSponsor>
  <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
  <id root="2.3.6.1.4.1.24263" assigningAuthorityName="Internet Assigned Numbers Authority"/>
  <id root="F1234567890" assigningAuthorityName="FDA FEI OID"/>
  <name>up to data professional service GmbH</name>
  <addr>
    <country>Germany</country>
    <city>Wörrstadt</city>
    <postalCode>55286</postalCode>
    <streetAddressLine>Am Pfäddchen 4</streetAddressLine>
  </addr>
</researchSponsor>

```

Subject3 – Type



Subject3

/stabilityStudy/subject/researchSubject/subjectOf

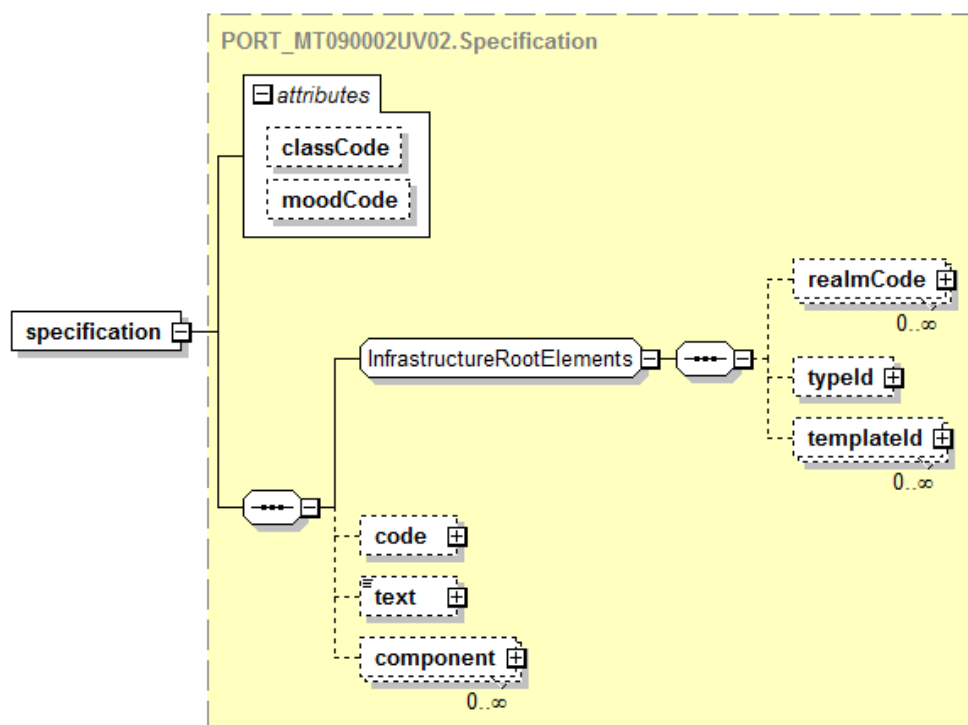
Description:

Reference to the specification (intermediate element).

Complex Children:

Name	Type	Description	H	F
specification	Specification	(Exactly one.)	M	M

Specification - Type



Specification				
/stabilityStudy/subject/researchSubject/subjectOf/specification				
Description:				
For this Element the “full” HL7 structure has to be provided for the specification.				
Simple Children:				
Name	Type	Description	H	F
code	CD	An ACTCODE: Specification identifier. i.e., the name and version of the specification (as displayName).	O	M
text	ED	URI for additional documentation.	O	R
Complex Children:				
Name	Type	Description		
component	Component6	The testdefinition and acceptance criteria for these tests.	O	M

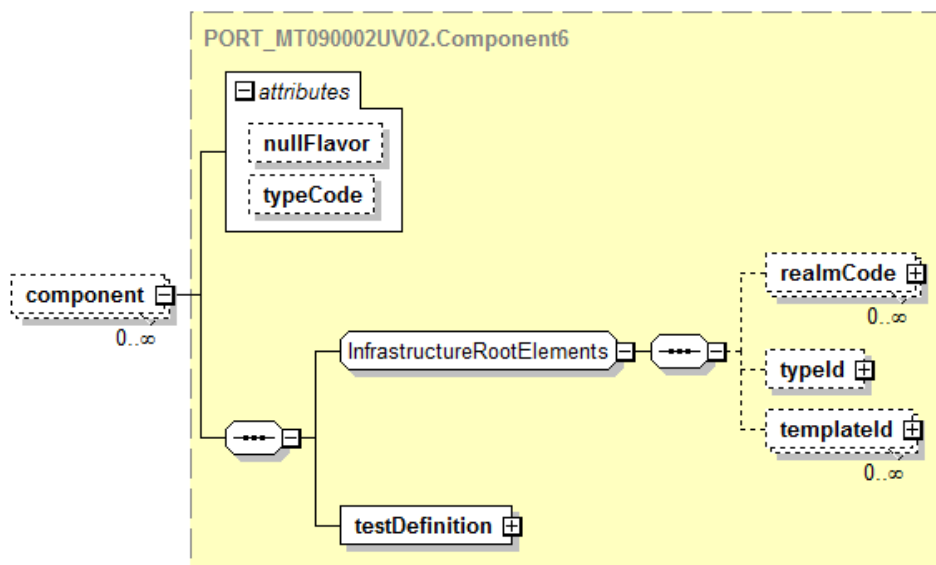
Sample Code

```

<specification>
  <code displayName="JBE1000 Version 3.5 as of 2. Jan 2007"/>
  <text>
    <reference value="//Spec_JBE1000_3.5.pdf"/>
  </text>
  <component>
    <testDefinition>
      ...
    </testDefinition>
  </component>
</specification>

```


Component6 - Type



Component6

/stabilityStudy/subject/researchSubject/subjectOf/specification/component

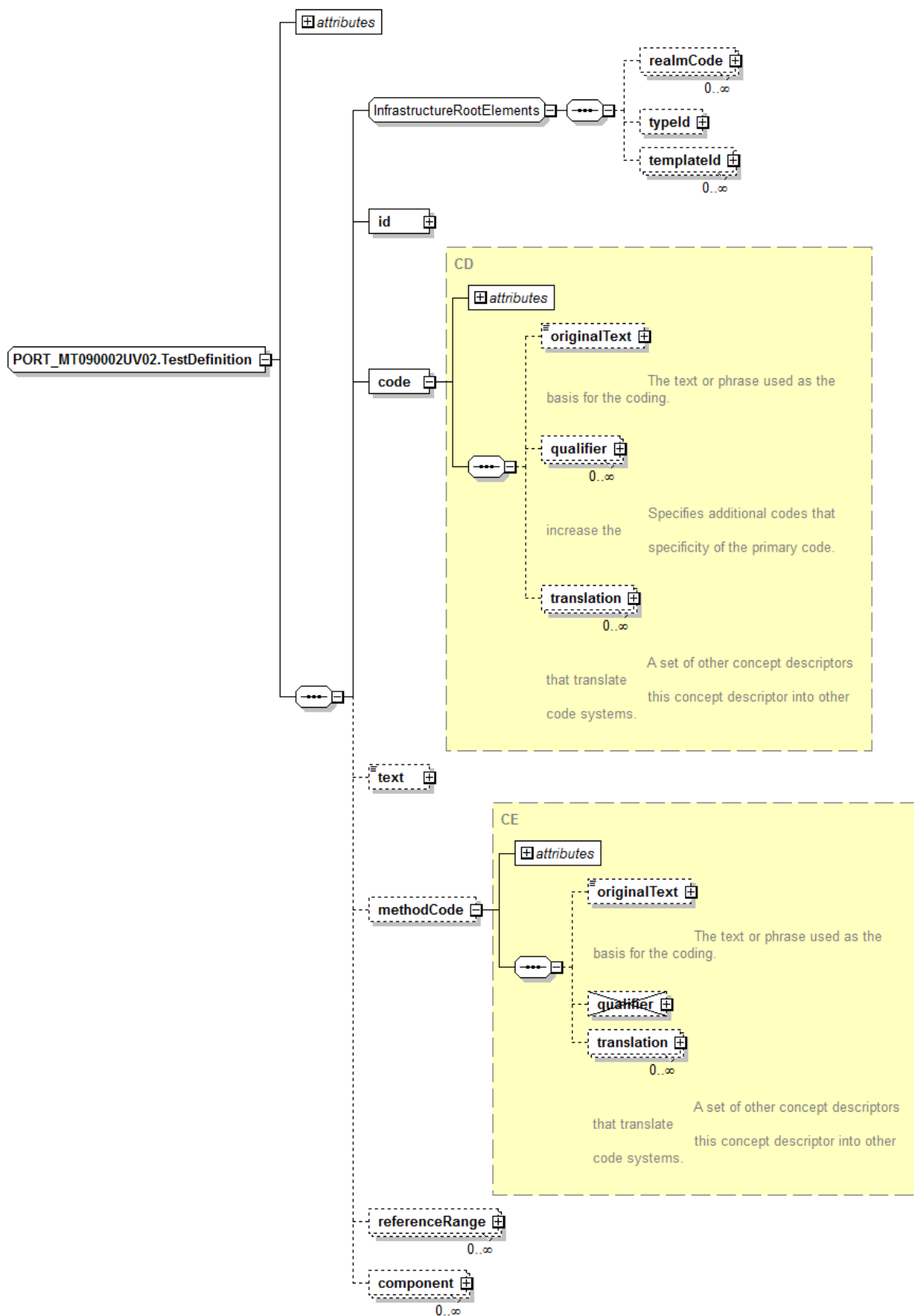
Description:

Intermediate element.

Complex Children:

Name	Type	Description	H	F
testDefinition	TestDefinition	Intermediate element	M	M

TestDefinition – Type



TestDefinition /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition												
Description:												
This is the definition of a method performed during the study or the definition of a parameter of a method. The recursive structure will not be implemented further than one level – methods and method parameters. Either the external document or the method parameters and the reference range have to be provided. The assigning authority is understood to be the study sponsor.												
Simple Children:												
Name	Type	Description	H	F								
id	II	A global unique identifier for this TestDefinition <table border="1"><tr><td colspan="4">Attributes</td></tr><tr><td>Root</td><td>OID</td><td>M</td><td>M</td></tr></table>	Attributes				Root	OID	M	M	M	M
Attributes												
Root	OID	M	M									
text	ED	URI for additional documentation for this test, (e.g. SOP or Specification document for this method).	O	R								
Complex Children:												
Name	Type	Description	H	F								
code	CD	An ACTCODE: Test code. (see page 20), for code list (see page 75)	O	M								
methodCode	CE	An ACTREASON: Method type. (see page 21) for code list (see page 76)	O	M								
referenceRange	ReferenceRange	The acceptance criterion for this parameter.	O	M								
component	Component7	Recursive reference to TestDefinition to define the method parameter of this method (i.e. a test assay for which the next level can be the ingredients or impurities). Only two additional levels may be provided.	O	M								

Sample Code

```

<component>
  <testDefinition>
    <id root="2.16.840.1.19927.1.12345.13.32.813" />
    <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
      displayName="chemical" >
      <originalText>Assay</originalText>
    </code>
    <text>
      <reference value="file://Reference Documents/Method_NH432.pdf"/>
    </text>
    <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
      Thesaurus" displayName="Proprietary" >
      <originalText>NH432 Assay</originalText>
    </methodCode>
    <referenceRange>
      <acceptanceCriterion>
        <text></text>
        <value xsi:type="PQ" value="90" unit="%_LC" />
        <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1"
          codeSystemName="NCI Thesaurus" displayName="NLT" />
      </acceptanceCriterion>
    </referenceRange>
  </testDefinition>
</component>

```

```

</referenceRange>
<referenceRange>
  <acceptanceCriterion>
    <text></text>
    <value xsi:type="PQ" value="110" unit="%_LC" />
  <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
  Thesaurus" displayName="NMT" />
  </acceptanceCriterion>
</referenceRange>
</testDefinition>
</component>

```

Code – Type

Code

/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/code

or

/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/code

Description:

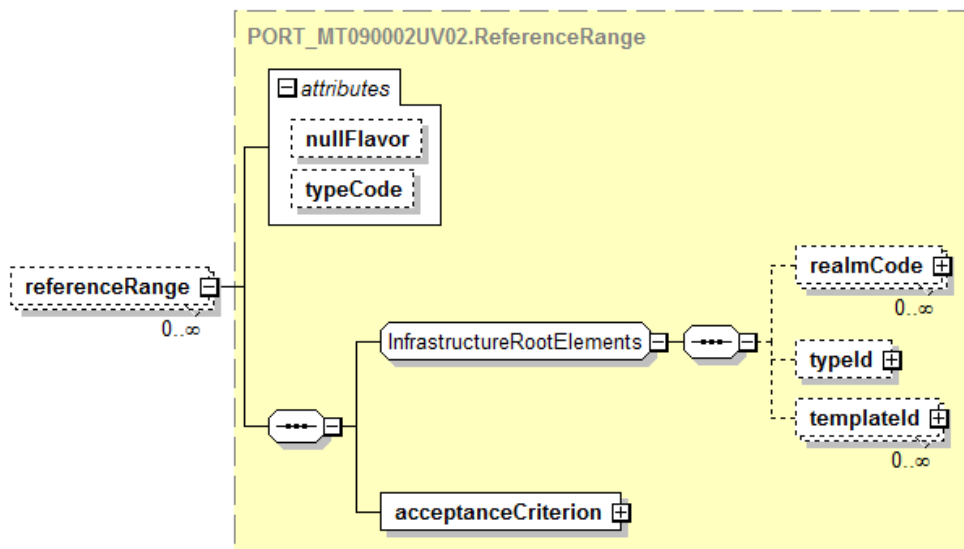
The test type

Name	Type	Description	H	F																		
code	CD	<div>The displayName documents the test type (Chemical, Physical, or Biological; see code list on page 75)</div> <table><tr><th colspan="3">Attributes</th></tr><tr><td>code</td><td>R</td><td>M</td></tr><tr><td>codeSystem</td><td>R</td><td>M</td></tr><tr><td>codeSytemName</td><td>R</td><td>R</td></tr><tr><td>codeSytemVersion</td><td>R</td><td>R</td></tr><tr><td>displayName</td><td>R</td><td>M</td></tr></table>	Attributes			code	R	M	codeSystem	R	M	codeSytemName	R	R	codeSytemVersion	R	R	displayName	R	M	O	M
Attributes																						
code	R	M																				
codeSystem	R	M																				
codeSytemName	R	R																				
codeSytemVersion	R	R																				
displayName	R	M																				
originalText	ED	The test name	O	M																		

MethodCode – Type

MethodCode /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/methodCode or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/methodCode				
Description:				
Test method type				
Name	Type	Description	H	F
code	CE	The displayName documents the test method type (Compendial or Proprietary; see code list on page 75)	O	M
		Attributes		
		code		
		codeSystem		
		codeSystemName		
		codeSystemVersion		
		displayName		
originalText	ED	The test method, or test SOP	O	M

ReferenceRange – Type

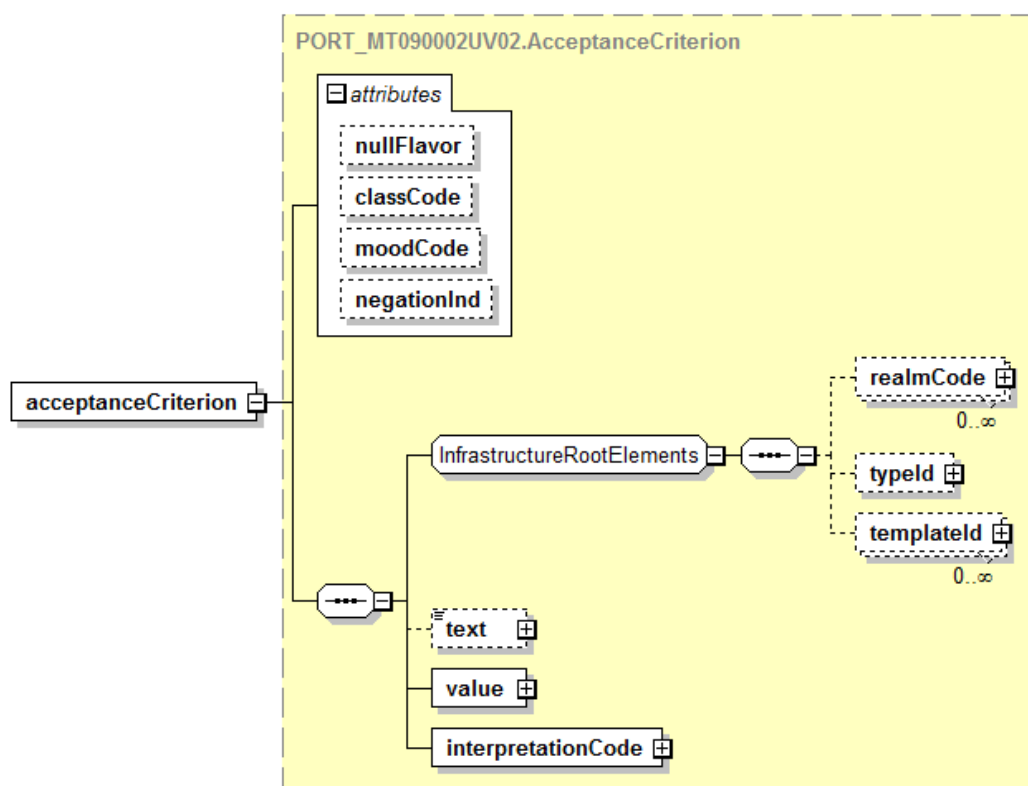


ReferenceRange /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange	
Description:	
The container for the set of acceptance criteria for a TestDefinition.	

Complex Children:

Name	Type	Description	H	F
acceptanceCriterion	AcceptanceCriterion	One or many acceptance criteria.	O	M

AcceptanceCriterion – Type



AcceptanceCriterion

/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/
acceptanceCriterion

or

/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange/
acceptanceCriterion

Description:

Describes one valid specification limit.

Simple Children:

Name	Type	Description	H	F
text	ST	URI for additional documentation or free text.	O	O
value	ANY	The value of the criterion.	M	M
interpretationCode	CV	e.g., not more than (NMT), not less than (NLT), ... (see page 76)	M	M

Sample Code

For an upper limit:

```
<referenceRange>
  <acceptanceCriterion>
    <text></text>
    <value xsi:type="PQ" value="90" unit="%_LC" />
    <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="NLT" />
  </acceptanceCriterion>
</referenceRange>
```

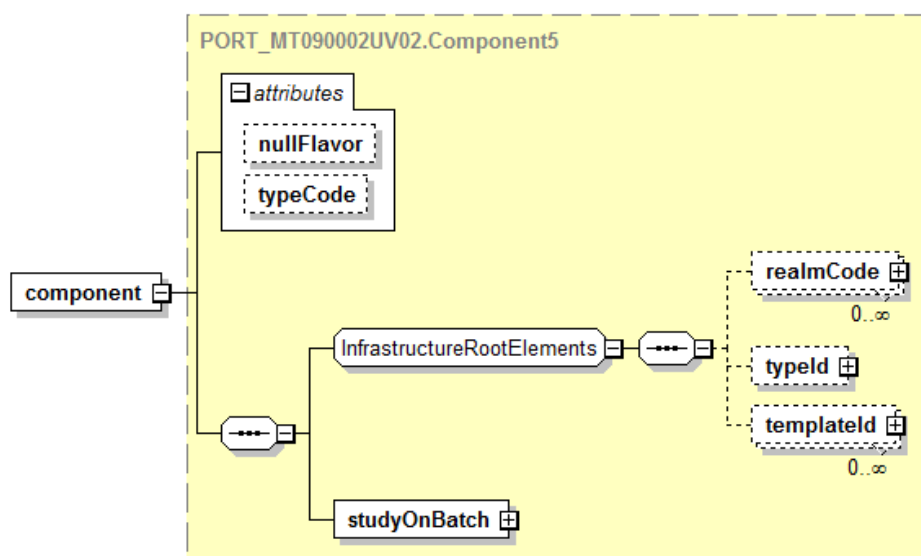
For an upper and lower limit:

