

# Version History

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## Version 0.1

Created by Norbert Bittner, on 18-May-2005

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## Version 0.2

revised by Michael Schubert, on 12-August-2005

- corrected the identifier, inserted new table design

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## Version 0.3

revised by Norbert Bittner and Norman Gregory, on 14-September-2005

finished by Michael Schubert and Norbert Bittner, on 28-September-2005

- added (M)andatory, (R)quired and (O)ptional for most attributes
- added comments
- added list of code values

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## Version 0.4

revised by Norbert Bittner and Michael Schubert, on 07-November-2005,  
based on implementation team teleconference since 17-October 2005

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## Version 0.4.1

revised by Norbert Bittner, on 09-November-2005,  
based on implementation team teleconference 07-November 2005

- added HL7 storyboard and comments on referenced models
- added "DRAFT" watermark

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## Version 0.5

revised by Norbert Bittner and Michael Schubert on 01-December-2005, and Norman Gregory and Norbert Bittner on 12-January-2006 to address ballot issues.

- added more sample code
- added "Object Identifiers" section
- added "XML Schema and Validation" section

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## Version 0.6

revised by Norbert Bittner on 21-June 2006

- added the agreed code lists and comments/examples to the code list section

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# Table of contents

<b>Version History</b>	<b>1</b>
Version 0.1.....	1
Version 0.2.....	1
Version 0.3.....	1
Version 0.4.....	1
Version 0.4.1.....	1
Version 0.5.....	2
Version 0.6.....	2
<b>Introduction to eStability</b>	<b>6</b>
Introduction .....	6
HL7 Basics .....	6
eStability Storyboard .....	7
Interactions: Stability Report (PORT_IN090001).....	7
Interactions: Stability Report Revision (PORT_IN090002).....	7
Interactions: Stability Report Retraction (PORT_IN090003) .....	7
The eStability Model (RMIM).....	9
Elements of an eStability Message .....	10
Stability Study .....	10
research(SpecifiedSubstanceOrProduct) .....	10
Specification.....	11
TestDefinition.....	11
AcceptanceCriterion .....	11
StudyOnBatch .....	11
Instance(Manufactured Material) .....	12
Manufacturer .....	12
Container .....	12
(TimePoint)Storage .....	13
StorageCondition.....	13
(TimePoint)Testing.....	13
Test .....	13
AssignedEntity(TestingSite).....	14
<b>Detailed Description of eStability Elements</b>	<b>15</b>
Required XML Elements .....	15
XML Schema and Validation.....	15
Object Identifiers (OID) .....	16
Usage of OIDs within eStability.....	17
Notation .....	18
Common Elements.....	19
ACTCODE .....	19
ACTREASON.....	20
StabilityStudy – Element .....	21
Sample Code.....	22
Subject2 – Element .....	22
Research Subject – Element .....	23
Sample Code.....	24
Product – Element.....	24

SpecifiedIngredient – Element.....	25
Substance – Element.....	25
Organization - Element.....	26
Sample Code.....	26
Subject3 – Element.....	27
Specification - Element.....	27
Sample Code.....	27
Component5 - Element.....	28
TestDefinition – Element.....	28
Sample Code.....	29
ReferenceRange – Element.....	29
AcceptanceCriterion – Element.....	30
Sample Code.....	30
Component1 – Element.....	31
StudyOnBatch - Element.....	31
Sample Code.....	32
Subject1 – Element.....	32
Instance – Element.....	33
ManufacturedMaterial – Element.....	33
Sample Code.....	34
ManufacturedProduct– Element.....	34
Manufacturer – Element.....	35
Sample Code.....	35
Content - Element.....	36
Sample Code.....	36
Container - Element.....	37
BatchIngredient – Element.....	38
Component2 – Element.....	39
Sample Code.....	40
Storage – Element.....	41
Sample Code.....	41
ControlVariable– Element.....	42
StorageCondition– Element.....	42
Testing – Element.....	43
Sample Code.....	43
Component3 – Element.....	44
Test – Element.....	44
Sample Code.....	45
Performer – Element.....	45
Sample Code.....	46
AssignedEntity – Element.....	46
TestingSite – Element.....	46
Definition - Element.....	47
Sample Code.....	47
DefinitionStub - Element.....	47
Component4 - Element.....	48

## Code Lists

50

Type of Data File.....	50
Reason for Data File.....	51
Product Code.....	52
Product Form Code.....	52
Substance Code.....	52
Test Code.....	53
Method Type Code.....	54
Interpretation Code.....	54
Study Type.....	55
Closure System Code.....	56
Container Code.....	58

Storage Condition Code.....58  
Pause Description Code.....58

DRAFT

# Introduction to eStability

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## 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.

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## 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”.

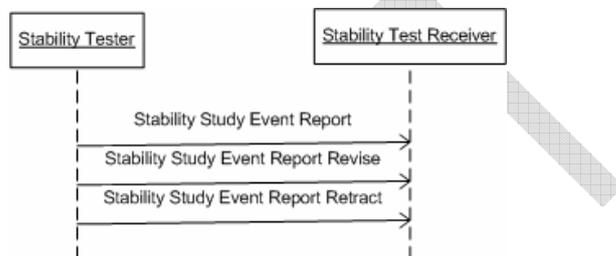
Besides the definition of data standards, HL7 defines message wrappers that define how to exchange HL7-XML documents between computer systems. These “wrappers” will not be in the scope of this document. Please refer to HL7 “Version 3 Guide, HL7 Messaging Components, V3 message wrappers and Infrastructure”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

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

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## eStability Storyboard

The HL7 storyboard describes three 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\_IN090001)

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\_IN090002)

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.