```
<referenceRange>
  <acceptanceCriterion>
    <text></text>
    <value xsi:type="PQ" value="90" unit="%_LC" />
    <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="NLT" />
  </acceptanceCriterion>
</referenceRange>
<referenceRange>
  <acceptanceCriterion>
    <text></text>
    <value xsi:type="PQ" value="110" unit="%_LC" />
    <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="NMT" />
  </acceptanceCriterion>
</referenceRange>
```

For a not applicable limit:

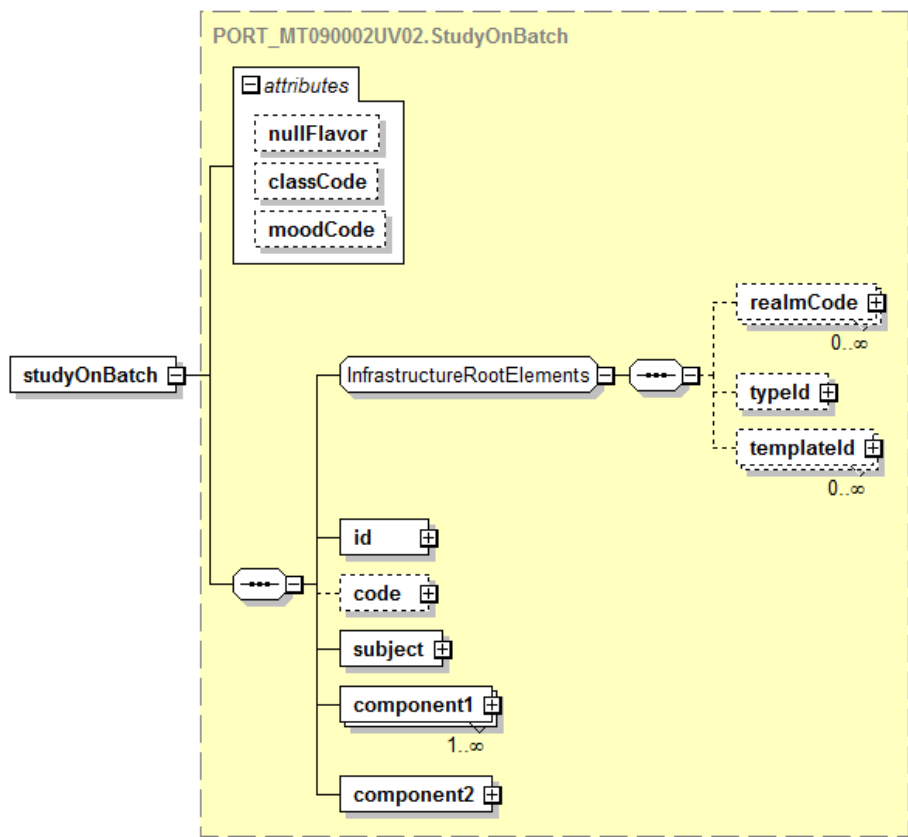
```
<referenceRange>
  <acceptanceCriterion>
    <text>Not established</text>
    <value xsi:type="ST" />
    <interpretationCode code="C48660" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="NA" />
  </acceptanceCriterion>
</referenceRange>
```

Component5 – Type



Component5 /stabilityStudy/component				
Description:				
Reference to the batch and result information for one study on one batch. Many of these elements can be provided.				
Complex Children:				
Name	Type	Description	H	F
studyOnBatch	StudyOnBatch	Intermediate element.	M	M

StudyOnBatch - Type



StudyOnBatch /stabilityStudy/component/studyOnBatch				
Description:				
The container for the batch information and results for the study performed on one batch.				
Simple Children:				
Name	Type	Description	H	F
id	II	A global unique identifier for the study. It should be the same in all submitted files for this study. <div>Attributes</div>	R	M

		Root	ID	M	M			
code	CE	An ACTCODE: study type (see page 77).					O	M
Complex Children:								
Name	Type	Description					H	F
subject	Subject2	The reference to the information on the material the study is performed on (e.g. a batch).					M	M
component1	Component3	The reference to the study design and the results section.					M	M
component2	Component4	The reference to the storage conditions used.					M	M

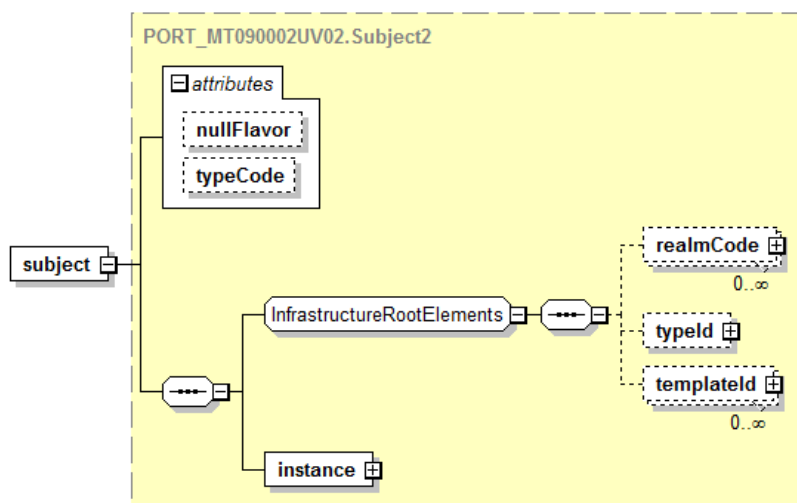
Sample Code

```

<studyOnBatch>
  <id root="2.3.6.1.4.1.24263.4711.1"/>
  <code code="C96109" displayName="Commercial" />
  <subject>
    <instance>
      <manufacturedMaterialInstance>
        ...
      </manufacturedMaterialInstance>
    </instance>
  </subject>
  <component1>
    ...
  </component1>
  <component2>
    ...
  </component2>
</studyOnBatch>

```

Subject2 – Type



Subject2

/stabilityStudy/component/studyOnBatch/subject

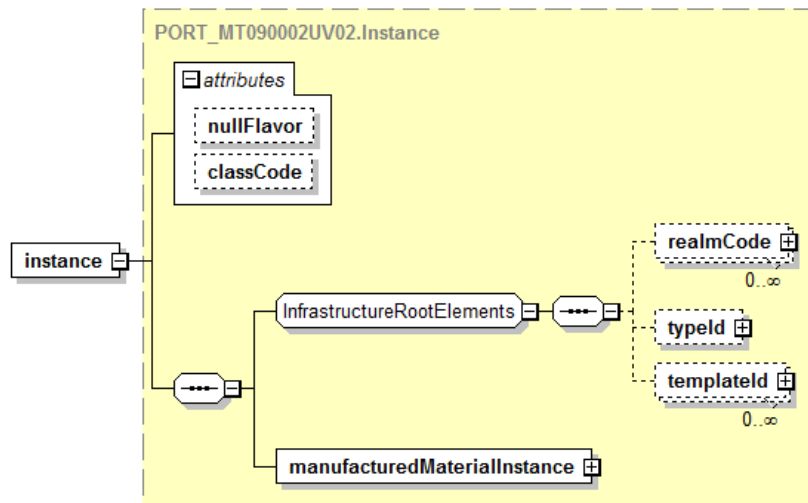
Description:

An intermediate element.

Complex Children:

Name	Type	Description	H	F
instance	Instance	The Instance of the material.	M	M

Instance – Type

**Instance**

/stabilityStudy/component/studyOnBatch/subject/instance

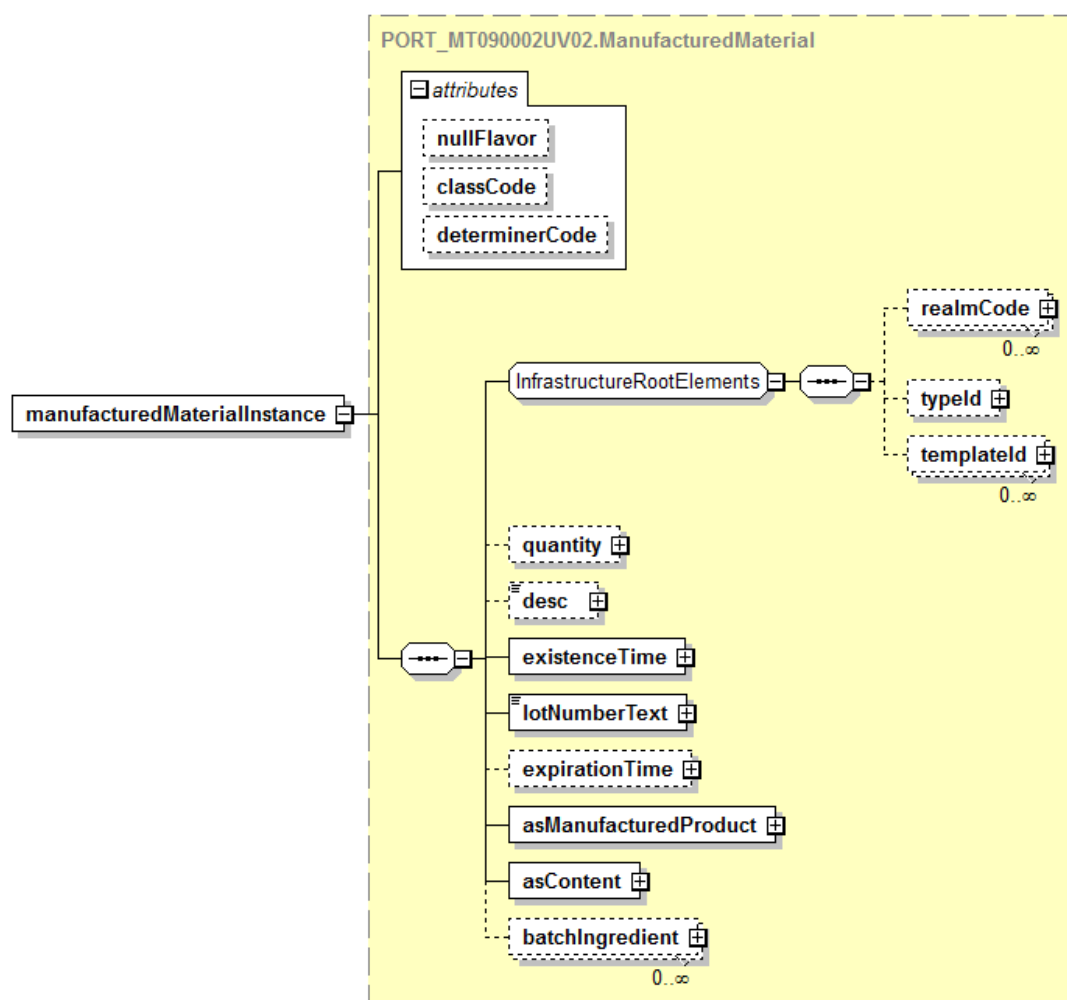
Description:

An intermediate element.

Complex Children:

Name	Type	Description	H	F
manufacturedMaterialInstance	ManufacturedMaterial	Intermediate element	M	M

ManufacturedMaterial – Element



ManufacturedMaterial

/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance

Description:

Describes the produced material used in the stability study. This is the specific lot of product or substance this report is about.

Simple Children:

Name	Type	Description	H	F
quantity	PQ	Total amount of material in the batch.	R	R
desc	ED	A textual Description or/and external reference to a PDF document describing details of this production. This is where the expirationTime can be specified as a retest date, an expiration date and/or a dating period.	O	O
existenceTime	IVL_TS	Date of production (use ISO 8601 format).	R	M
lotNumberText	ST	Company internal lot number.	R	M
expirationTime	IVL_TS	Date of expiration (based on the provided expirationCode of the "Product" element) or the proposed expiration date of the material.	R	M

		<p>Interpretation for a product: -In the XML code if a high value is provided the expiration date is approved (e.g., for an annual report or supplement), and if a low value is provide the expiration date is proposed (e.g., for a new drug application that has not been approved).</p> <p>Interpretation for “substances” (i.e. intermediates or APIs): -In the XML code if a high value is provided the retest date is approved (e.g., for an annual update), and if a low value is provide the retest date is proposed (e.g., for a new drug master file).</p> <p>This value works in conjunction with the “expirationTime” in “Subject Product” or “Subject Substance”.</p>		
Complex Children:				
Name	Type	Description	H	F
asManufacturedProduct	Manufactured Product	A reference to the manufacturer of this material. If this document is part of an application of a new active ingredient, this information has to be provided.	M	M
AsContent	Content	A reference to the container/closure system.	M	M
BatchIngredient	BatchIngredient	A list of ingredients of type “ManufacturedMaterial”, so that a kind of “Batch Record” can be provided. Using this element leads to a recursive structure.	O	O

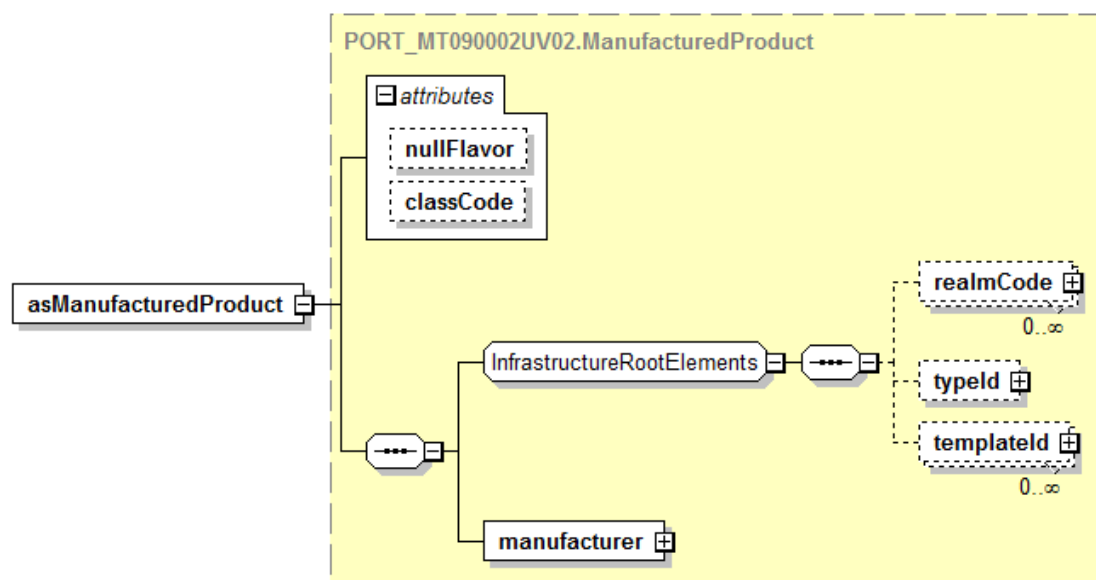
Sample Code

```

<manufacturedMaterialInstance>
  <quantity value="100000" unit="Tablets"/>
  <desc>Production from 2003-01-01</desc>
  <existenceTime>
    <high value="20030101"/>
  </existenceTime>
  <lotNumberText>JBE1000_001</lotNumberText>
  <expirationTime>
    <high value="20050101"/>
  </expirationTime>
  <asManufacturedProduct>
    <manufacturer>
      ...
    </manufacturer>
  </asManufacturedProduct>
  <asContent>
    ...
  </asContent>
</manufacturedMaterialInstance>

```

ManufacturedProduct– Element



ManufacturedProduct

/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct

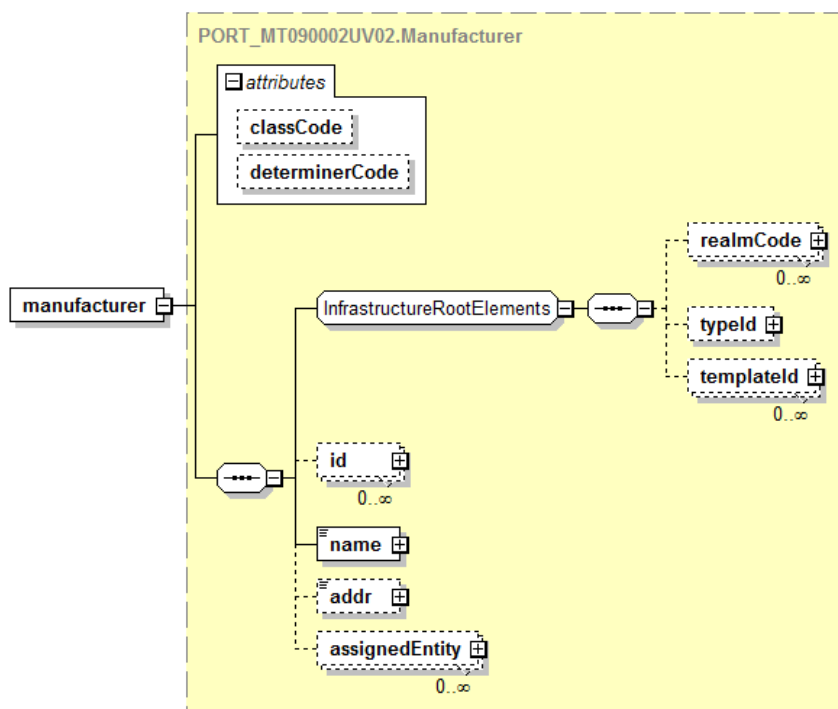
Description:

Intermediate element, containing the manufacturer of the Manufactured Material.

Complex Children:

Name	Type	Description	H	F
manufacturer	Manufacturer	Intermediate element	M	M

Manufacturer – Element



Manufacturer

/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/
manufacturer

Description:

The details about a manufacturer or a manufacturing site that produced the “ManufacturedMaterial”.

Simple Children:

Name	Type	Description	H	F								
id	II	<p>A set of identifiers that is used to uniquely identify the manufacturer or a manufacturing site.</p> <p>Use the DUNS number as the primary identifier. Other examples can be FEI number or a global unique identifier for the sponsoring organization assigned by IANA. For DUNS number, remove hyphens if present and prefix with "D" and if an FEI number prefix with an "F". Note: The assigningAuthorityName for a DUNS number is "Dun and Bradstreet D-U-N-S Number" and for a FEI number is "FDA FEI OID". A DUNS number and FEI number example are shown here. The assigning authority name is mandatory for all OIDs for organizations. Always list the DUNS number first if listing multiple numbers. It is the submitter's responsibility to ensure that the DUNS number id along with the firm's postal code (if any) and country match the DUNS number, postal code and country in the Dun and Bradstreet database.</p> <p><id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <id root="F1234567890" assigningAuthorityName="FDA FEI OID"/></p> <table><tr><th colspan="4">Attributes</th></tr><tr><td>Root</td><td>ID</td><td>M</td><td>M</td></tr></table>	Attributes				Root	ID	M	M	O	M
Attributes												
Root	ID	M	M									

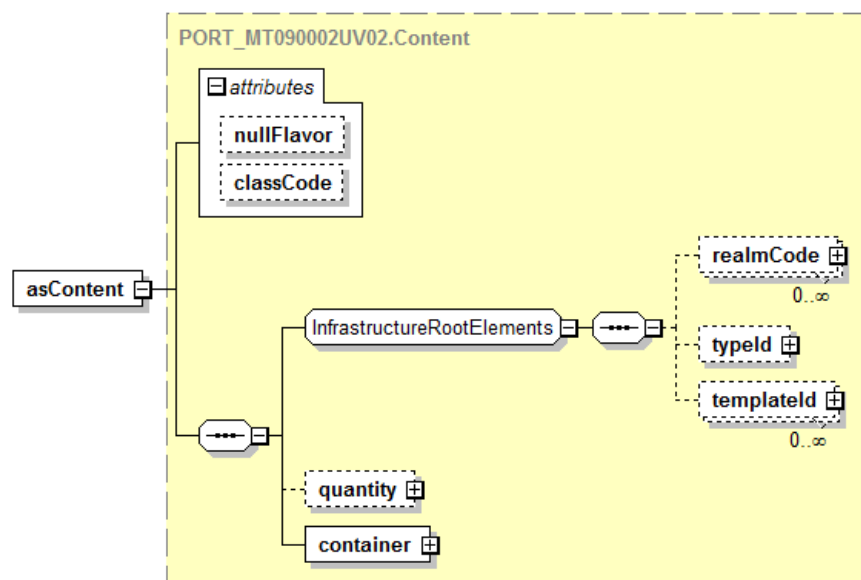
		Extension		N	N			
		assigningAuthorityName		N	M			
		Displayable		N	N			
name	ON	Name of the manufacturer (or manufacturing site).					R	M
addr	AD	Address.					O	M
Complex Children:								
Name	Type	Description					H	F
assignedEntity	AssignedEntity2	One or many sub elements of “Manufacturer” type called “representedManufacturer” who produced this product on behalf of the “Manufacturer” given here or who partially produced the product.					O	M

Sample Code

```
<manufacturer classCode="ORG" determinerCode="INSTANCE" >
  <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
  <id root="2.3.6.1.4.1.24263" assigningAuthorityName="Internet Assigned Numbers Authority"/>
  <name>ABC Co.</name>
  <addr>
    <country>USA</country>
    <state>MO</state>
    <city>St. Louis</city>
    <postalCode>32142</postalCode>
    <streetAddressLine>100 North Blvd.</streetAddressLine>
  </addr>
</manufacturer>
```

```
<manufacturer classCode="ORG" determinerCode="INSTANCE" >
  <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
  <id root="2.3.6.1.4.1.24263" assigningAuthorityName="Internet Assigned Numbers Authority"/>
  <name>up to data professional service GmbH</name>
  <addr>
    <country>Germany</country>
    <city>Wörrstadt</city>
    <postalCode>55286</postalCode>
    <streetAddressLine>Am Pfäddchen 4</streetAddressLine>
  </addr>
</manufacturer>
```

Content - Element



Content				
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent				
Description:				
The container closure system				
Simple Children:				
Name	Type	Description	H	F
Quantity	RTO_PQ_PQ	The actual quantity of “manufacturedMaterialInstance” in the container (e.g., 50 tablets).	R	R
Complex Children:				
Name	Type	Description	H	F
container	Container	A reference to the structure for the container closure system.	M	M

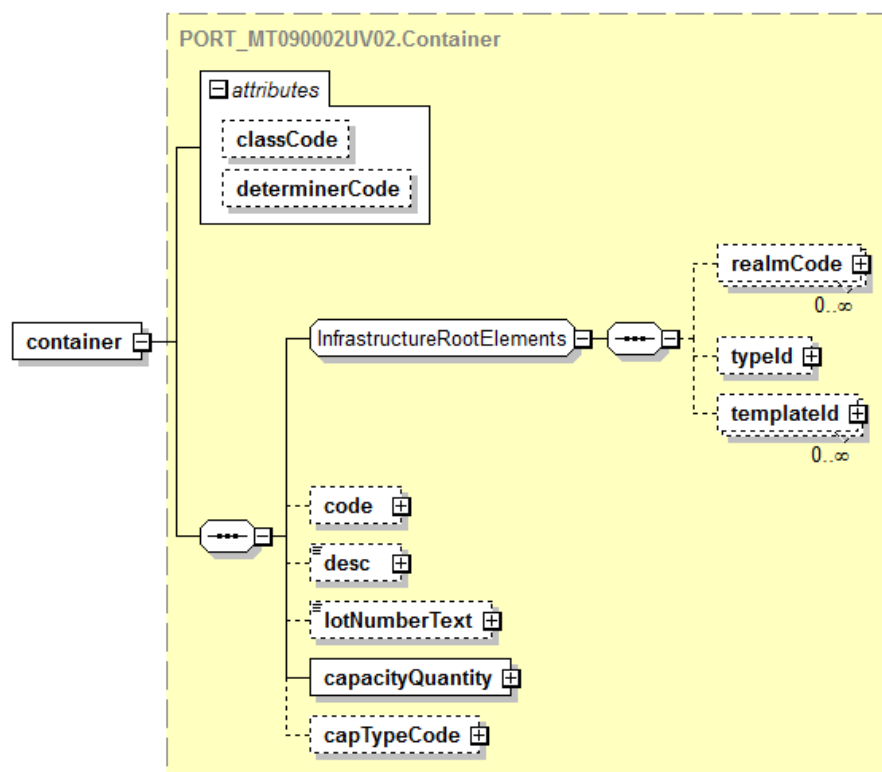
Sample Code

```

<asContent classCode="CONT">
  <quantity>
    <numerator xsi:type="PQ" value="50" unit="tablet" />
    <denominator xsi:type="PQ" value="1" unit="bottle" />
  </quantity>
  <container classCode="CONT" determinerCode="INSTANCE" >
    <code code="C43173" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
    displayName="BOTTLE, PLASTIC" />
    <desc>optional - enter a verbal Description of the container closure system or a reference to an external
    document which holds this Description.</desc>
    <lotNumberText>EX123456-12DS</lotNumberText>
    <capacityQuantity xsi:type="PQ" value="100" unit="TABLET" />
    <capTypeCode code="C96118" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
    Thesaurus" displayName="Tamper-evident, Plastic" />
  </container>
</asContent>

```


Container - Element



Container

/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container

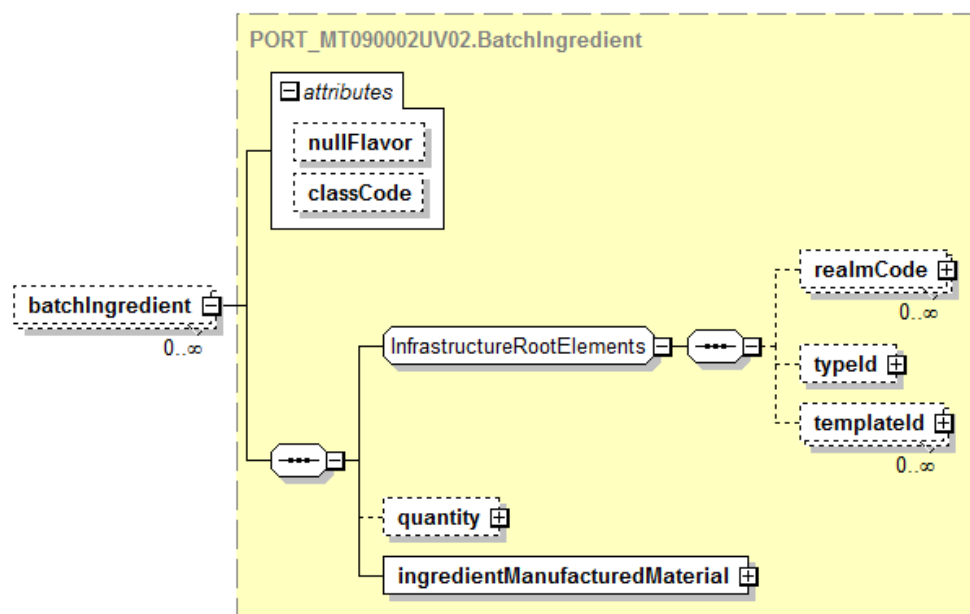
Description:

A simple structure to store the makeup of the container closure system.

Simple Children:

Name	Type	Description	H	F
Code	CE	Type of Container (e.g., bottle). (see page 78)	R	M
Desc	ED	A verbal Description of the container closure system or a reference to an external document which holds this Description.	O	O
lotNumberText	ST	The lot number of the production lot for this container.	O	O
capacityQuantity	PQ	The capacity of the container, not necessarily identical to "quantity of the "Content" element (e.g., 100 ml bottle, even if the quantity of tablets in the bottle is 50).	R	R
capTypeCode	CE	The code for the used closure system (e.g., plastic cap). (see page 78)	O	M

BatchIngredient – Element



BatchIngredient

/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient

Description:

An intermediate element to store a recursive reference to a “ManufacturedMaterial” to provide a kind of batch record for the product.

Simple Children:

Name	Type	Description	H	F
quantity	RTO_PQ_PQ	The actual quantity of referenced material used to produce the product (e.g., the referenced material might be used in parts for this product).	O	O

Complex Children:

Name	Type	Description	H	F
ingredientManufacturedMaterial	ManufacturedMaterial	This is a link to ManufacturedMaterial, so that more ingredients of each BatchIngredient can be given – which leads to a recursive structure of a batch record.	M	M

Sample Code

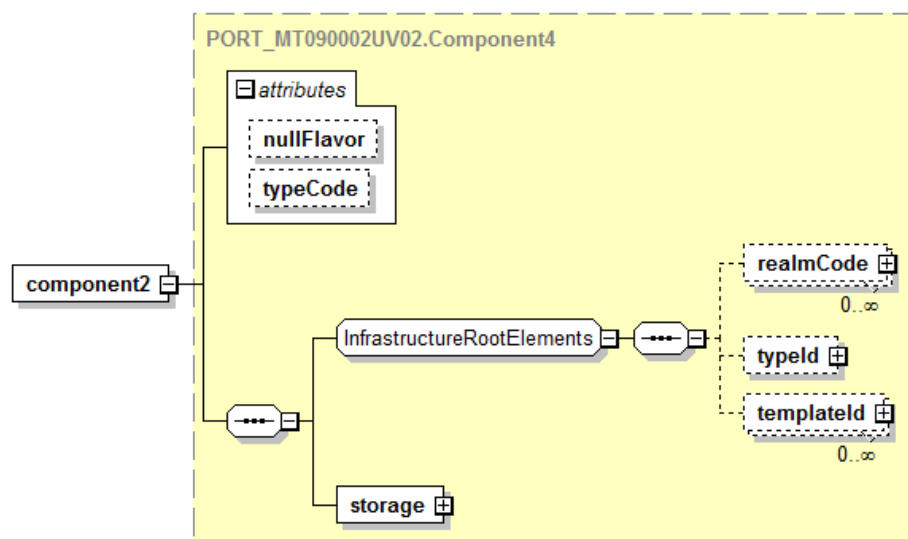
```
<batchIngredient classCode="INGR">
  <quantity>
    <numerator xsi:type="PQ" nullFlavor="NI" />
    <denominator xsi:type="PQ" nullFlavor="NI" />
  </quantity>
  <ingredientManufacturedMaterial classCode="MMAT" determinerCode="INSTANCE">
    <quantity xsi:type="PQ" value="50" unit="kg" />
    <desc>acetylsalicylic acid</desc>
    <existenceTime>
      <high value="20011012" />
    </existenceTime>
  </ingredientManufacturedMaterial>
</batchIngredient>
```

```

</existenceTime>
<lotNumberText>asd123</lotNumberText>
<expirationTime>
  <high value="20041112" />
</expirationTime>
<asManufacturedProduct classCode="MANU">
  <manufacturer classCode="ORG" determinerCode="INSTANCE" >
    <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
    <name>Some Company</name>
    <addr>
      <country>US</country>
      <state>CA</state>
      <city>Mountain View</city>
      <postalCode>92111</postalCode>
      <streetAddressLine>9998 Green Blvd</streetAddressLine>
    </addr>
  </manufacturer>
</asManufacturedProduct>
<asContent classCode="CONT">
  <quantity>
    <numerator xsi:type="PQ" value="1" unit="VAL" />
    <denominator xsi:type="PQ" value="1" nullFlavor="NI" />
  </quantity>
  <container>
    < code code="C43180" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="Can"/>
    <desc>Metal Drum with metal ring lock</desc>
    <lotNumberText>VAL</lotNumberText>
    <capacityQuantity xsi:type="PQ" value="1" unit="VAL" />
    < capTypeCode code="C96127" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Roll On Metal Container Closure"/>
  </container>
</asContent>
</ingredientManufacturedMaterial>
</batchIngredient>

```

Component4 – Element



Component4

/stabilityStudy/component/studyOnBatch/component2

Description:

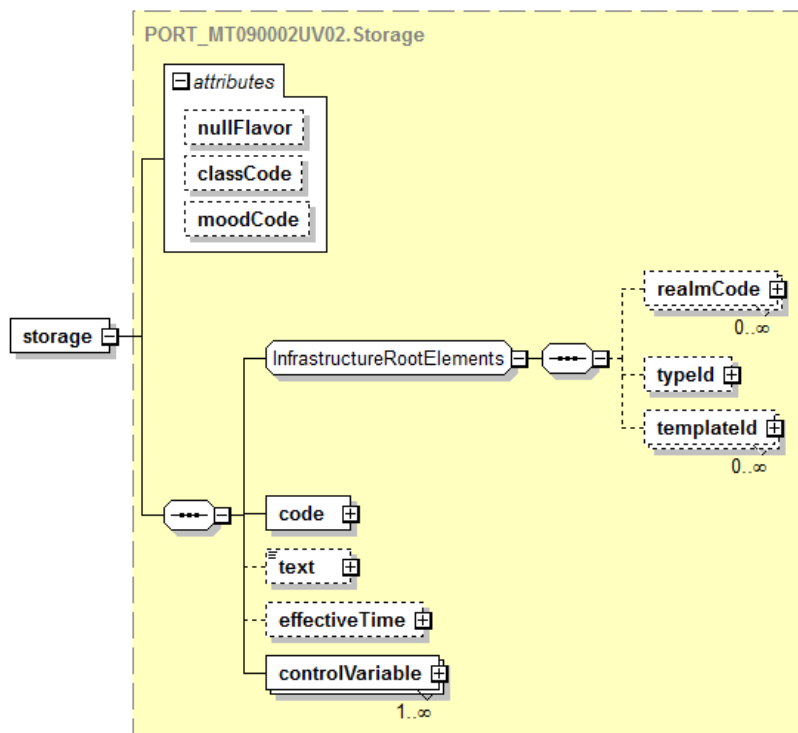
This element represents the storage condition used for the current “studyOnBatch”.

Complex Children:

Name	Type	Description	H	F
------	------	-------------	---	---

storage	Storage	A structure to describe the storage condition used in the study.	M	M
---------	---------	--	---	---

Storage – Element



Storage

/stabilityStudy/component/studyOnBatch/component2/storage

Description:

A list of one or many storage conditions (e.g., one reference to “25°/60%” and one to “upright” – or alternatively one reference to “25°/60% upright”).

Simple Children:

Name	Type	Description	H	F
code	CE	An ACTCODE: fixed code value, may be used for other purposes in future versions.	M	M
text	ED	A textual description of this storage condition or an external reference to a PDF document to describe this storage condition.	O	O
effectiveTime	IVL_TS	The time the product is put on stability. The date the stability storage is started for this condition, (e.g. 20080412 for 12 th of April 2008).	O	R

Complex Children:

Name	Type	Description	H	F
controlVariable	ControlVariable	Reference to the predefined storage conditions (one or many may be used).	M	M

Sample Code

Example 1:

```
<component2>
  <storage>
    <code code="C96146" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
    displayName="ICH" />
    <text></text>
    <effectiveTime value="20090727"/>
    <controlVariable>
      <storageCondition>
        <code displayName="ICH25C60RH" />
        <text></text>
        <value xsi:type="ST">25±176;C ± 2±176;C/60% RH ± 5% RH</value>
      </storageCondition>
    </controlVariable>
  </storage>
</component2>
```

Example 2:

```
<component2>
  <storage>
    <code code="C96148" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
    displayName="Proprietary" />
    <text></text>
    <effectiveTime value="20090727"/>
    <controlVariable>
      <storageCondition>
        <code displayName="ICH25C60RH" />
        <text></text>
        <value xsi:type="ST">25±176;C ± 2±176;C/60% RH ± 5% RH</value>
      </storageCondition>
    </controlVariable>
    <controlVariable>
      <storageCondition>
        <code displayName="Upright" />
        <text></text>
        <value xsi:type="ST">Upright Orientation</value>
      </storageCondition>
    </controlVariable>
  </storage>
</component2>
</studyOnBatch>
</component>
```

ControlVariable– Element

ControlVariable				
/stabilityStudy/component/studyOnBatch/component2/storage/controlVariable				
Description:				
Intermediate element				
Complex Children:				
Name	Type	Description	H	F
storageCondition	StorageCondition	Intermediate element	M	M

StorageCondition– Element

StorageCondition

/stabilityStudy/component/studyOnBatch/component2/storage/controlVariable/storageCondition

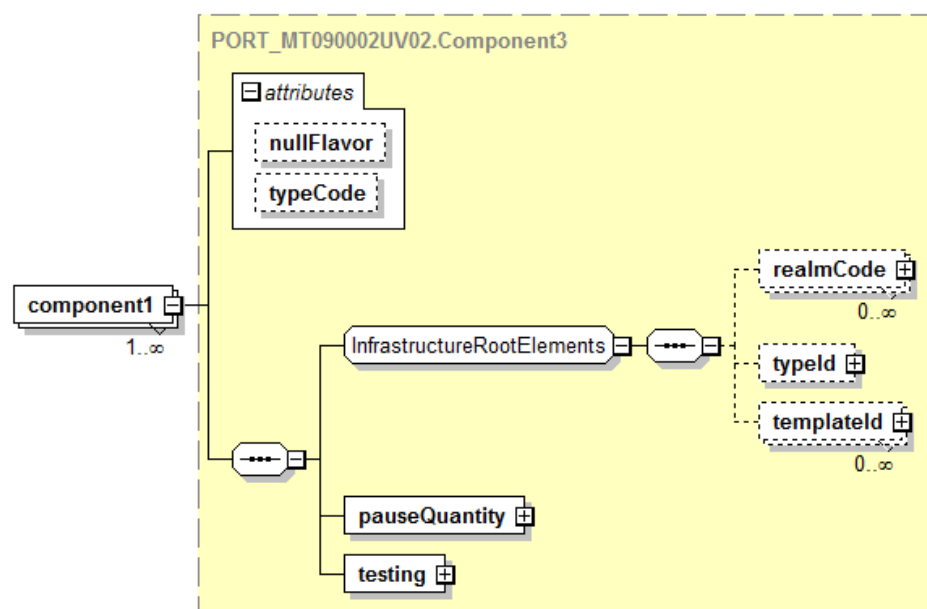
Description:

A structure to describe one storage condition. Dependent of the internal company definitions this condition might be simple (e.g., 25°) or complex (e.g., 25° C/60% R.H. upright)..Complex definitions can be made up of many controlVariables referencing simple storageConditions.

Simple Children:

Name	Type	Description	H	F
Code	CE	An ACTCODE: Storage condition code (see page 78)	M	M
text	ED	A textual description or an external reference.	O	O
value	ANY	The condition, e.g. "25°" or "25°/60%" or "25°/60% upright."	M	M

Component3 – Element



Component3

/stabilityStudy/component/studyOnBatch/component1

Description:

This element gives the results for a given storage time of a batch.

Simple Children:

Name	Type	Description	H	F
------	------	-------------	---	---

Component3				
/stabilityStudy/component/studyOnBatch/component1				
pauseQuantity	PQ	Storage time of the batch in a climatic chamber. The unit of the pauseQuantity has to be homogenous for all XML message files that are connected to this specific study, (e.g., only months are used throughout the XML message files). Fractions of the unit are allowed (e.g., 0.25 months to denote a week). For more than one pauseQuantity, the connection between the storage to the concerning testing section is done by the value of the pauseQuantity.	M	M
Complex Children:				
Name	Type	Description	H	F
testing	Testing	A structure to store the results of measurement.	M	M

Sample Code

Only one storage condition is used in one file:

```
<component1>
  <pauseQuantity xsi:type="PQ" value="0" unit="days"/>
  <testing>
    ...
  </testing>
</component1>
<component1>
  <pauseQuantity xsi:type="PQ" value="30" unit="days"/>
  <testing>
    ...
  </testing>
</component1>
```

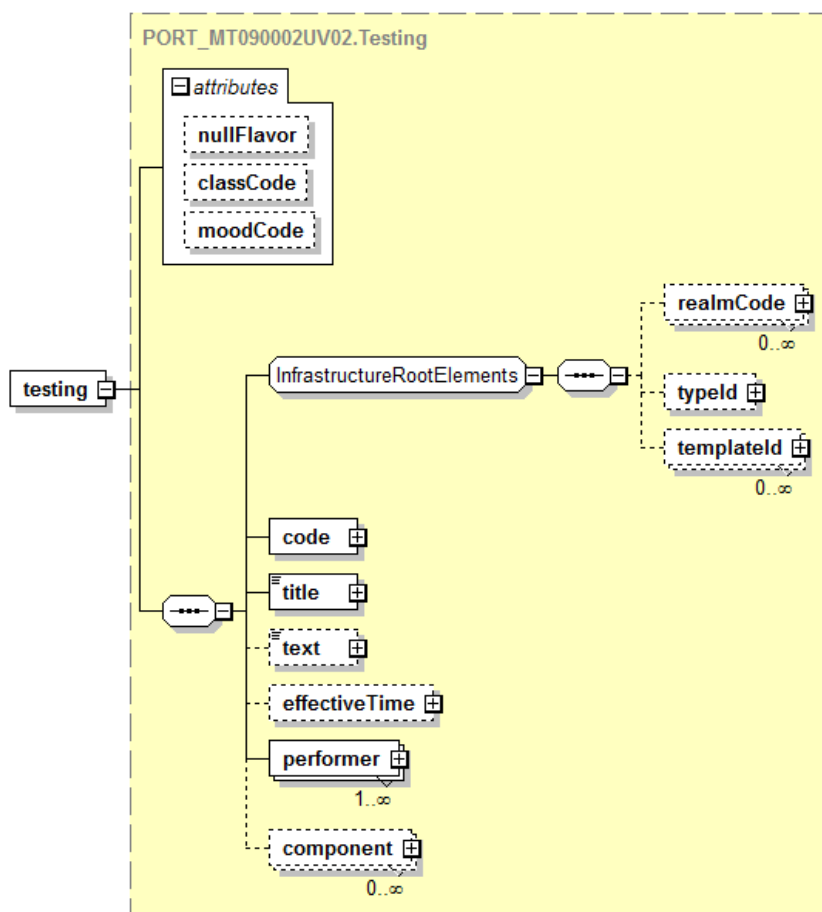
In cases other than simple freeze thaw studies, multiple eStability data files can be used to submit the results. These files must be linked by association and the sequence number of the file indicates the order in which the storage conditions were encountered. Examples of instances when associated cycled reports are indicated include:

- Transportation studies.
- Freeze thaw studies that do not share the same conditions and time points between their component1 elements.
- Self-life testing of products in climatic Zones III, IV, and IVb shipped in packaging originally designed for Zone 1.
- Use studies that simulate the preparation of drugs within a hospital pharmacy. Preparation may have been reconstituted and be stored in a refrigerator or freezer, possible both in sequence until use.

See examples on page 71

In-use stability testing over a period of time that simulates the use of the product in practice, especially when multiple batches will be compared. An example is photostability in-use testing of a dermal cream. Not all photostability testing would require a cycled message, although it would most likely require its own message. Cycled reporting is indicated when the study simulates multiple storage conditions such as refrigeration after opening.

Testing – Element



Testing				
/stabilityStudy/component/studyOnBatch/component1/testing				
Description:				
This is a representation of “pulling a sample from the climatic chamber”.				
Simple Children:				
Name	Type	Description	H	F
code	CE	An ACTCODE: pauseDescription. (see page 80) Something done with the sample, e.g., freeze sample.	M	M
title	ST	A title that labels a collection of related tests across pauseQuantities.	M	M
text	ED	A textual description or an external reference.	O	O
effectiveTime	IVL_TS	The date the sample was scheduled to be pulled from the chamber and tested (use ISO 8601 notation).	R	M
Complex Children:				
Name	Type	Description	H	F

Testing				
/stabilityStudy/component/studyOnBatch/component1/testing				
component	Component1	A reference to the tests performed with this sample.	M	M
performer	Performer1	A list of all testing sites involved in this testing.	M	M

Sample Code

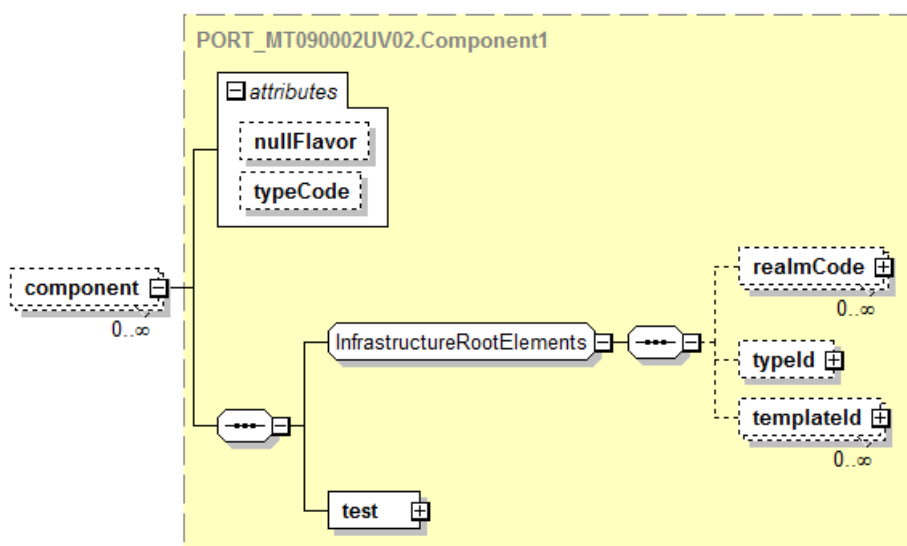
```

<testing>
  <code code="C96153" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Delayed, Frozen" />
  <title xsi:type="ST">36-Month testing</title>
  <effectiveTime>
    <high value="20080413"/>
  </effectiveTime>

  <component>
    <test>
      ...
    </test>
  </component>
  <performer>
    <assignedEntity>
      ...
    </assignedEntity>
  </performer>
  <performer>
    <assignedEntity>
      ...
    </assignedEntity>
  </performer>
</testing>

```

Component1 – Element



Component1	
/stabilityStudy/component/studyOnBatch/component1/component/testing/component	
Description:	
Intermediate element	

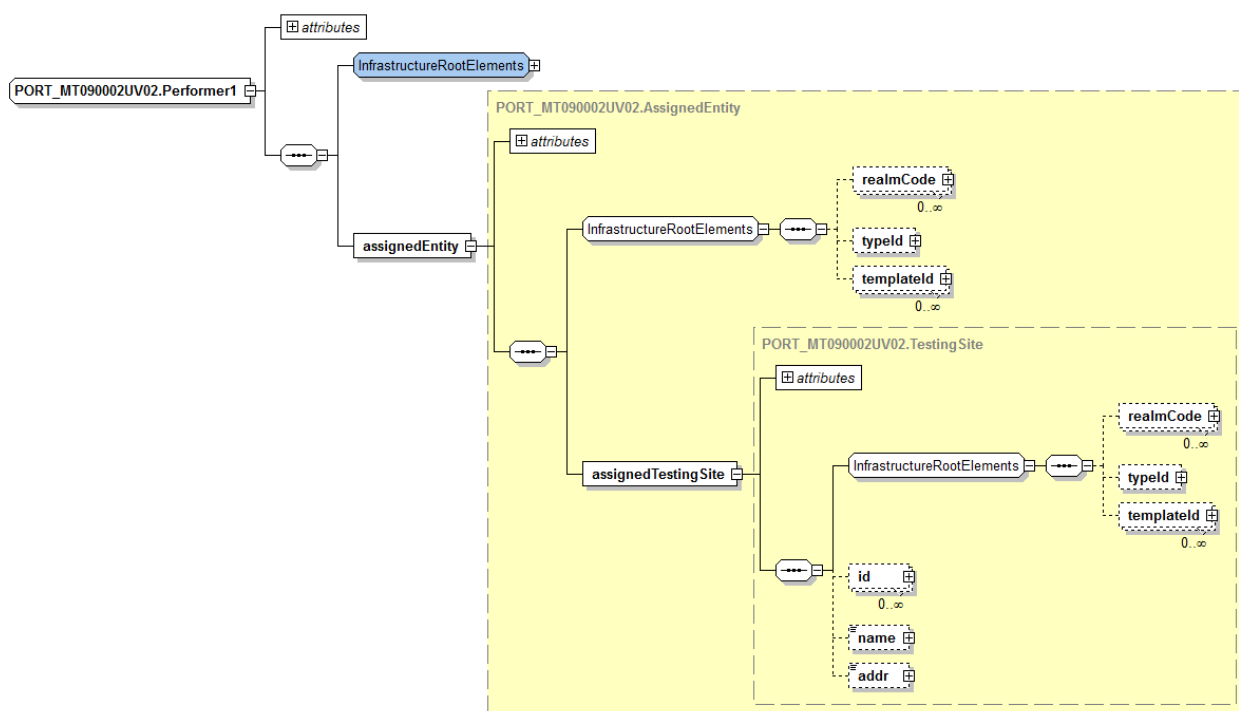
Complex Children:

Name	Type	Description	H	F
test	Test	Intermediate element	O	M

Create empty component1 elements which are equivalent to test intervals to the maximum time to be stored on stability as per stability protocol. This is an example of a component1 without test results XML:

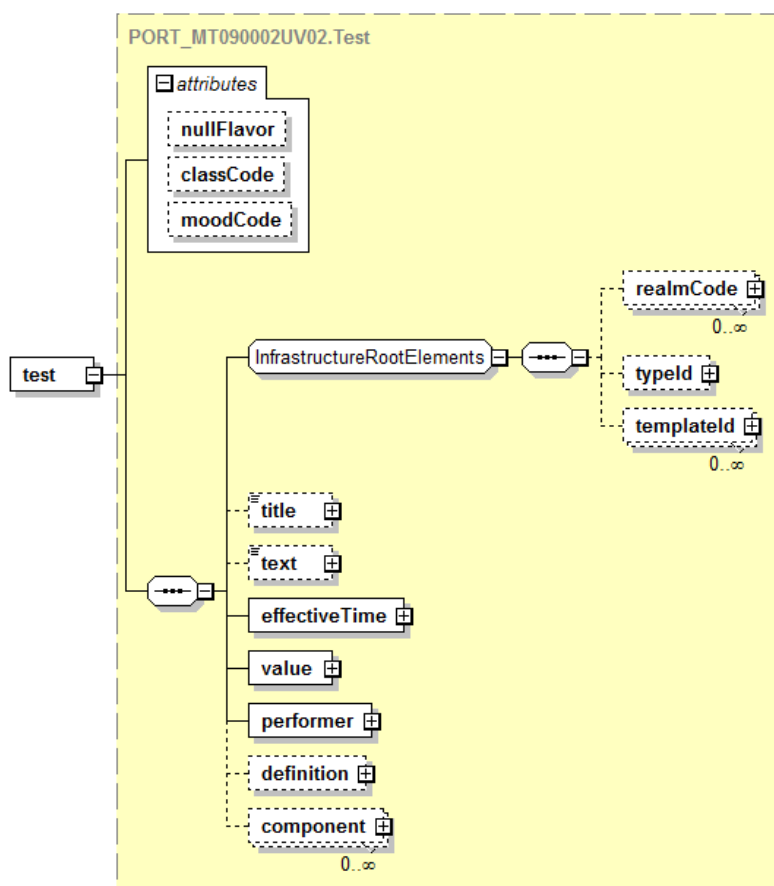
```
<component1>
  <pauseQuantity xsi:type="PQ" value="36" unit="Month"/>
  <testing>
    <code code="C96150" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus -
    Stability Study Pause Description Terminology" displayName="Immediate"/>
    <title></title>
    <text></text>
    <effectiveTime value="20110315"/>
    <performer>
      <assignedEntity>
        <assignedTestingSite>
          <id root="D000000000" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
          <name>TBD</name>
          <addr>
            <country>TBD</country>
            <city>TBD</city>
            <postalCode>TBD</postalCode>
            <streetAddressLine>TBD</streetAddressLine>
          </addr>
        </assignedTestingSite>
      </assignedEntity>
    </performer>
  </testing>
</component1>
```

Performer1 – Element



Performer1				
/stabilityStudy/component/studyOnBatch/component1/testing /performer				
Description:				
Intermediate element				
Complex Children:				
Name	Type	Description	H	F
assignedEntity	AssignedEntity	A reference to a list of testing sites involved in this testing.	M	M

Test – Element



Test
/stabilityStudy/component/studyOnBatch/component1/testing/component/test or /stabilityStudy/component/studyOnBatch/component1 /testing/component/test/component/test
Description:
Representation of a test performed on a sample. It applies the same scheme as in “TestDefinition”; there might be parameters for a test which are represented by the “Component2” reference.
Simple Children:

Name	Type	Description	H	F
title	ED	<p>Alternative name of the measured result. An example use is to identify “specified unknowns”, since all of these results point to the same specification (i.e., “definition”).</p> <p>This attribute can be used to identify “specified unknowns”, since all of these results point to the same specification (i.e., “definition”).</p>	O	R
text	ED	A textual description or an external reference. This is where lab comments and/or notebook reference can be specified.	O	O
effectiveTime	IVL_TS	A testing date that is mandatory on the first level. On the second level, a nullFlavour has to be provided where no actual result is available.	M	M
value	ANY	<p>For PQ data type, eStability supports the following nullFlavor terms when appropriate:</p> <p>NI – No Information NA – Not Applicable (see example) NAV – Temporarily Unavailable TRC – Trace UNK - unknown</p> <p>To report PQ data that is less than the limit of detection (LOD) or limit of quantitation (LOQ), eStability supports the method of reporting it as a ST data in the format of ‘<0.02’ where 0.02 is the LOD or LOQ. It is recommended that the LOD value is reported in the <text> tag as a data comment (see example below).</p> <p>When the submitter elects to report a face value of this type of data, the data can be reported normally. Reporting as such, It is essential to document that the nature of data in the <text> tag (see example below).</p>	M	M
Complex Children:				
Name	Type	Description	H	F
performer	Performer2	A reference to a testing site.	M	M
definition	Definition	Reference to a specification for this test.	O	M
component	Component2	Recursive reference to a “Test”.	R	R

	Acceptance Criteria	Test Result
PQ Reporting of LOD as PQ	<code><text>NMT 35%</text></code> <code><value xsi:type="PQ" value="35" unit="%" nullFlavor="NI"/></code> <code><interpretationCode ... displayName="NMT"/></code>	<code><text>Limit of Detection is 30%</text></code> <code><effectiveTime value="20120828" /></code> <code><value xsi:type="PQ" value="0" unit="%" /></code>
PQ Reporting of LOD as ST	<code><text>NMT 35%</text></code> <code><value xsi:type="PQ" value="35" unit="%" nullFlavor="NI"/></code> <code><interpretationCode ... displayName="NMT"/></code>	<code><text>Limit of Detection is 30%</text></code> <code><effectiveTime value="20120828" /></code> <code><value xsi:type="ST" nullFlavor="NA">&lt;30</value></code>
PQ Reporting of Not Scheduled	<code><text>NMT 35%</text></code> <code><value xsi:type="PQ" value="35" unit="%" nullFlavor="NI"/></code> <code><interpretationCode ... displayName="NMT"/></code>	<code><text>Not Scheduled</text></code> <code><effectiveTime value="20120828" /></code> <code><value xsi:type="PQ" nullFlavor="NI" /></code>
ST Reporting of LOD	<code><text>Limit of Detection is 20%</text></code> <code><value xsi:type="ST" nullFlavor="NA">Passed</value></code> <code><interpretationCode ... displayName="Passed"/></code>	<code><text>Limit of Detection is 20%</text></code> <code><effectiveTime value="20120828" /></code> <code><value xsi:type="ST" nullFlavor="NA">Passed</value></code>

Sample Code

```

<test>
  <effectiveTime value="20050628"/>

  <value xsi:type="PQ" value="92.3" unit="mg" />
  <performer>
    ...
  </performer>
  <definition>
    ...
  </definition>
  <component>
    <test>
      ...
    </test>
  </component>
</test>

```

Reporting nullFlavor of NA for PQ data type

```

<test>
  <effectiveTime value="20050628" />
  <value xsi:type="PQ" nullFlavor="NA" />
  <performer>
    ...
  </performer>
  <definition>
    ...
  </definition>
  <component>
    <test>
      ...
    </test>
  </component>
</test>

```

Reporting LOD data

```

<component>
  <test classCode="OBS" moodCode="EVN">
    <text></text>
  </test>
</component>

```

```

<text>LOD=0.02</text>
<effectiveTime value="21010626"/>
<!--To report '<LOD' or '<LOQ' type of data-->
<value xsi:type="ST">&lt;0.02</value>
<performer typeCode="PRF">
  <assignedEntityStub>
    <assignedSiteStub>
      <id root="D3299955539" />
    </assignedSiteStub>
  </assignedEntityStub>
</performer>

```

Reporting LOD data as a face value

```

<component>
  <test classCode="OBS" moodCode="EVN">
    <text>This data is &lt;LOD. LOD = 0.02</text>
    <effectiveTime value="21010626"/>
    <!--To report '<LOD' or '<LOQ' with a face value -->
    <value xsi:type="PQ" value="0" unit="mg" />
    <performer typeCode="PRF">
      <assignedEntityStub>
        <assignedSiteStub>
          <id root="D3299955539" />
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>

    <definition>
      <definitionStub>
        <id root="2.2.3.4.5.6.7.88.99.88888.3.4.3"/>
      </definitionStub>
    </definition>
  </test>
</component>

```

The following code example documents four (4) unspecified unknowns which are associated with one single second level test. Each unspecified unknown is represented by a RRT (Relative Retention Time) value:

Unspecified Unknown Data

RRT1.23	0.01 %
RRT2.34	0.02 %
RRT4.54	0.03 %
RRT6.25	0.02 %

```

<component>
  <test classCode="OBS" moodCode="EVN">
    <title></title>
    <text></text>
    <effectiveTime value="20080315" />
    <value xsi:type="ST">NA</value>
    <performer typeCode="PRF">
      <assignedEntityStub>
        <assignedSiteStub>
          <id root="D123456789" />
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>
    <definition>
      <definitionStub>
        <id root="2.12.345.6789.1.88888.1.10.11.5.8" />
      </definitionStub>
    </definition>
    <component>
      <test classCode="OBS" moodCode="EVN">
        <title>RRT1.23</title>
        <text></text>
        <effectiveTime value="20080315" />
        <value xsi:type="PQ" value="0.01" unit="%" />
        <performer typeCode="PRF">
          <assignedEntityStub>

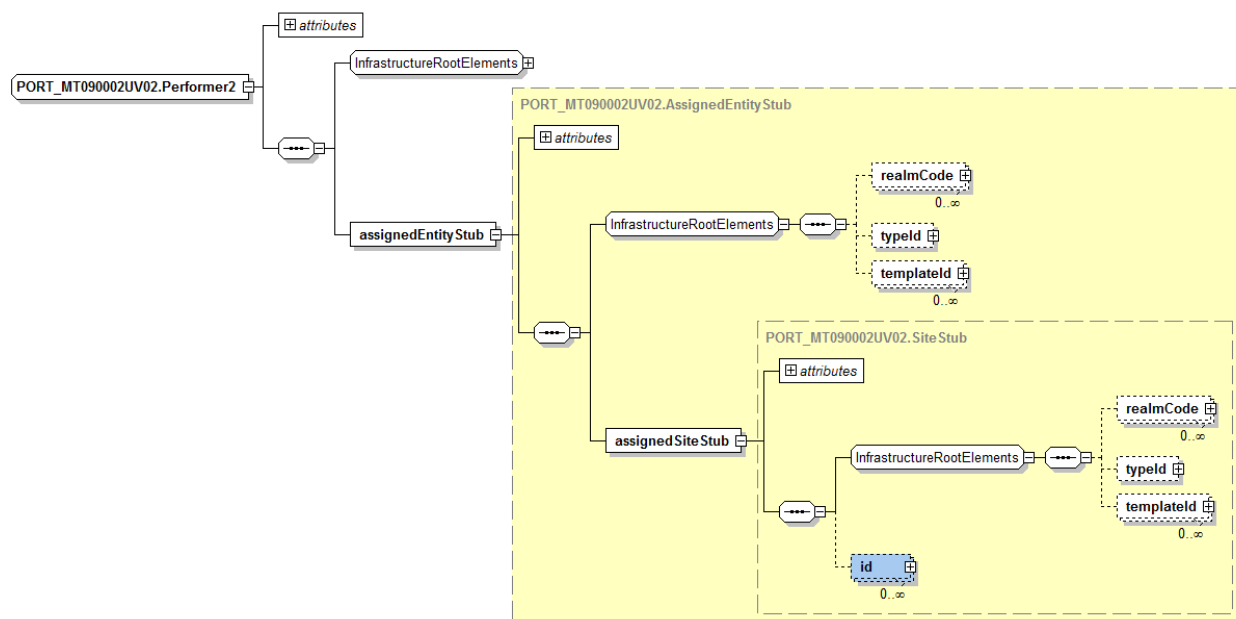
```

```

        <assignedSiteStub>
          <id root="D123456789" />
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>
  <definition>
    <definitionStub>
      <id root="2.12.345.6789.1.88888.1.10.11.5.9" />
    </definitionStub>
  </definition>
</test>
</component>
<component>
  <test classCode="OBS" moodCode="EVN">
    <title>RRT2.34</title>
    <text></text>
    <effectiveTime value="20080315" />
    <value xsi:type="PQ" value="0.02" unit="%" />
    <performer typeCode="PRF">
      <assignedEntityStub>
        <assignedSiteStub>
          <id root="D123456789" />
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>
  <definition>
    <definitionStub>
      <id root="2.12.345.6789.1.88888.1.10.11.5.9" />
    </definitionStub>
  </definition>
</test>
</component>
<component>
  <test classCode="OBS" moodCode="EVN">
    <title>RRT4.54</title>
    <text></text>
    <effectiveTime value="20080315" />
    <value xsi:type="PQ" value="0.03" unit="%" />
    <performer typeCode="PRF">
      <assignedEntityStub>
        <assignedSiteStub>
          <id root="D123456789" />
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>
  <definition>
    <definitionStub>
      <id root="2.12.345.6789.1.88888.1.10.11.5.9" />
    </definitionStub>
  </definition>
</test>
</component>
<component>
  <test classCode="OBS" moodCode="EVN">
    <title>RRT6.25</title>
    <text></text>
    <effectiveTime value="20080315" />
    <value xsi:type="PQ" value="0.02" unit="%" />
    <performer typeCode="PRF">
      <assignedEntityStub>
        <assignedSiteStub>
          <id root="D123456789" />
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>
  <definition>
    <definitionStub>
      <id root="2.12.345.6789.1.88888.1.10.11.5.9" />
    </definitionStub>
  </definition>
</test>
</component>
</test>
</component>

```

Performer2 – Element



Performer2

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/performer

or

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/component/test/performer

Description:

Intermediate element

Complex Children:

Name	Type	Description	H	F
assignedEntityStub	AssignedEntityStub	See sample code	M	M

Sample Code

```
<component>
  <test classCode="OBS" moodCode="EVN">
    <text></text>
    <effectiveTime value="20040723" />
    <value xsi:type="PQ" value="1.55" unit="minute" />
    <performer typeCode="PRF">
      <assignedEntityStub>
        <assignedSiteStub>
          <id root="D345661122" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
        </assignedSiteStub>
      </assignedEntityStub>
    </performer>
  </test>
  <definition>
    <definitionStub>
      <id root="2.2.3.4.5.6.7.88.99.1.98721.1.3.2.3.4" />
    </definitionStub>
  </definition>
</component>
<sequenceNumber value="1" />
<test classCode="OBS" moodCode="EVN">
  <text></text>
  <effectiveTime value="20040723" />
</test>
```



```

<value xsi:type="PQ" value="1.6" unit="minute" />
<performer typeCode="PRF">
  <assignedEntityStub>
    <assignedSiteStub>
      <id root=" D345661122" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number" />
    </assignedSiteStub>
  </assignedEntityStub>
</performer>
<definition>
  <definitionStub>
    <id root="2.2.3.4.5.6.7.88.99.1.98721.1.3.2.3.5" />
  </definitionStub>
</definition>
</test>
</component>
...
...
</test>
</component>

```

AssignedEntity – Element

AssignedEntity				
/stabilityStudy/component/studyOnBatch/component1/testing /performer/assignedEntity				
Description:				
Intermediate element, a reference to a list of testing sites involved in this testing on behalf of the ResearchSponsor.				
Complex Children:				
Name	Type	Description	H	F
assignedtestingSite	TestingSite	Intermediate element	M	M

TestingSite – Element

TestingSite				
/stabilityStudy/component/studyOnBatch/component1/testing /performer/assignedEntity/assignedTestingSite				
Description:				
The details about a tester who performs the tests on behalf of the ResearchSponsor.				
Simple Children:				
Name	Type	Description	H	F
id	II	<p>A set of identifiers that is used to uniquely identify the testing site.</p> <p>Use the DUNS number as the primary identifier. Other examples can be FEI number or a global unique identifier for the sponsoring organization assigned by IANA. For DUNS number, remove hyphens if present and prefix with "D" and if an FEI number prefix with an "F". Note: The assigningAuthorityName for a DUNS number is "Dun and Bradstreet D-U-N-S Number" and for a FEI number is "FDA FEI OID". A DUNS number and FEI number example are shown here. The assigning authority name is mandatory for all OIDs for organizations. Always list the DUNS number first</p>	O	M

		<p>if listing multiple numbers. It is the submitter's responsibility to ensure that the DUNS number id along with the firm's postal code (if any) and country match the DUNS number, postal code and country in the Dun and Bradstreet database.</p> <p><id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <id root="F1234567890" assigningAuthorityName="FDA FEI OID"/></p> <p>If this site element is referencing a single person (i.e., the test performer with the testing organisation) the "id" element must be unique for this person.</p> <table><tr><th colspan="4">Attributes</th></tr><tr><td>Root</td><td>OID of the testing site company</td><td>M</td><td>M</td></tr><tr><td>assigningAuthorityName</td><td></td><td>N</td><td>M</td></tr></table>	Attributes				Root	OID of the testing site company	M	M	assigningAuthorityName		N	M		
Attributes																
Root	OID of the testing site company	M	M													
assigningAuthorityName		N	M													
name	ON	The name of the testing site.	R	M												
addr	AD	The address of the testing site. Use the "additionalLocator" to reference a single person/tester.	R	M												

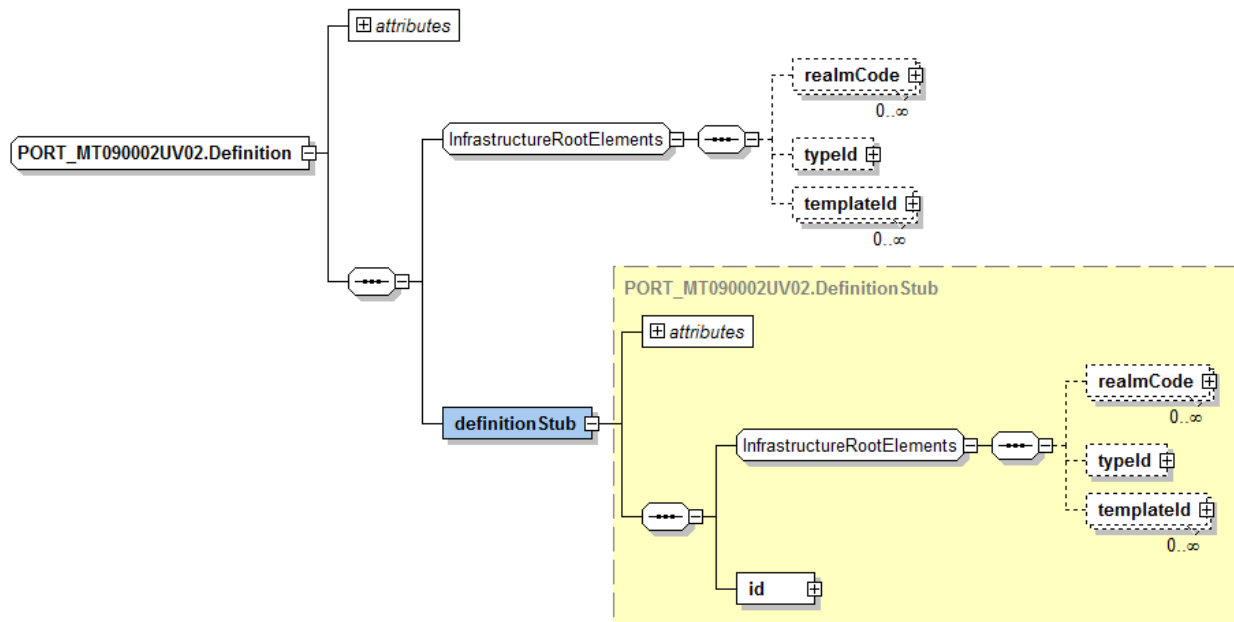
Sample Code

```

<component1>
  <pauseQuantity xsi:type="PQ" value="24" unit="month" />
  <testing>
    <code code="C96150" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
    displayName="Immediate" />
    <title>Stability testing for 24 month</title>
    <text></text>
    <effectiveTime value="20040723" />
    <performer>
      <assignedEntity>
        <assignedTestingSite>
          <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
          <name>XYZ Pharmaceuticals, Inc.</name>
          <addr>
            <country>USA</country>
            <state>CA</state>
            <city>Utopia</city>
            <postalCode>90021</postalCode>
            <streetAddressLine>84 Main Street</streetAddressLine>
          </addr>
        </assignedTestingSite>
      </assignedEntity>
    </performer>
    ...
  </testing>
</component1>

```

Definition - Element



Definition

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/definition

or

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/component/test/definition

Description:

Intermediate element which references the testDefinition.

Complex Children:

Name	Type	Description	H	F
definitionStub	DefinitionStub	Intermediate element	M	M

DefinitionStub - Element

DefinitionStub

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/definition/definitionStub

or

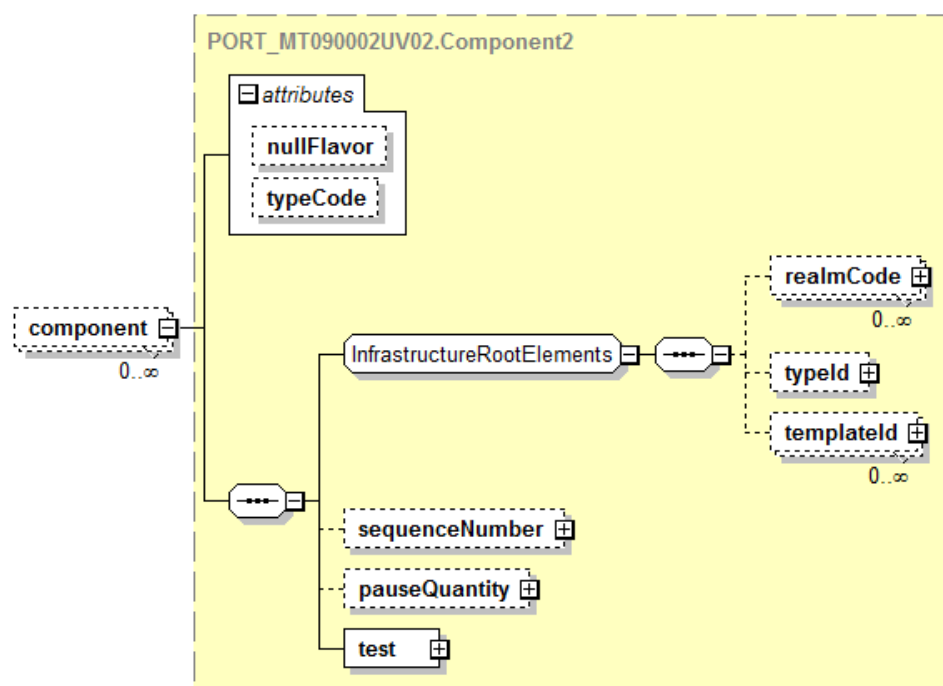
/stabilityStudy/component/studyOnBatch/component1/testing/component/test/component/test/definition/definitionStub

Description:

Simple Children:

Name	Type	Description	H	F
Id	Id	The unique identifier (id) of the referenced specification (TestDefinition).	M	M
Attributes				
Root		OID of the referenced specification.	M	M

Component2 - Element



Component2

/stabilityStudy/component/studyOnBatch/component1/testing/component/test/component

Description:

If a test has parameters (e.g., Assay and ingredients) this structure is used to store the parameters and document their order ("sequenceNumber")

or

Use this structure to indicate any special handling after the sample was drawn from the chamber before the real testing took place (pauseQuantity).

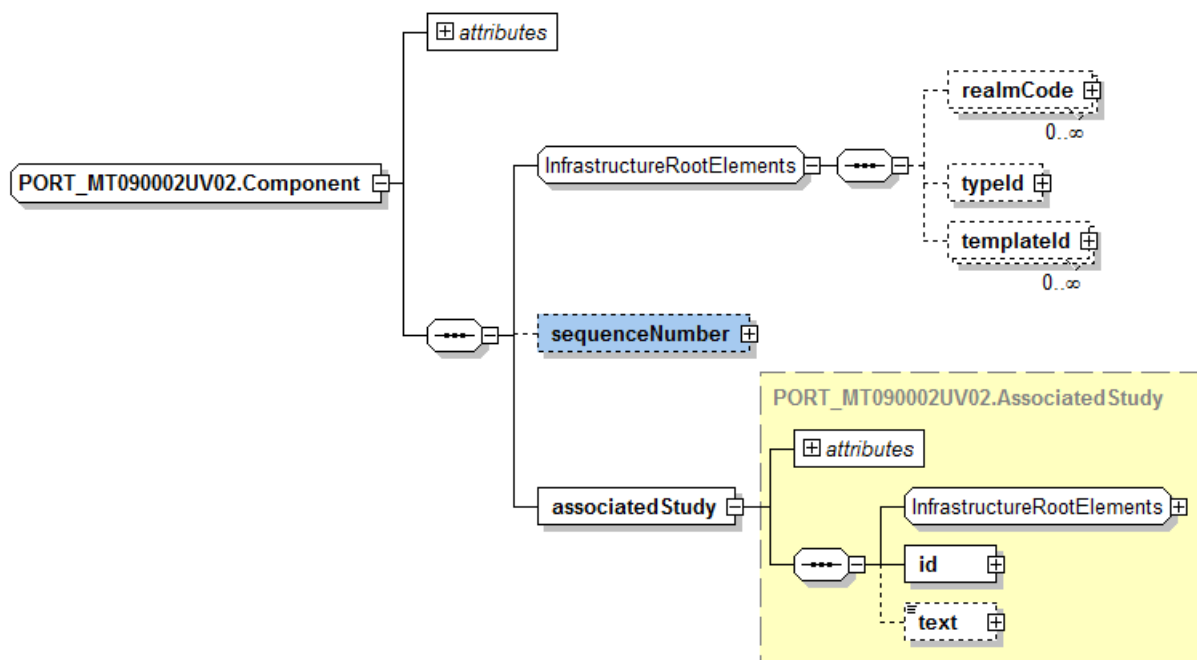
Simple Children:

Name	Type	Description	H	F
sequenceNumber	INT	The sequence of parameters of the test.	O	R
pauseQuantity	PQ	To use e.g. with growth of bacteria, etc.	O	R

Complex Children:

Name	Type	Description	H	F
test	Test		O	M

Component - Element



Component

/stabilityStudy/componentOf

Description:

The componentOf associates the current data file with another data file that has to be part of the same submission.

Simple Children:

Name	Type	Description	H	F
sequenceNumber	INT	Defines the sequence in which the associated files have to be interpreted.	O	R

Complex Children:

Name	Type	Description	H	F
associatedStudy	AssociatedStudy	The reference to the associated file.	M	M

Sample Code

```

<componentOf typeCode="COMP">
  <sequenceNumber value="1" />
  <associatedStudy>
    <id root="2.2.3.4.5.6.7.88.99.1.98721.1.3.2.4" />
    <text>
      <reference value="//estabilityexample-2.xml"/>
    </text>
  </associatedStudy>
</componentOf>

```

Associated Study

AssociatedStudy				
/stabilityStudy/componentOf/associatedStudy				
Description:				
The reference to the associated file.				
Simple Children:				
Name	Type	Description	H	F
id	II	The unique id used within the “StabilityStudy” element of the associated file.	O	R
text	ED	The file name of the associated study.	O	M

Sample Code

```

<componentOf typeCode="COMP">
  <sequenceNumber value="1" />
  <associatedStudy>
    <id root="2.2.3.4.5.6.7.88.99.1.98721.1.2.2.3" />
    <text>
      <reference value="//associatedstudy2.xml"/>
    </text>
  </associatedStudy>
</componentOf>
<componentOf typeCode="COMP">
  <sequenceNumber value="2" />
  <associatedStudy>
    <id root="2.2.3.4.5.6.7.88.99.1.98721.1.3.2.3" />
    <text>
      <reference value="//associatedstudy3.xml" />
    </text>
  </associatedStudy>
</componentOf>

```

Code Lists

The implementation team intensely discussed the necessity of defining code values and agreed on the general approach that for some codes, this would be a far too complex task for this group. Instead it will be allowed to submit only descriptive text for some of the codes. After this standard has been in use, the authorities should give feedback on the submitted values and, if reasonable, standardization will be approached by the implementation team.

For those values defined the NCI Thesaurus will be used to map the defined code to an OID and the code values can be found at <http://evs.nci.nih.gov/ftp1/FDA/Stability>. To get a new term and code for that term contact Terminology@fda.hhs.gov.

Type of Data File for Stability Study

Element Name / Attribute	/stabilityStudy/code (see page 22)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
This code should reflect if the file in hand is a standard data file for one storage condition, cycled-simple, or a partial file as part of a cycled-complex. Other file types may be possible. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov . As examples, a simple study could be a freeze-thaw study and a complex study could be a transportation study.	

Example:

```

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.1.1"/>
  <code code="C96085" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Standard" />
  ...
</stabilityStudy>

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.1.2"/>
  <code code="C96086" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Cycled-Simple" />
  ...
</stabilityStudy>

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.1.2"/>
  <code code="C103853" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Cycled-Complex" />
  ...
</stabilityStudy>

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.1.2"/>
  <code code="C96087" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Photostability" />
  ...
</stabilityStudy>

```

Reason for Data File for Stability Study

Element Name	/stabilityStudy/reasonCode (see page 22)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1

This code should indicate the type of application the data supports or whether the data is submitted to an existing application. The codes indicate that the data is part of an “Annual Report”, “New Drug Application”, “New Active Ingredient”, “Biologics License Application”, “Premarket Approvals”, or “Supplement to an Approved Application”. Code values can be found at <http://evs.nci.nih.gov/ftp1/FDA/Stability>. To get a new term and code for that term contact Terminology@fda.hhs.gov.

Example:

```

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.1.1"/>
  ....
  <reasonCode code="C72899" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="New Drug Application" />
  ...
</stabilityStudy>

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.3.1"/>
  ....
  <reasonCode code="C96092" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="New Active Ingredient" />
  ...
</stabilityStudy>

<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.4.1"/>
  ....
  <reasonCode code="C72901" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="New Animal Drug Application" />

```



```

...
</stabilityStudy>
-- Brief Description of why update: e.g. opening a new facility, reference to the cover letter
<stabilityStudy>
  <id root="2.3.6.1.4.1.24263.4711.5.1"/>
  ...
  <reasonCode code="C96089" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
  displayName="Annual Report" />
  ...
</stabilityStudy>

```

Product Code

Element Name	/stabilityStudy/subject/researchSubject/subjectProduct/code (see page 25)
Code System Name	Food and Drug Administration Drug Registration and Listing System
Code System (OID)	2.16.840.1.113883.6.69
<p>There is no code for the official product name. For FDA implementation, only the “displayName” (i.e., the product name) is mandatory. The code values should be provided if available (e.g., when used in other submissions like SPL or Drug Registration and Listing). If the NDC number exists for the product, it should be entered and prefix with "N".</p> <p>For NDA this is a new identifier.</p> <p>For ongoing studies the identifier should be identical to an already submitted code, so that a unique relationship can be established.</p>	
<p>Example:</p> <pre> <researchSubject> <subjectProduct> <code code="N12345-678" codeSystem="2.16.840.1.113883.6.69" codeSystemName="Food and Drug Administration Drug Registration and Listing System" displayName="JBE1000"/> <desc>Gummi Bears 100g Bag</desc> ... </subjectProduct> </pre>	

Product Form Code

Element Name	/stabilityStudy/subject/researchSubject/subjectProduct/formCode (see page 25)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
<p>This code describes the form of the reported product. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability. To get a new term and code for that term contact Terminology@fda.hhs.gov.</p>	
<p>Example:</p> <pre> <researchSubject> <subjectProduct> ... <formCode code="C42897" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="TABLET, COATED" /> ... </subjectProduct> </pre>	

Substance Code

Element Name	/stabilityStudy/subject/researchSubject/subjectSubstance/code (see page 28) or /stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient/ingredientSubstance/code
Code System Name	Food and Drug Administration Substance Registration System
Code System (OID)	2.16.840.1.113883.4.9
<p>The official code for a referenced substance (e.g., "acetylsalicylic acid"), as a single entity or part of a product (e.g., "aspirin").</p> <p>This code should be identical in all submissions, when referencing the same substance.</p> <p>Code values should be provided if available (e.g., when used in other submissions like SPL), please refer to "Substance Registration System - Unique Ingredient Identifier (UNII)", at http://fdasis.nlm.nih.gov. If you have a new compound that is not in the Substance Registration System (SRS) it can be registered by contacting fda-srs@fda.hhs.gov. The Preferred Substance Name must be used as listed at the FDA Substance Registration System - Unique Ingredient Identifier (UNII) web page. The compound can be given a code and the other information about the compound can remain confidential.</p>	
<p>Example:</p> <pre><subjectSubstance classCode="MMAT" determinerCode="INSTANCE" > <code code=" WYQ7N0BPYC " codeSystem="2.16.840.1.113883.4.9" codeSystemName=" Food and Drug Administration Substance Registration System " displayName="ACETYLCYSTEINE" /></pre> <p>Remark: The Code System name is required and note that in the above example for Substance that it matches the code system.</p>	

Stability Study Test Code

Element Name	/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/code (see page 36) or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/code
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
<p>This code describes the test performed during a study within the specification section. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability. To get a new term and code for that term contact Terminology@fda.hhs.gov.</p>	
<p>Example:</p> <pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.13.32.813" /> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="chemical" > <originalText>Assay</originalText> </code> <text> <reference value="file://Reference Documents/Method_NH432.pdf"/> </text> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary" > <originalText>NH432 Assay</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text></text> <value xsi:type="PQ" value="90" unit="%_LC" /> <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NLT" /> </acceptanceCriterion> </referenceRange> <referenceRange> <acceptanceCriterion> <text></text> <value xsi:type="PQ" value="110" unit="%_LC" /> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT" /> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	

Stability Study Method Type Code

Element Name	/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/methodCode (see page 37) or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/component/ testDefinition/ methodCode
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
A classification of the methods used in stability testing. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov.	
Example: See. Test Code	

Stability Study Interpretation Code

Element Name	/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/ referenceRange/acceptanceCriterion/interpretationCode (see page 38) or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/ component/testDefinition/referenceRange/acceptanceCriterion/interpretationCode
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
<p>For a single acceptance criterion (i.e., limit) this code describes how to relate the given value to a measured value, (e.g., a result should not be greater (not more) than the given value). The common accepted nomenclature should be used here:</p> <p>NMT (not more than) – the value should not be greater than the given value and includes the given value, which is equivalent to “less than or equal to”.</p> <p>NLT (not less than) – the value should not be smaller than the given value and includes the given value, which is equivalent to “greater than or equal to”.</p> <p>MT (more than) - the value should not be smaller than the given value excluding the given value, which is equivalent to “greater than”.</p> <p>LT (less than) - the value should not be greater than the given value excluding the given value, which is equivalent to “less than”.</p> <p>Passed or Failed - if the limit has a textual structure (i.e., such as “appearance”, where the limit is “white to yellow-white round tablet” and the result is complies). A Failed result should be documented in the comments field.</p> <p>Not Applicable – if a value for test has to be provided, but has no given criteria (e.g., the result is for “report only” or “monitoring”).</p>	

Code values can be found at <http://evs.nci.nih.gov/ftp1/FDA/Stability>. To get a new term and code for that term contact Terminology@fda.hhs.gov.

Example:

```
<acceptanceCriterion>
  <value xsi:type="PQ" value="1900" unit="ug"/>
  <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="NLT" />
</acceptanceCriterion>

<acceptanceCriterion>
  <value xsi:type="ST" value="Yellow" />
  <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Passed" />
</acceptanceCriterion>
```

Remark: In the tag `<value xsi:type="PQ" value="..." unit="..." />`, the qualifier `xsi:type` has to be used to allow schema validation, since `<value>` is of type "ANY".

Stability Study Type

Element Name	/stabilityStudy/component/studyOnBatch/code (see page 40)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
This code classifies the type of study performed on the given ResearchSubject, e.g., Commercial, Development, Clinical. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov.	
<p>Example:</p> <pre><studyOnBatch> <id root="2.3.6.1.4.1.24263.4711.1"/> <code code="C96109" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Commercial" /> <subject> <instance> <manufacturedMaterialInstance> ... </manufacturedMaterialInstance> </instance> </subject> </component> ... </component> </studyOnBatch></pre>	

Closure System Code

Element Name	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container/capTypeCode (see page 49)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
The closure system of the container. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov.	

Container Code

Element Name	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container/code (see page 49)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
As reported entity or as part of a reported packaged product, this is the official code for a referenced package type. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov.	

Stability Study Storage Condition Code

Element Name	/stabilityStudy/component/studyOnBatch/component1/storage/controlVariable/storageCondition/code (see page 54)
Code System Name	Stability Study Pause Description Terminology, NCI Thesaurus Codes
Code System (OID)	2.16.840.1.113883.3.26.1.1
The code provided represents a storage condition. Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov.	
Dependent of the internal company definitions this condition might be simple (e.g., 25°) or complex (e.g., 25° C/60% R.H. upright). The following contain links to other defined storage conditions: ICH storage temperature, Q1A-Q1F and WHO Technical Report Series, No. 953, 2009, Stability testing of active pharmaceutical ingredients and finished pharmaceutical products .	
There is no specific usage of the number of controlVariable elements used to describe the storage. This ensures the maximum flexibility to collect this information from data sources. The stylesheet all values in	

a vertical concatenation.

Example 1:

```
<component2>
  <storage>
    <code code="C96148" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="Proprietary" />

    <text></text>
    <effectiveTime value="20090727"/>

    <controlVariable>
      <storageCondition>
        <code displayName="ICH25C60RH" />
        <text></text>
        <value xsi:type="ST">25&#176;C ± 2&#176;C/60% RH ± 5% RH</value>
      </storageCondition>
    </controlVariable>

    <controlVariable>
      <storageCondition>
        <code displayName="Inverted" />
        <text></text>
        <value xsi:type="ST"> Inverted Orientation</value>
      </storageCondition>
    </controlVariable>
  </storage>
</component2>
```

There are two storage condition statements: one is based on ICH, one is proprietary (for Inverted Orientation). The style sheet displays the information for all <value>'s:

Storage Condition and Sample Orientation:

25°C/60% RH ± 5% RH

Inverted Orientation

Example 2:

```
<component2>
  <storage>
    <code code="C96146" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="ICH" />

    <text></text>
    <effectiveTime value="20090727"/>

    <controlVariable>
      <storageCondition>
        <code displayName="ICH25C60RH" />
        <text></text>
        <value xsi:type="ST">25&#176;C ± 2&#176;C/60% RH ± 5% RH</value>
      </storageCondition>
    </controlVariable>

  </storage>
</component2>
```

There is one storage condition statement that is proprietary and combines all storage conditions into one statement. The style sheet displays the information for the single <value> in a single line:

Storage Condition and Sample Orientation:

25°C/60% RH ± 5% RH Upright

Example 3:

```
<component2>
  <storage>
    <code code="C96148" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
```

```
displayName="Proprietary" />
```

```
<text></text>
<effectiveTime value="20090727"/>

<controlVariable>
  <storageCondition>
    <code displayName="25C" />
    <text></text>
    <value xsi:type="ST">25&#176;C</value>
  </storageCondition>
</controlVariable>

<controlVariable>
  <storageCondition>
    <code displayName="60RH" />
    <text></text>
    <value xsi:type="ST">60% RH ± 5% RH</value>
  </storageCondition>
</controlVariable>

<controlVariable>
  <storageCondition>
    <code displayName="Upright" />
    <text></text>
    <value xsi:type="ST">Upright</value>
  </storageCondition>
</controlVariable>
</storage>
</component2>
```

There are three storage condition statements that are proprietary. The style sheet displays the information for three <value>:

Storage Condition and Sample Orientation:

25°C

60% RH ± 5% RH

Upright

Stability Study Pause Description Code

Element Name	/stabilityStudy/component/studyOnBatch/component2/testing/code (see page 56)
Code System Name	National Cancer Institute Thesaurus
Code System (OID)	2.16.840.1.113883.3.26.1.1
This code describes any “delay that happened during testing, e.g. none (Immediate) or freeze sample (Delayed Frozen). Code values can be found at http://evs.nci.nih.gov/ftp1/FDA/Stability . To get a new term and code for that term contact Terminology@fda.hhs.gov.	

Example:

```
<component>
  <pauseQuantity xsi:type="PQ" value="0" unit="MONTHS"/>
  <testing>
    <code code="C96150" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus"
displayName="Immediate" />
    <title xsi:type="ST">Normal Testing</title>
  </component>
  <test>
    <effectiveTime>
      <high value="20051115"/>
    </effectiveTime>
    <value xsi:type="PQ" nullFlavor="NA"/>
    <definition>
      <definitionStub>
        <id root="2.3.6.1.4.1.24263.4711.1.1.1"/>
      </definitionStub>
    </definition>
    ...
  </test>
</component>
```

Appendix

Version History

Version	Date	Comments
0.1	18-MAY-2005	Original
0.2	12-AUG-2005	Corrected the identifier, inserted new table design
0.3	28-SEP-2005	Added (M)andatory, (R)equired and (O)ptional for most attributes, added comments, added list of code values
0.4	07-NOV 2005	Changes based on implementation team teleconference
0.4.1	09-NOV-2005	Added HL7 storyboard and comments on referenced models, added "DRAFT" watermark
0.5	12-JAN-2006	Added more sample code, added "Object Identifiers" section, added "XML Schema and Validation" section
0.6	21-JUN 2006	Added the agreed code lists and comments/examples to the code list section
0.7	04-APR 2008	Cover Release 2 DSTU of HL7 data model
1.0	01-JUL 2008	Cover modified Release 2 DSTU data model, cover changes from IG discussions
1.1	13-NOV 2008	Cover changes to Release 2 DSTU data model based on Sept. 08' ballot, cover changes based on Sept. 08' ballot
1.2	01-DEC 2008	Updated all WSDL diagrams to PORT_MT090002UV01 message, updated Associated Studies, Subjects and component numbering, updated all message names to the correct version
1.3	02-FEB 2009	Cover changes based on Jan. 09' ballot
1.4	22-APR 2009	Corrected iteration PORT_IN numbers, PORT_MT schema number, Stability Study HMD PORT_HD number, and content models
1.5	12-AUG-2010	Cover changes to Release 2 Normative data model based on May 10' ballot, cover changes from IG discussions
1.6	12-OCT-2010	Cover changes based on October 10' ballot of IG, cover changes from IG discussions
1.7	21-MAR-2011	Changes based on schematron (business rules) development and HL7 Drug Stability Reporting (eStability) Validation Procedures, fixed attributes listed under Simple Children and Complex Children and the order they are listed, Updated Code Lists
1.8	08-NOV-2011	Cover changes based on May 11' ballot of IG
1.9	04-FEB-2013	Wording and format, update location of schema files, corrections to examples, information on acceptable null values, and explanation of ST and PQ Date Types and the values that can be used.

Code System Reference List

Path Fragment	Code System	Subset
acceptanceCriterion/interpretationCode	2.16.840.1.113883.3.26.1.1	C96078
actOrderRequired/code	Not used in eStability	Not used in eStability
asLicensedEntity/code	Not used in eStability	Not used in eStability
asMember/code	Not used in eStability	Not used in eStability
asOrganizationPartOf/code	Not used in eStability	Not used in eStability
assignedDevice/code	Not used in eStability	Not used in eStability
assignedPerson/administrativeGenderCode	Not used in eStability	Not used in eStability
assignedPerson/code	Not used in eStability	Not used in eStability
authorOrPerformer/modeCode	Not used in eStability	Not used in eStability
authorOrPerformer/signatureCode	Not used in eStability	Not used in eStability
contactParty/code	Not used in eStability	Not used in eStability
contactPerson/administrativeGenderCode	Not used in eStability	Not used in eStability
container/capTypeCode	2.16.840.1.113883.3.26.1.1	C96080
container/code	2.16.840.1.113883.3.26.1.1	C96081
controlActProcess/languageCode	Not used in eStability	Not used in eStability
controlActProcess/priorityCode	Not used in eStability	Not used in eStability
controlActProcess/reasonCode	Not used in eStability	Not used in eStability
group/code	Not used in eStability	Not used in eStability
languageCommunication/languageCode	Not used in eStability	Not used in eStability
languageCommunication/modeCode	Not used in eStability	Not used in eStability
languageCommunication/moodCode	Not used in eStability	Not used in eStability
languageCommunication/proficiencyLevelCode	Not used in eStability	Not used in eStability
location/code	Not used in eStability	Not used in eStability
ocationPlace/code	Not used in eStability	Not used in eStability
notificationParty/code	Not used in eStability	Not used in eStability
organizationContains/code	Not used in eStability	Not used in eStability
overseer/modeCode	Not used in eStability	Not used in eStability
overseer/signatureCode	Not used in eStability	Not used in eStability
partOrganization/code	Not used in eStability	Not used in eStability
partOrganization/standardIndustryClassCode	Not used in eStability	Not used in eStability
representedOrganization/code	Not used in eStability	Not used in eStability
representedOrganization/standardIndustryClassCode	Not used in eStability	Not used in eStability
role/code	Not used in eStability	Not used in eStability
scopingOrganization/code	Not used in eStability	Not used in eStability
scopingOrganization/standardIndustryClassCode	Not used in eStability	Not used in eStability
stabilityStudy/code	2.16.840.1.113883.3.26.1.1	C96070
stabilityStudy/reasonCode	2.16.840.1.113883.3.26.1.1	C42930
studyOnBatch/code	2.16.840.1.113883.3.26.1.1	C96079
subjectProduct/formCode	2.16.840.1.113883.3.26.1.1	C96074
testDefinition/methodCode	2.16.840.1.113883.3.26.1.1	C96077
testing/code	2.16.840.1.113883.3.26.1.1	C96083
wholeOrganization/code	Not used in eStability	Not used in eStability
wholeOrganization/standardIndustryClassCode	Not used in eStability	Not used in eStability
subjectSubstance/code	2.16.840.1.113883.4.9	NA

ingredientSubstance/code	2.16.840.1.113883.4.9	NA
//stabilityStudy/subject/researchSubject/subjectProduct/code	2.16.840.1.113883.6.69	NA
//stabilityStudy/component/studyOnBatch/component2/storage/control Variable/storageCondition	2.16.840.1.113883.3.26.1.1	NA

HL7 Data Types

The following table lists the HL7 data types.

Data type	HL7 Description
AD	Postal and Residential Address - This Address data type is used to communicate postal addresses and residential addresses.
ANY	General Purpose – Can represent different data types.
CD	Concept Descriptor - Concept descriptors are the way to refer to real world concepts (e.g. diagnoses, procedures, etc.).
CE	Coded Entry – Identifies the source of the coding system.
CV	Code Value - A code value is used to refer to technical concepts and is also the basic building block for constructing more complex concept descriptors for real world concepts.
ED	Encapsulated Data - Typically used for things like additional information, attachments, or URI.
II	Instance Identifier – Identification such as OID.
INT	Integer Number - Embody the usual concept of integer numbers. Integers are used almost only for counts or values derived from counts by addition and subtraction.
IVL_TS	Time interval. Interval (IVL) - Also called "range". A continuous subset of an ordered type. Intervals are expressed by boundaries of the base type. Boundaries may be undefined. Point in Time (TS) - A difference scale quantity in the physical dimension of time.
ON	Organization Name - A collection of organization name variants.
PQ	Physical Quantity - A physical measurement with units.
RTO_PQ_PQ	Ratio of Quantities - A quotient of any two PQ quantities. As used in HL7 context, this is usually not the mathematical ratio, rather something that is conventionally expressed in the form of a mathematical ratio. An example is the fill size that is expressed as 100 tables/bottle or 10 mL/vial.
ST	Character String - A character string is a primitive data type that contains Unicode characters.

Stability Message Example

The following table contains an example of an eStability message with annotations in the right column. The product is hypothetical. The data is taken from many different products. It is unlikely that any product would be characterized by these tests.

The tests were chosen to illustrate all of the possible combination of ST and PQ tests and level 1 and level 2 in component1. The combinations also include the cardinality of the tests at multiple levels, for example ,no test results for Microbial Limits and twelve test results for Individual Alkali Oxide Extractables. The only combination that does not exist is a 0 cardinality PQ test at level one with either PQ or ST at level two. Although the PQ data type is nillable, the nil value is represented as NI or NA, both of which are ST. While an example was not provided in this message, there is no requirement for the level two tests to share the same data type.

This is the anatomy of a stability message. The number in parenthesis is the page number of the appropriate section of the table which contains an entire message. Elements that are underlined are hyperlinked to the appropriate section of the message. The message is broken into table rows with annotations in the right hand column. The example is long, but is provided as a complete example without interruptions. It has been validated against the schema. The annotation also includes images of how the particular portions of the message will display in the stylesheet (eStability.xsl).

```
<?xml version="1.0" encoding="UTF-8" ?> (87)
  <starter xsi:schemaLocation="urn:hl7 org:v3 PORT_MT090002UV02.xsd" xmlns:xsi="http://www.w3.org/2001/XMLSchema instance"
    xsi:schemaLocation="urn:hl7-org:v3 PORT_IN090004UV02.xsd" ITSVersion="XML_1.0"> (86)
    <stabilityStudy /> (87)
    <subject> (87)
      <researchSubject> (87)
        <subjectSubstance> or <subjectProduct> (87)
        <expirationTime /> (87)
        <specifiedIngredient /> (87)
        </subjectSubstance> or </subjectProduct> (87)
        <researchSponsor /> (88)
        <subjectOf> (88)
        <specification /> (88)
        <component /> 88-97)
        <testDefinition />
        .
        . repeating components for each test in the specification
        .
      </subjectOf> (97)
    </researchSubject> (97)
  </subject> (97)
  <component> (98)
  <studyOnBatch> (98)
  <subject> (98)
```

```

—   <instance>
—     <manufacturedMaterialInstance>
—       <existenceTime />
—       <lotNumberText />
—       <expirationTime />
—     <asManufacturedProduct> (98)
—       <manufacturer>
—     </asManufacturedProduct>
—     <asContent>
—       ../Users/Cath/AppData/Roaming/Microsoft/Users/Cath/AppData/Local/Temp/Local Settings/Local
—       Settings/Temp/IG/Users/Cath/AppData/Local/Temp/Users/Example\_message/skeleton.xml <batchIngredient>
—     </manufacturedMaterialInstance>
—   </instance>
— </subject>
— <component1_0m> (100)
—   <pauseQuantity />
—   <testing>
—     <performer>
—     <component>
—     <test>
—   </testing>
— </component1> (117)
— <component1> (117)
— .
— .
— . repeating component1s for each time point
— <component1> (132)
— <component1> (144)
— <component1> (163)
— <component1> (179)
— .
— .
— .
— <component2> (199)
—   <storage>
—     <controlVariable>
—       <storageCondition>
—     </controlVariable>
—   </storage>
— </component2>
— </studyOnBatch>
— </component>
— <componentOf> (200)
—   <associatedStudy>
— </stabilityStudy>

```

<pre> <?xml version="1.0" encoding="UTF-8"?> <?xml-stylesheet type="text/xsl" href="http://www.accessdata.fda.gov/stabilitydata/stylesheet/eStability.xsl"?> <PORT_IN090004UV02 ITSVersion="XML_1.0" xsi:schemaLocation="urn:hl7-org:v3 http://www.accessdata.fda.gov/stabilitydata/schema/multicacheschemas/PORT_IN090004UV02.xsd" xmlns="urn:hl7-org:v3" xmlns:xsi="http://www.w3.org/2001/XMLSchema-instance"> <id/> <creationTime value="20121216"/> <interactionId/> <processingCode/> <processingModeCode/> <acceptAckCode/> <receiver typeCode="RCV"> <device determinerCode="INSTANCE" classCode="DEV"> <id/> </device> </receiver> <sender typeCode="SND"> <device determinerCode="INSTANCE" classCode="DEV"> <id/> </device> </sender> <controlActProcess classCode="INFO" moodCode="EVN"> <subject typeCode="SUBJ"> </pre>	<p>The message header also referred to as a wrapper. For eStability purpose, this is an empty message header which must be included for validation purpose. It is therefore static text. The stylesheet should refer to that on the FDA website.</p>
<pre> <stabilityStudy> <id root="2.16.840.1.19927.1.12345.1.2010.5758.2.1"/> <code code="C96085" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Standard"/> <text>The purpose of this study EX 2010PRD5758 is to confirm the stability of BellaVie &#8482; (2 AMINOBTYROLE ACID, DL) 2.0 mg, Pink Film Coated Extended Release Tablets (Product 54321) per the NDA post approval stability commitments.</text> <reasonCode code="C96089" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Annual Report"/> </pre>	<p>Beginning of stability message payload. Corresponds to PORT_MT090002UV02.xsd</p> <p>Provide a unique id for the message.</p> <p>For eStability stylesheet, the text is the study purpose and in this case, also includes the submitter's internal study number.</p> <p>Stability Study Data Message: 2.16.840.1.19927.1.12345.1.2010.5758.2.1</p> <p>Study Code: Standard Reason Code: Annual Report</p> <p>Study Purpose: The purpose of this study EX 2010PRD5758 is to confirm the stability of BellaVie™ (2 AMINOBTYROLE ACID, DL) 2.0 mg, Pink Film Coated Extended Release Tablets (Product 54321) per the NDA post approval stability commitments.</p>
<pre> <subject> <researchSubject> <subjectProduct determinerCode="KIND"> <code code="N54321-123" codeSystem="2.16.840.1.113883.6.96" codeSystemName="Food and Drug Administration Drug Registration and Listing System" displayName="BellaVie &#8482;"/> <desc> BellaVie &#8482; 2-AMINOBTYRIC ACID, DL 2.0 mg Modified ReleaseTablets</desc> <formCode code="C42930" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Tablet, Film Coated, Extended Release"/> <expirationTime> <width value="14" unit="Month"/> </expirationTime> <specifiedIngredient> <quantity> <numerator xsi:type="PQ" value="2" unit="mg"/> <denominator xsi:type="PQ" value="1" unit="tablet"/> </quantity> <ingredientSubstance determinerCode="KIND"> <code code="8306QPJ19P" codeSystem="2.16.840.1.113883.4.9" codeSystemName="FDA Substance Registration System" displayName=".ALPHA.-AMINOBTYRIC ACID"/> <desc/> <expirationTime> <expirationTime/> </expirationTime> </ingredientSubstance> </specifiedIngredient> </subjectProduct> </pre>	<p>This section describes the product. This example message is for a drug product. For API, use subjectSubstance.</p> <p>&#8482; will display as ™ in the stylesheet. All special characters used in a message should be coded appropriately for html display. If the product is approved the stylesheet will display the registration number and preferred name. Otherwise the text supplied in the desc element will be displayed.</p> <div data-bbox="1048 1169 1377 1297"> <p>Product Code:</p> <p>N54321-123; BellaVie™</p> </div> <p>The specifiedIngredient is expressed as a ratio.</p>

	<div> Drug Substance: 2 mg / 1 8306QPJ19P FDA Substance Registration tablet System .ALPHA.-AMINO BUTYRIC ACID </div> <p>A multi-API is indicated with a specifiedIngredient element for each drug. E.g., Lansprazole /Rabeprazole</p>
<pre> <researchSponsor> <id root="D242634712" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <name>XYZ Pharmaceuticals, Inc.</name> <addr> <country>USA</country> <state>CA</state> <city>Utopia</city> <postalCode>90021</postalCode> <streetAddressLine>84 Main Street</streetAddressLine> </addr> </researchSponsor> </pre>	<p>Identification of the company submitting the data includes the unique identifier for the company and the address.</p> <div> Manufacturer: XYZ Pharmaceuticals, Inc. 84 Main Street, Utopia, CA, 90021, USA </div> <p>Use the DUNS number as the primary identifier. Other examples can be FEI number or a global unique identifier for the sponsoring organization assigned by IANA. For D-U-N-S® number, remove hyphens and prefix with "D" and if an FEI number prefix with an "F". Note: The assigningAuthorityName for a DUNS number is "Dun and Bradstreet D-U-N-S Number" and for a FEI number is "FDA FEI OID". A DUNS number and FEI number example are shown here.</p> <pre> <id root="D242634712" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <id root="F1234567890" assigningAuthorityName="FDA FEI OID"/> </pre>
<pre> <subjectOf> <specification> <code displayName="spec54321v01"/> <text> <reference value="..\m3\32-body-data\32p-drug-prod\text-rel-tab-2-mg\32p5-manu- dp\spec54321v01.pdf"/> </text> </specification> </subjectOf> </pre>	<p>Test procedures and acceptance criteria for drug substances and drug products are characterized in the specification. Each component in this section has been selected to illustrate the flexibility of the schema in capturing analytical procedures. This is by no means a complete enumeration of all the combinations and permutation of test types that can be structured with the message.</p> <p>Identify the specification and provide a reference to the specification.</p> <div> Specification Code: <u>SPEC-54321-V01</u> </div>
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.85.24.1497"/> <code code="C96100" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Biological"/> <originalText>Sterility</originalText> </code> <text/> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"> <originalText>USP &lt;math>\leq 71</math> Sterility</originalText> </methodCode> </pre>	<p>This is an example of a ST data type test with a single test at the first component level. A unique identifier is required. This is a compendial test, USP <math>\leq 71</math>. The test results are recorded within a component1 element and the id root 2.16.840.1.19927.1.12345.85.24.1497 will tie the test results to this specification.</p> <p>See the component below for an example.</p>

<pre> <referenceRange> <acceptanceCriterion> <text> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	<p>The testDefinition identifiers in this example are OIDs. If UID listing would look like this.</p> <pre><id root="f47ac10c-58cc-4372-a765-0e02b2c3d497"/></pre> <p>The same UID must be associated with the test for the life of the dossier (product or substance).</p>
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.9.25.14"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"> <originalText>Appearance</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"> <originalText>NH401 General appearance method</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>Pink round, film-coated tablet scored 99 OT9 one side and plain on the other</text> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	<p>This is another example of a ST data type test with a single test at the first component level. It is a proprietary test and text is provided in the acceptance criterion to clarify the interpretation of Passed.</p> <p>See the component below for an example.</p>
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.28.19.849"/> <code code="C96100" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Biological"> <originalText>Microbial Limits</originalText> </code> <text/> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"> <originalText>USP &lt;61> Microbial Limits</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text> <value xsi:type="ST" nullFlavor="NA">NA</value> <interpretationCode code="C48660" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NA"/> </acceptanceCriterion> </referenceRange> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.28.19.1668"/> <code code="C96100" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Biological"> <originalText>P. aeruginosa</originalText> </code> <text/> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"> <originalText>USP &lt;61> Microbial Limits</originalText> </methodCode> <referenceRange> <acceptanceCriterion> </pre>	<p>This is an example of ST data type tests that are associated. The test definition for the first level test has no acceptance criteria. It is used to group P. aeruginosa and Salmonella as Microbial Limits. A unique id is required for Microbial Limits and it must be represented in the component1 reporting.</p> <p>See the component below for an example.</p> <p>The codeSystemName for this method is given with the NCI subgroup extension. The short and long versions of the codeSystemName for the NCI Thesaurus are acceptable.</p>

<pre> </text/> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.28.19.1669"/> <code code="C96100" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Biological"/> <originalText>S. aureus</originalText> </code> </text/> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"/> <originalText>USP &lt;61&gt; Microbial Limits</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text/> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.28.19.1670"/> <code code="C96100" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Biological"/> <originalText>Salmonella</originalText> </code> </text/> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"/> <originalText>USP &lt;61&gt; Microbial Limits</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text/> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </pre>	
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.10.25.1671"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"/> <originalText>Container Integrity</originalText> </code> </text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH401 General appearance method</originalText> </methodCode> </pre>	<p>This is an example of a ST data type test that evaluates two subordinate tests that are also ST data type. The subordinate tests are encoded in level two. The test definition for the first level test has acceptance criteria. The Container Integrity passes if the Closure Appearance passes and Container Appearance passes.</p> <p>See the component below for an example.</p>

<pre> <referenceRange> <acceptanceCriterion> <text> <value xsi:type="ST"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </component> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.10.25.1672"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"> <originalText>Closure Appearance</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"> <originalText>NH401 General appearance</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>Closure sealed, crimped, and fitted properly</text> <value xsi:type="ST"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.10.25.1673"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"> <originalText>Container Appearance</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"> <originalText>NH401 General appearance method</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>Primary container appearance is visually consistent with reference</text> <value xsi:type="ST"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </pre>	
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.28.31.859"/> <code code="C96100" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Biological"> <originalText>Total Viable Aerobic Count</originalText> </code> <text/> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"> <originalText>2.6.12 Ph. Eur. Total Viable Aerobic count</originalText> </methodCode> </pre>	<p>This is an example of a PQ data type test with a single test at the first component level. The acceptance criteria must be given as a combination of the interpretation code (such as NMT, NLT, MT, LT) and values (which contains a value and a unit of measure). The text within the acceptance criteria is optional but allows for a full Description of the criteria. This full Description is displayed in the stylesheet.</p>

<pre> <referenceRange> <acceptanceCriterion> <text>&lt; 100 CFU/g</text> <value xsi:type="PQ" value="200" unit="CFU/g"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	<p>See the component below for an example.</p>
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.13.32.813"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"/> <originalText>Assay</originalText> </code> <text> <reference value="..\m3\32-body-data\32p-drug-prod\ext-rel-tab-2-mg\32p5-manu- dp\spec54321v01.pdf"/> </text> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH432 Assay</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>90.0% 110.0% of labeled claim (n=3) </text> <value xsi:type="PQ" value="90" unit="%_LC"/> <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NLT"/> </acceptanceCriterion> </referenceRange> <referenceRange> <acceptanceCriterion> <text>90.0% 110.0% of labeled claim (n=3) </text> <value xsi:type="PQ" value="110" unit="%_LC"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	<p>This is another example of a PQ data type test with a single test at the first component level. The test has both an upper and lower limit and thus has two acceptanceCriterion elements. The text Description of the criteria notes that three (n=3) replicates are expected in component1.</p> <p>See the component below for an example.</p>
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.86.26.820"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"/> <originalText>pH Measurement Average</originalText> </code> <text> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"/> <originalText>USP &lt;791> pH Measurement</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>3.3 to 4.5</text> <value xsi:type="PQ" value="3.3" unit="pH"/> <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NLT"/> </acceptanceCriterion> </referenceRange> <referenceRange> <acceptanceCriterion> </pre>	<p>This is an example of a PQ data type test that evaluates one subordinate test with many replicates that are also PQ data types. The subordinate test is encoded in level two. The test definition for the first level test has acceptance criteria as well as the second level. The acceptance criteria of the first level are the same the second level in the example, but this is not always the case. The average could have had tighter limits. Also, the upper and lower criteria do not need to be symmetric. For some tests, the first level may have an upper limit while the second level has both an upper and lower limit. The specification is set by the submitter appropriate for each product.</p> <p>See the component below for an example.</p>

<pre> <text>3.3 to 4.5</text> <value xsi:type="PQ" value="4.5" unit="pH"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.86.26.823"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"/> <originalText>pH Measurement</originalText> </code> </test> <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Compendial"/> <originalText>USP &lt;791> pH Measurement</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>3.3 to 4.5</text> <value xsi:type="PQ" value="3.3" unit="pH"/> <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NLT"/> </acceptanceCriterion> </referenceRange> <referenceRange> <acceptanceCriterion> <text>3.3 to 4.5</text> <value xsi:type="PQ" value="4.5" unit="pH"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </pre>	
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.200.27.342"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"/> <originalText>Dissolution Average</originalText> </code> </test> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH772 Dissolution Profile</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>1 hr: Average (n=6) is 26% - 34%; 4 hr: Average is 56% - 73%; 12 hr: Average is NLT 72% </text> <value xsi:type="PQ" value="26" unit="%"> <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NLT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	<p>This is an example of a PQ data type test. An example of this structure was already seen with the Assay example above. It has been included as an example of poor fit between the acceptance criteria and the data encoding in the message. The text Description of the criteria is “1 hr: Average (n=6) is 26% -34%; 4 hr: Average is 56% - 73%; 12 hr: Average is NLT 72%.” However the element for the acceptance criteria is NLT 26. There are two ranges and on lower limit in the text. It is impossible to capture these limits in a single acceptance criterion element or even two, because the limits from the different hours are not congruent. It would have been to either have an empty Dissolution Average and level 1 with three subordinate at level 2, “Average 1 Hour”, “Average 4 Hour” and “Average 12 Hour” or have the three separate tests at the first level. Another approach to this situation would have “Average 1 Hour” as the first level and followed by a subordinate test “Individual 1 Hour”. Ditto for 4 hour and 12 hour. Doing it this manner, one can have a specific test specification for each dissolution time point.</p> <p>See the component below for an example.</p>

<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.200.27.344"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"/> <originalText>Dissolution</originalText> </code> </testDefinition> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH772 Dissolution Profile</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>1 hr: Each tablet is 20%-40%; 4 hr: Each tablet is 50%-75%; 12 hr: Each tablet is NLT 85%</text> <value xsi:type="ST"/> <interpretationCode code="C48660" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NA"/> </acceptanceCriterion> </referenceRange> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.200.27.343"/> <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Physical"/> <originalText>Dissolution Hour</originalText> </code> </testDefinition> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH772 Dissolution Profile</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text> <value xsi:type="PQ" value="20" unit="%"> <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NLT"/> </interpretationCode> </text> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </pre>	<p>This structuring of a dissolution test has the same acceptance criteria issues as the previous example. However, it was included to show how the pauseQuantity element, available only for a subordinate test of the test component, can be used to record time units associated with testing.</p> <p>See the component below for an example and additional annotations.</p>
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.201.28.333"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"/> <originalText>Impurity - Elemental</originalText> </code> </testDefinition> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH740 Elemental Impurity Estimation</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C48660" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NA"/> </text> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </pre>	<p>This is an example of a ST data type a level one with multiple subordinate PQ tests at level 2. This is similar to the microbial limits test above. There is no difference in declaring an acceptance criterion with an interpretation code of “NA” and not declaring an acceptance criterion. In both cases the component1 data must record exactly one “NA” value for the top level element for each time interval where the test is performed.</p> <p>See the component below for an example.</p>

<pre> <id root="2.16.840.1.19927.1.12345.201.28.334"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"> <originalText>Nickel</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"> <originalText>NH740 Elemental Impurity Estimation</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>NMT 25 &#181;g</text> <value xsi:type="PQ" value="25" unit="&#181;g"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.201.28.335"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"> <originalText>Chromium</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"> <originalText>NH740 Elemental Impurity Estimation</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>NMT 25 &#181;g</text> <value xsi:type="PQ" value="25" unit="&#181;g"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.201.28.336"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"> <originalText>Palladium</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"> <originalText>NH740 Elemental Impurity Estimation</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>NMT 10 &#181;g</text> <value xsi:type="PQ" value="10" unit="&#181;g"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </component> </pre>	
</component>	This is an example of a ST data type a level one with multiple subordinate PQ


```

<testDefinition>
  <id root="2.16.840.1.19927.1.12345.202.30.339"/>
  <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Physical">
    <originalText>Permeation</originalText>
  </code>
  <text/>
  <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Compendial">
    <originalText>USP &lt;671>&gt; Containers Performance Testing</originalText>
  </methodCode>
  <referenceRange>
    <acceptanceCriterion>
      <text>NA</text>
      <value xsi:type="ST" nullFlavor="NA"/>
      <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Passed"/>
    </acceptanceCriterion>
  </referenceRange>
  <component>
    <testDefinition>
      <id root="2.16.840.1.19927.1.12345.202.30.340"/>
      <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Physical">
        <originalText>Water Weight Loss</originalText>
      </code>
      <text/>
      <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Compendial">
        <originalText>USP &lt;671>&gt; Containers Performance Testing</originalText>
      </methodCode>
      <referenceRange>
        <acceptanceCriterion>
          <text>NMT to 2.5% (w/w)</text>
          <value xsi:type="PQ" value="2.5" unit="%"/>
          <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="NMT"/>
        </acceptanceCriterion>
      </referenceRange>
    </testDefinition>
  </component>
  <component>
    <testDefinition>
      <id root="2.16.840.1.19927.1.12345.202.30.341"/>
      <code code="C96098" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI
Thesaurus" displayName="Physical">
        <originalText>Light Transmission</originalText>
      </code>
      <text/>
      <methodCode code="C96102" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="Compendial">
        <originalText>USP &lt;671>&gt; Containers Performance Testing</originalText>
      </methodCode>
      <referenceRange>
        <acceptanceCriterion>
          <text>290 nm to 450 nm</text>
          <value xsi:type="PQ" value="290" unit="nm"/>
          <interpretationCode code="C61583" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="NLT"/>
        </acceptanceCriterion>
      </referenceRange>
      <referenceRange>
        <acceptanceCriterion>
          <text>290 nm to 450 nm</text>
          <value xsi:type="PQ" value="450" unit="nm"/>
          <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1"
codeSystemName="NCI Thesaurus" displayName="NMT"/>
        </acceptanceCriterion>
      </referenceRange>
    </testDefinition>
  </component>
  </component>
</testDefinition>

```

tests at level 2. It differs from the test above it that a value is recorded for level one. If both of the subordinate tests are within their limits, then Permeation, the level one test, passes.

See the [component](#) below for an example.

<pre> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </pre>	
<pre> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.203.32.345"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"/> <originalText>Total Count of Failures</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH432 Extractables</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text>NMT 1 (n = 12)</text> <value xsi:type="PQ" value="1" unit="count"/> <interpretationCode code="C61586" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="NMT"/> </acceptanceCriterion> </referenceRange> <component> <testDefinition> <id root="2.16.840.1.19927.1.12345.203.32.346"/> <code code="C96099" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Chemical"/> <originalText>Individual Alkali Oxide Extractables</originalText> </code> <text/> <methodCode code="C96103" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Proprietary"/> <originalText>NH432 Extractables</originalText> </methodCode> <referenceRange> <acceptanceCriterion> <text/> <value xsi:type="ST" nullFlavor="NA"/> <interpretationCode code="C81275" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Passed"/> </acceptanceCriterion> </referenceRange> </testDefinition> </component> </testDefinition> </component> </specification> </subjectOf> </researchSubject> </subject> </pre>	<p>This is an example of a PQ data type a level one with one subordinate ST tests at level 2. The top level value is a count of failures found in the level 2 testing.</p> <p>See the component below for an example.</p>
<p>This specification as displayed in the stylesheet.</p>	

Specification			
Test	Acceptance Criteria	Analytical Procedure	Component Tests
Sterility (biological)	Passed	USP <71> Sterility (Compendial)	
Appearance (physical)	Pink round, film-coated tablet scored 99 0T9 one side and plain on the other	NH401 General appearance method (Proprietary)	
Microbial Limits (biological)		USP <61> Microbial Limits (compendial)	P. aeruginosa S. aureus Salmonella
Container Integrity (physical)	Passed	NH401 General appearance method (Proprietary)	Closure Appearance Container Appearance
Total Viable Aerobic Count (biological)	< 100 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count (Compendial)	
Assay (chemical)	90.0% - 110.0% of labeled claim 90.0% - 110.0% of labeled claim	NH432 Assay (Proprietary)	
pH Measurement Average (chemical)	3.3 to 4.5 3.3 to 4.5	USP <791> pH Measurement (Compendial)	pH Measurement
Dissolution Average (physical)	1 hr: Average (n=6) is 26%-34%; 4 hr: Average is 56%-73%; 12 hr: Average is NLT 72%	NH772 Dissolution Profile (Proprietary)	
Dissolution (physical)	1 hr: Each tablet is 20%-40%; 4 hr: Each tablet is 50%-75%; 12 hr: Each tablet is NLT 85%	NH772 Dissolution Profile (Proprietary)	Dissolution Hour
Impurity - Elemental (chemical)		NH740 Elemental Impurity Estimation (Proprietary)	Nickel Chromium Palladium
Permeation (physical)	NA	USP <671> Containers Performance Testing (Compendial)	Water Weight Loss Light Transmission
Total Count of Failures (chemical)	NMT 1 (n = 12)	NH432 Extractables (Proprietary)	Individual Alkali Oxide Extractables

```

<component>
  <studyOnBatch>
    <id root="2.16.840.1.19927.1.12345.1.2010.5758"/>
    <code code="C96109" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Commercial"/>
    <subject typeCode="SBJ"/>
    <instance classCode="INST">
      <manufacturedMaterialInstance classCode="MMAT" determinerCode="INSTANCE">
        <quantity xsi:type="PQ" value="100000" unit="tablet"/>
        <desc/>
        <existenceTime>
          <high value="20090726"/>
        </existenceTime>
        <lotNumberText>EX-5758</lotNumberText>
        <expirationTime>
          <high value="20101019"/>
        </expirationTime>
        <asManufacturedProduct classCode="MANU">
          <manufacturer classCode="ORG" determinerCode="INSTANCE">
            <id root="D284143234" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/>
            <id root="2.16.840.343.2343.333" assigningAuthorityName="Internet Assigned Numbers Authority"/>
          </manufacturer>
        </asManufacturedProduct>
      </manufacturedMaterialInstance>
    </instance>
  </studyOnBatch>
</component>

```

StudyOnBatch contains information about the specific lot that was tested. The images illustrate how the XML displays in the first table of the stylesheet. The elements are rather straight forward, and the main body of the Implementation Guide is a good source if the reader needs clarification.

Protocol Code:

Commercial

Lot/Batch Size:

100000 tablet

Lot/Batch Number:

EX-5758

Since the expiration time was reported as a high value, the expiration date is designated as approved.

<pre> <name>Vandechemie</name> <addr> <country>Belgium</country> <state> <city>Blankenberge</city> <postalCode>8370</postalCode> <streetAddressLine>Ruzettelaan 39234</streetAddressLine> </addr> <assignedEntity> <representedManufacturer> <id root="D123456789" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> </representedManufacturer> </assignedEntity> </manufacturer> </asManufacturedProduct> <asContent classCode="CONT"> <quantity> <numerator xsi:type="PQ" value="100" unit="count"/> <denominator xsi:type="PQ" value="1" nullFlavor="NI"/> </quantity> <container classCode="CONT" determinerCode="INSTANCE"> <code code="C43169" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Bottle"/> <desc>100 tablets are contained in a 600 cc, white, HDPE bottle with a 28 mm continuous threading metal cap.</desc> <lotNumberText> <capacityQuantity xsi:type="PQ" value="100" unit="Bottle"/> <capTypeCode code="C96115" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus" displayName="Continuous Thread, Metal"/> </container> </asContent> <batchIngredient classCode="INGR"> <quantity> <numerator xsi:type="PQ" nullFlavor="NI"/> <denominator xsi:type="PQ" nullFlavor="NI"/> </quantity> <ingredientManufacturedMaterial classCode="MMAT" determinerCode="INSTANCE"> <quantity xsi:type="PQ" value="1" unit="kg"/> <desc>.ALPHA.-AMINO BUTYRIC ACID</desc> <existenceTime> <high value="20071121"/> </existenceTime> <lotNumberText>593421</lotNumberText> <expirationTime> <high value="20130125"/> </expirationTime> </asManufacturedProduct classCode="MANU"> <manufacturer classCode="ORG" determinerCode="INSTANCE"> <id root="D26535539" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> </manufacturer> </asManufacturedProduct> <name>Bervem Inc</name> <addr> <country>USA</country> <state>MA</state> <city>Peabody</city> <postalCode>01520</postalCode> <streetAddressLine>3498 Northumberland Drive</streetAddressLine> </addr> </pre>	<div> <div> Expiration Dating: 14 Month 19-Oct-2010 (approved) </div> <div> Manufacturing Site: Vandechemie Ruzettelaan 39234, 830 Blankenberge, Belgium Assignee: Specialty Pharma 100 Spring St., Philadelphia, PA, 01972, USA </div> <div> Amount in Container: 100 count </div> <div> Container/Closure Description: 100 tablets are contained in a 600 cc, white, HDPE bottle with a 28 mm continuous threading metal cap. </div> <p>The code for Bottle is C43169 in the National Cancer Institute Thesaurus. The codeSystem and codeSystemName must be entered.</p> <div> Container/Closure Code: Bottle Continuous Thread, Metal </div> <p>All ingredient lot information can be listed here including the API lot information.</p> <div> Drug Substance - Lot/Batch Numbers - Manufacturing Sites: .ALPHA.-AMINO BUTYRIC ACID 593421 Bervem Inc 3498 Northumberland Drive, Peabody, MA, 01520, USA Microcrystalline Cellulose MI3345-CEL Haorui Pharma-Chem Inc. 100 Menlo Park Drive, Edison, New Jersey, 08837, USA </div> </div>
--	--


<pre> </manufacturer> </asManufacturedProduct> <asContent classCode="CONT"> <container> <capacityQuantity/> </container> </asContent> </ingredientManufacturedMaterial> </batchIngredient> <batchIngredient classCode="INGR"> <quantity> <numerator xsi:type="PQ" nullFlavor="NI"/> <denominator xsi:type="PQ" nullFlavor="NI"/> </quantity> <ingredientManufacturedMaterial classCode="MMAT" determinerCode="INSTANCE"> <quantity xsi:type="PQ" value="10" unit="kg"/> <desc> Microcrystalline Cellulose</desc> <existenceTime> <high value="20080227"/> </existenceTime> <lotNumberText>MI3345-CEL</lotNumberText> <expirationTime> <high value="20130515"/> </expirationTime> <asManufacturedProduct classCode="MANU"> <manufacturer classCode="ORG" determinerCode="INSTANCE"> <id root="D223367996" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <name>Haorui Pharma-Chem Inc.</name> <addr> <country>USA</country> <state>New Jersey</state> <city>Edison</city> <postalCode>08837</postalCode> <streetAddressLine>100 Menlo Park Drive</streetAddressLine> </addr> </manufacturer> </asManufacturedProduct> <asContent classCode="CONT"> <container> <capacityQuantity/> </container> </asContent> </ingredientManufacturedMaterial> </batchIngredient> </manufacturedMaterialInstance> </instance> </subject> </pre>	
<pre> <component1> <pauseQuantity xsi:type="PQ" value="0" unit="month"/> <testing> <code code="C96150" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName=" NCI Thesaurus" displayName="Immediate" /> <title>Initial testing</title> <text/> <effectiveTime value="20090727"/> <performer> <assignedEntity> <assignedTestingSite> <id root="D436776341" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <name>Sterile Testing Corp.</name> <addr> <country>Canada</country> <state/> <city>London, ONT</city> <postalCode>N6A 4L9</postalCode> </pre>	<p>The first component 1. This message reports six time point. This is the initial testing at time point 0. The date entered for the earliest pauseQuantity is taken as the study start date.</p> <div data-bbox="925 1187 1234 1279"> <p>Starting Date: 30-Jul-2009</p> </div> <p>Enter only the testing sites that reported at this time interval.</p>

<pre><streetAddressLine>291 Windermere Drive</streetAddressLine> </addr> </assignedTestingSite> </assignedEntity> </performer> </performer> <assignedEntity> <assignedTestingSite> <id root="D567227566" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <name>Northeastern Analytic Services</name> <addr> <country>USA</country> <state>OH</state> <city>Denver</city> <postalCode>45874</postalCode> <streetAddressLine>23 North Washington Street</streetAddressLine> </addr> </assignedTestingSite> </assignedEntity> </performer></pre>																																		
<pre><component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090727"/> <value xsi:type="ST">Passed</value> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D436776341"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.85.24.1497"/> </definitionStub> </definition> </test> </component></pre>	<p>This example has a single test result.</p> <table><tr><th>Test</th><th>Acceptance Criteria</th><th>Analytical Procedure</th><th>0</th></tr><tr><td>Sterility</td><td>Passed</td><td>USP <71> Sterility</td><td>Passed</td></tr></table> <p>The code and the effectiveTime are displayed in the stylesheet by hovering over the time point.</p> <table><tr><th colspan="5">Sampling Intervals: Months</th></tr><tr><th></th><th>0</th><th>1</th><th>3</th><th>6</th></tr><tr><td></td><td>Passed</td><td></td><td></td><td>Passed</td></tr><tr><td>Passed</td><td colspan="4">Tested on: 27-Jul-2009. By: Sterile Testing Corp..</td></tr><tr><td></td><td>NA</td><td></td><td></td><td>NA</td></tr></table>	Test	Acceptance Criteria	Analytical Procedure	0	Sterility	Passed	USP <71> Sterility	Passed	Sampling Intervals: Months						0	1	3	6		Passed			Passed	Passed	Tested on: 27-Jul-2009. By: Sterile Testing Corp..					NA			NA
Test	Acceptance Criteria	Analytical Procedure	0																															
Sterility	Passed	USP <71> Sterility	Passed																															
Sampling Intervals: Months																																		
	0	1	3	6																														
	Passed			Passed																														
Passed	Tested on: 27-Jul-2009. By: Sterile Testing Corp..																																	
	NA			NA																														
<pre><component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090727"/> <value xsi:type="ST">Passed</value> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D567227566"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.9.25.14"/> </definitionStub> </definition> </test> </component> <component> <test classCode="OBS" moodCode="EVN"> <title/></pre>	<p>The number of data points, i.e., replicates is not necessarily given in specification. The message author must include all replicate test data. Counts are dynamically calculated and displayed by the stylesheet. The test has five replicates. Each replicate is contained in a component.</p> <table><tr><td>Appearance</td><td>Passed</td><td>NH401 General appearance method</td><td>Passed(5)</td></tr></table> <p>The individual results display by clicking on the grouped result value.</p>	Appearance	Passed	NH401 General appearance method	Passed(5)																													
Appearance	Passed	NH401 General appearance method	Passed(5)																															

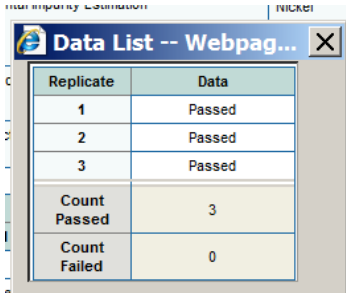
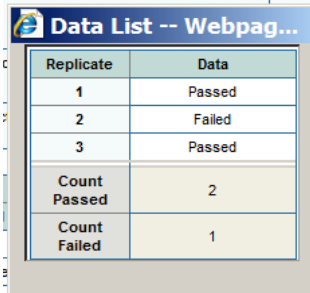
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 Data List -- Webpag...

Replicate	Data
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2	Passed
3	Passed
4	Passed
5	Passed
Count Passed	5
Count Failed	0

<pre></assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.9.25.14"/> </definitionStub> </definition> </test> </component></pre>													
<pre><component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090827"/> <value xsi:type="ST">Passed</value> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D567227566"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.10.25.1671"/> </definitionStub> </definition> </component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090827"/> <value xsi:type="ST">Passed</value> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D567227566"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.10.25.1672"/> </definitionStub> </definition> </test> </component> <component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090827"/> <value xsi:type="ST">Passed</value> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D567227566"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.10.25.1672"/> </definitionStub> </definition> </test> </component></pre>	<p>This is an example of two levels of ST results. There are two different ST tests at level two. The P/F cannot be found in the message. It is created by the stylesheet based on the values of the test results.</p> <table><tr><td>Container Integrity</td><td>Passed</td><td>NH401 General appearance method</td><td>Passed</td></tr><tr><td>Closure Appearance</td><td>Passed</td><td>NH401 General appearance method</td><td>Passed(3)</td></tr><tr><td>Container Appearance</td><td>Passed</td><td>NH401 General appearance method</td><td>P/F(3)</td></tr></table> <p>Level two individual results display in separate windows.</p> <div><div></div><div></div></div>	Container Integrity	Passed	NH401 General appearance method	Passed	Closure Appearance	Passed	NH401 General appearance method	Passed(3)	Container Appearance	Passed	NH401 General appearance method	P/F(3)
Container Integrity	Passed	NH401 General appearance method	Passed										
Closure Appearance	Passed	NH401 General appearance method	Passed(3)										
Container Appearance	Passed	NH401 General appearance method	P/F(3)										

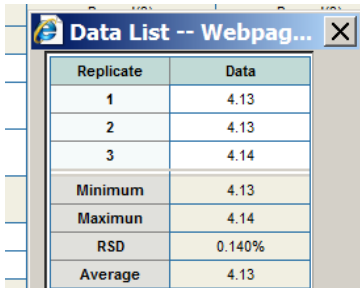

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<title/>
<text/>
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<value xsi:type="ST">Passed</value>

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The text appears when a data value is hovered.

The text appears when a data value is hovered.					
Data List -- Webpag... X		NH740 Elemental Impurity Estimation (Proprietary)	Nickel Chromium Palladium		
Replicate	Data	USP <671> Containers Performance Testing (Compendial)	Water Weight Loss Light Transmission		
1	Passed	NH432 Extractables (Proprietary)	Tested on: 27-Jul-2009. Label scuffed. The investigation determined that it was due to testor mishandling and does not effect the stability of the product.		
2	Failed				
3	Passed				
Count Passed	2				
Count Failed	1				
		1	3	6	9
		Passed			

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Total Viable Aerobic Count	NMT 200 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count	20																						
<pre><component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090727"/> <value xsi:type="PQ" value="4.13" unit="pH"/> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D567227566"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.86.26.820"/> </definitionStub> </definition> </component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090727"/> <value xsi:type="PQ" value="4.13" unit="pH"/> <performer typeCode="PRF"> <assignedEntityStub> <assignedSiteStub> <id root="D567227566"/> </assignedSiteStub> </assignedEntityStub> </performer> <definition> <definitionStub> <id root="2.16.840.1.19927.1.12345.86.26.820"/> </definitionStub> </definition> </component></pre>	<p>This is an example of a bi-level PQ data type test. There are three replicates at the second level.</p> <table><tr><td>pH Measurement Average</td><td>NLT 3.3 pH NMT 4.5 pH</td><td>USP <791> pH Measurement</td><td>4.13</td></tr><tr><td>pH Measurement</td><td>NLT 3.3 pH NMT 4.5 pH</td><td>USP <791> pH Measurement</td><td>4.13(3)</td></tr></table> <p>Individual values. The Minimum, Maximum, RSD and Average are calculated by the stylesheet.</p>  <table><tr><th>Replicate</th><th>Data</th></tr><tr><td>1</td><td>4.13</td></tr><tr><td>2</td><td>4.13</td></tr><tr><td>3</td><td>4.14</td></tr><tr><td>Minimum</td><td>4.13</td></tr><tr><td>Maximum</td><td>4.14</td></tr><tr><td>RSD</td><td>0.140%</td></tr><tr><td>Average</td><td>4.13</td></tr></table>	pH Measurement Average	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13	pH Measurement	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13(3)	Replicate	Data	1	4.13	2	4.13	3	4.14	Minimum	4.13	Maximum	4.14	RSD	0.140%	Average	4.13
pH Measurement Average	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13																						
pH Measurement	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13(3)																						
Replicate	Data																								
1	4.13																								
2	4.13																								
3	4.14																								
Minimum	4.13																								
Maximum	4.14																								
RSD	0.140%																								
Average	4.13																								

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Dissolution Average	NLT 26 %	NH772 Dissolution Profile	74.0(6		

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Data List -- Webpag... X	
Replicate	Data
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2	42.9
3	82.8
4	82.2
5	97.4
6	98.1
Minimum	41.2
Maximum	98.1
RSD	34.70%
Average	74.1

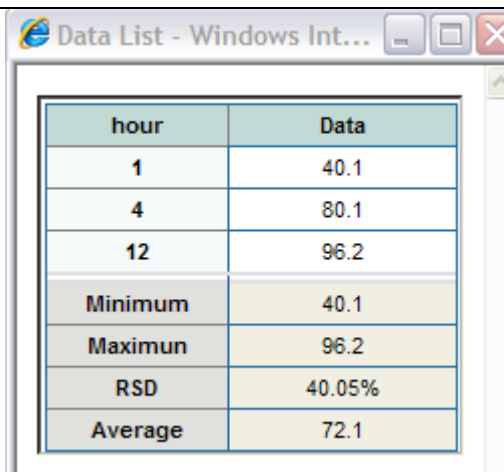
Tested on: 27-Jul-2009. 4 hour

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Dissolution	NA	NH772 Dissolution Profile	NA						
Dissolution Hour	NLT 20 %	NH772 Dissolution Profile	72.1(3)						

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hour	Data
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4	80.1
12	96.2
Minimum	40.1
Maximum	96.2
RSD	40.05%
Average	72.1

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This is an example of a second level PQ test with several tests at level two.

Impurity - Elemental	NA	NH740 Elemental Impurity Estimation	NA
Nickel	NMT 25 µg	NH740 Elemental Impurity Estimation	19.4
Chromium	NMT 25 µg	NH740 Elemental Impurity Estimation	12.5
Palladium	NMT 10 µg	NH740 Elemental Impurity Estimation	4.9

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<pre> <component> <test classCode="OBS" moodCode="EVN"> <title/> </pre>	<p>This is an example of an ST data type at level one that reports a value. It has two level two PQ data type test. Both have three replicates.</p>

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Permeation	Passed	USP <671> Containers Performance Testing	Passed
Water Weight Loss	NMT 2.5 %	USP <671> Containers Performance Testing	2.04(3)
Light Transmission	NLT 290 nm NMT 450 nm	USP <671> Containers Performance Testing	358.(3)

The Water Weight Loss results. Note that the average reported at level one was reported in the message and the Average in the replicate window is calculated by the stylesheet.

Replicate	Data
1	2.24
2	1.84
3	2.06
Minimum	1.84
Maximum	2.24
RSD	9.788%
Average	2.05

Light Transmission replicate values.

Replicate	Data
1	354
2	398
3	323
Minimum	323
Maximum	398
RSD	10.5%
Average	358.


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Total Count of Failures	NMT 1 count	NH432 Extractables	0						
Individual Alkali Oxide Extractables	PASSED	NH432 Extractables	Passed(12)						

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<pre> <component> <test classCode="OBS" moodCode="EVN"> <title/> <text/> <effectiveTime value="20090727"/> </pre>	<p>Assay is an example of a PQ test with multiple replicates at the first component level. The average displayed is calculated by the stylesheet and is not found in the message.</p>

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Assay	NLT 90 %_LC NMT 110 %_LC	NH432 Assay	102.19(3		
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Salmonella must be reported as level two tests under a Microbial Limits parent test.

Microbial Limits in the specification.

Microbial Limits		USP <61> Microbial Limits	NA
P. aeruginosa	Passed	USP <61> Microbial Limits	Passed
S. aureus	Passed	USP <61> Microbial Limits	Passed
Salmonella	Passed	USP <61> Microbial Limits	Passed
Container Integrity	Passed	NH401 General appearance method	Passed
Closure Appearance	Passed	NH401 General appearance method	Passed(3)
Container Appearance	Passed	NH401 General appearance method	Passed(3)
Total Viable Aerobic Count	NMT 200 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count	20
Assay	NLT 90 %_LC NMT 110 %_LC	NH432 Assay	102.19(3)

Microbial Limits data on the main page of the stylesheet.

Test		Specification		Sampling Intervals: Months					
		Acceptance Criteria	Analytical Procedure	0	1	3	6	9	12
Sterility	Passed	USP <71> Sterility	Passed	Passed	Passed(5)	Passed(5)	Passed(5)	Passed(5)	Passed(5)
Appearance	Passed	NH401 General appearance method	Passed(5)	Passed(5)	Passed(5)	Passed(5)	Passed(5)	Passed(5)	Passed(5)
Microbial Limits		USP <61> Microbial Limits	NA				NA		NA
P. aeruginosa	Passed	USP <61> Microbial Limits	Passed				Passed		Passed
S. aureus	Passed	USP <61> Microbial Limits	Passed				Passed		Passed
Salmonella	Passed	USP <61> Microbial Limits	Passed				Passed		Passed
Container Integrity	Passed	NH401 General appearance method	Passed	Passed	Passed	Passed	Passed	Passed	Passed
Closure Appearance	Passed	NH401 General appearance method	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)
Container Appearance	Passed	NH401 General appearance method	PF(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)
Total Viable Aerobic Count	NMT 200 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count	20				18		20

Microbial Limit on the alternate view page of the stylesheet.

NA	Assay	NLT 90 %_LC; NMT 110 %_LC	NH432 Assay	0	month	102.10	%_LC
NA	Assay	NLT 90 %_LC; NMT 110 %_LC	NH432 Assay	0	month	102.30	%_LC
NA	Assay	NLT 90 %_LC; NMT 110 %_LC	NH432 Assay	0	month	102.20	%_LC
NA	Microbial Limits	NA	USP <61> Microbial Limits	0	month	NA	
Microbial Limits	P. aeruginosa	PASSED	USP <61> Microbial Limits	0	month	Passed	
Microbial Limits	S. aureus	PASSED	USP <61> Microbial Limits	0	month	Passed	
Microbial Limits	Salmonella	PASSED	USP <61> Microbial Limits	0	month	Passed	


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</performer>
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        <assignedSiteStub>
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</test>
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</performer>
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<title/>

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  <text/>
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  <performer typeCode="PRF">
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  <text/>
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  <text/>
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<pre> <component1> <pauseQuantity xsi:type="PQ" value="15" unit="month"/> <testing> <code code="C96150" codeSystem="2.16.840.1.113883.3.26.1.1" codeSystemName="NCI Thesaurus - Stability Study Pause Description Terminology" displayName="Immediate"/> <title>15 month testing</title> <text/> <effectiveTime value="20101028"/> <performer> <assignedEntity> <assignedTestingSite> <id root="D436776341" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <name>Sterile Testing Corp.</name> <addr> <country>Canada</country> <state/> <city>London, ONT</city> <postalCode>N6A 4L9</postalCode> <streetAddressLine>291 Windermere Drive</streetAddressLine> </addr> </assignedTestingSite> </assignedEntity> </performer> <performer> <assignedEntity> <assignedTestingSite> <id root="D567227566" assigningAuthorityName="Dun and Bradstreet D-U-N-S Number"/> <name>Northeastern Analytic Services</name> <addr> <country>USA</country> <state>OH</state> <city>Denver</city> <postalCode>45874</postalCode> <streetAddressLine>23 North Washington Street</streetAddressLine> </addr> </assignedTestingSite> </assignedEntity> </performer> </pre>	<p>The sixth component1 reports the fifteenth month values. Note: two testing sites are reported because USP <61> and USP <71> are tested at this time point.</p>

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  </assignedEntityStub>
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    </performer>
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</component>
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</component1>

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All component1 elements as displayed on the main page of the stylesheet.

Specification			Sampling Intervals: Months					
Test	Acceptance Criteria	Analytical Procedure	0	1	3	6	9	15
Sterility	Passed	USP <71> Sterility	Passed			Passed		Passed
Appearance	Passed	NH401 General appearance method	Passed(5)	Passed(5)	Passed(5)	Passed(5)	Passed(5)	P/F(5)
Microbial Limits		USP <61> Microbial Limits	NA			NA		NA
P. aeruginosa	Passed	USP <61> Microbial Limits	Passed			Passed		Passed
S. aureus	Passed	USP <61> Microbial Limits	Passed			Passed		Passed
Salmonella	Passed	USP <61> Microbial Limits	Passed			Passed		Passed
Container Integrity	Passed	NH401 General appearance method	Passed	Passed	Passed	Passed	Passed	Passed
Closure Appearance	Passed	NH401 General appearance method	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)
Container Appearance	Passed	NH401 General appearance method	P/F(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)	Passed(3)
Total Viable Aerobic Count	NMT 200 CFU/g	2.6.12 Ph. Eur. Total Viable Aerobic count	20			18		21
Assay	NLT 90 %_LC NMT 110 %_LC	NH432 Assay	102.19(3)	100.3(3)	102.0(3)	102.4(3)	103.3(3)	103.2(3)
pH Measurement Average	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13	4.12	4.1	4.12	4.09	4.07
pH Measurement	NLT 3.3 pH NMT 4.5 pH	USP <791> pH Measurement	4.13(3)	4.11(3)	4.10(3)	4.12(3)	4.08(3)	4.06(3)
Dissolution Average	NLT 26 %	NH772 Dissolution Profile	74.0(6)	74.4(6)	73.8(6)	74.9(6)	75.2(6)	75.6(6)
Dissolution	NA	NH772 Dissolution Profile	NA	NA	NA	NA	NA	NA
Dissolution Hour	NLT 20 %	NH772 Dissolution Profile	72.1(3)	77.3(3)	75.9(3)	74.6(3)	74.7(3)	77.1(3)
Impurity - Elemental	NA	NH740 Elemental Impurity Estimation	NA			NA		NA
Nickel	NMT 25 g	NH740 Elemental Impurity Estimation	19.4			20.5		21.3
Chromium	NMT 25 g	NH740 Elemental Impurity Estimation	12.5			19.8		19.8
Palladium	NMT 10 g	NH740 Elemental Impurity Estimation	4.9			6.6		6.4
Permeation	Passed	USP <671> Containers Performance Testing	Passed	Passed	Passed	Passed	Passed	Passed
Water Weight Loss	NMT 2.5 %	USP <671> Containers Performance Testing	2.04(3)	2.01(3)	2.11(3)	2.01(3)	2.13(3)	2.01(3)
Light Transmission	NLT 290 nm NMT 450 nm	USP <671> Containers Performance Testing	358.(3)	353.(3)	360.(3)	376.(3)	368(3)	385(3)
Total Count of Failures	NMT 1 count	NH432 Extractables	0			0	0	1
Individual Alkali Oxide Extractables	Passed	NH432 Extractables	Passed(12)			Passed(12)	Passed(12)	P/F(12)

```

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Component2 describes the storage condition. The storage condition can be composed of as many storageCondition elements as required. In this case, 25 °C could have been a storageCondition element and 60% RH could have been another and would have been displayed on three lines instead of two.

Storage Condition and Sample Orientation:

25 Deg C/60% RH

Upright Orientation

Note: The term of 'storage' as used in eStability is the entire 'storage condition'

<pre></controlVariable> </storage> </component2></pre>	statement as commonly understood. The term of ‘storage condition’ as used in eStability represents a single storage condition component which can be a temperature, temperature/humidity combination, or an orientation.									
<pre></studyOnBatch> </component> <componentOf typeCode="COMP"> <sequenceNumber value="1"/> <associatedStudy> <id root="2.3.6.1.4.1.24263.4711.1.1" assigningAuthorityName="XYZ Pharmaceuticals, Inc."/> <text> <reference value="examplemessage2.xml"/> </text> </associatedStudy> </componentOf> <componentOf typeCode="COMP"> <sequenceNumber value="2"/> <associatedStudy> <id root="2.3.6.1.4.1.24263.4711.1.10" assigningAuthorityName="XYZ Pharmaceuticals, Inc."/> <text> <reference value="examplemessage3.xml"/> </text> </associatedStudy> </componentOf></pre>	<p>Identification of related messages. The reference value is a hyperlinked value. In this case the files are in the same directory as this message.</p> <table><tr><th>Associated Messages:</th><th>Sequence</th><th>File Reference</th></tr><tr><td></td><td>1</td><td>- 2.3.6.1.4.1.24263.4711.1.1 (Lot: FDS6758AA Storage: ICH 25C/60% RH)</td></tr><tr><td></td><td>2</td><td>- 2.3.6.1.4.1.24263.4711.1.10 (Lot: FDS1873 Storage: ICH 40C / 75% RH)</td></tr></table> <p>If the study is cycled, then the sequence has meaning and must correspond to the order the samples were exposed to the storage conditions. Otherwise, sequence can have meaning to the reporter, such as study start time or climatic region order.</p>	Associated Messages:	Sequence	File Reference		1	- 2.3.6.1.4.1.24263.4711.1.1 (Lot: FDS6758AA Storage: ICH 25C/60% RH)		2	- 2.3.6.1.4.1.24263.4711.1.10 (Lot: FDS1873 Storage: ICH 40C / 75% RH)
Associated Messages:	Sequence	File Reference								
	1	- 2.3.6.1.4.1.24263.4711.1.1 (Lot: FDS6758AA Storage: ICH 25C/60% RH)								
	2	- 2.3.6.1.4.1.24263.4711.1.10 (Lot: FDS1873 Storage: ICH 40C / 75% RH)								
<pre></stabilityStudy> </subject> </controlActProcess> </PORT_IN090004UV02></pre>	End of message									