### Interactions: Stability Report Retraction (PORT\_IN090003)

ChemCentric Drug Company recently submitted a stability report on its CureAll product. However, the management of ChemCentric has discovered that Rudy Reliable, a lab technician has submitted false results in order to disguise the fact that he totally neglected to carry out the testing. As a result, ChemCentric has decided to withdraw the Stability Study so that a replacement can be prepared and submitted.

These three types of messages reference two schema definitions:

PORT\_MT090001UV01

for sending and revising a stability report and

PORT\_MT090002UV01

for retracting a report.

Both schema definitions are identical, but to send a correct “retraction” message the second schema has to be referenced.

For this reason, only the implementation of the PORT\_MT090001UV01 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 Ballot site.

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## Elements of an eStability Message

The Drug Stability Report RMIM captures information relevant for the drug stability testing process. This testing is required in the United States 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.** This additional documentation would either be provided along with the stability report, or would be stored at the sender's site 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.)

### 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. Note, in some cases such as dissolution studies, 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.

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 many instances of StudyOnBatch.

#### **research(SpecifiedSubstanceOrProduct)**

The role of research subject is played by either a drug substance or a drug product, that is by the thing whose stability the study is about. It is also possible to use the desc (description) attribute to include a URL link that gives access to additional product information. The organization 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 SubstanceBatch or ProductBatch that are the actual batches that provide the samples on which tests are carried out.

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

## Specification

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 is associated with one to many tests.

## TestDefinition

Defines the tests and test components that are to be performed. Information collected directly about the test definition includes the test type, any relevant description, and the test method. The same can be said regarding the information to be collected for a test component.

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 the tests that are performed.

Note that a test definition can have zero to many components, and be associated with zero to many acceptance criteria. It is also true, although the multiplicity is not directly documented; that a test definition can be associated with zero to many tests (performed tests).

## AcceptanceCriterion

Defines the limits within which performed observations are interpreted. Information collected directly about the acceptance criterion include the criterion type, the actual criterion value, an indicator showing whether the criterion or its inverse is to be applied, and descriptive text.

## StudyOnBatch

Indicates 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:

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

Note that a study on batch is related to a single stability study, a single instance of material, and can be related to many testing and storage time points. (There will be a single storage time point that indicates when samples are placed in storage, and generally multiple testing time points - one for each pull of samples from storage.)

## **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 that it is made up of. 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:

- a) the product or substance the batch is an instance of,
- b) the study on batch that uses samples from this batch,
- c) 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.),
- d) the manufacturer of the batch,
- e) 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 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, 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)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, descriptive text, and the condition value.

## **(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 effective date on which samples were drawn. Note, component pause quantity 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 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.

## **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 (location) 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.

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# Detailed Description of eStability Elements

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## Required XML Elements

### XML Schema and Validation

The eStability file is defined in the PORT\_HD090001UV01.xsd 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\_IN090001UV01.

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 like:

```
<?xml version="1.0" encoding="UTF-8"?>
<PORT_IN090001UV01
  xsi:schemaLocation="urn:hl7-org:v3 PORT_IN090001UV01.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>
  <device>
  <id/>
  </device>
  </receiver>
  <sender>
  <device>
  <id/>
  </device>
  </sender>
  <controlActProcess moodCode="EVN">
  <subject>
  <!--eStability data begins here.-->
  <stabilityStudy>
  ...
  </stabilityStudy>
  <!--eStability data ends here.-->
  </subject>
  </controlActProcess>
</PORT_IN090001UV01>
```

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\_IN090001UV01 element, like:

```
xsi:schemaLocation="urn:hl7-org:v3  
C:\HL7\processable\multicacheschemas\PORT_IN090001UV01.xsd"
```

### **How to validate an eStability file**

To validate an XML file, you need a facility which has the ability to validate an XML file against an XML Schema. This may be a function of the IDE you are using. Described here is a more general approach, which does not rely on any specific IDE.

It makes use of Apache Xerces (Xerces C, to be exact), which is a XML parser. It can be downloaded from <http://xml.apache.org/xerces-c/download.cgi>. Included in the package (in the "bin" folder) is a small application StdInParse.exe, which is used to validate the file. (On windows, StdInParse.exe relies on xerces-c\_x\_x.dll, which has to be in the same directory).

On command line level, enter

```
StdInParse.exe -n -s < Path/file.xml
```

and you should be presented with a message like

```
stdin: 547 ms (905 elems, 1512 attrs, 14201 spaces,  
7022 chars)
```

if it complies to the referenced XML Schema, or something like

```
Error at (file stdin, line 229, char 62): Datatype  
error: Type:InvalidDatatypeValueException,  
Message:Value '' does not match any member types (of  
the union)
```

if there is a problem.

### **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.

OIDs are intended to be globally unique. They are formed by taking a unique numeric string (e.g. 1.3.5.7.9.24.68) and adding additional digits in a unique fashion (e.g. 1.3.5.7.9.24.68.1, 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., 1.3.5.7.9.24.68) 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. OIDs 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

The Basis of the OID usage within eStability is a root or arc OID which is identifying the company. This root OID should 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 should be used with the "code" attribute of the "Product" or "Substance" element. (e.g. companies OID is 1.3.6.1.4.1.24263, the according product OID might be 1.3.6.1.4.1.24263.1.32 – for some internal reasons there is a substructure in the added digits). This OID should be registered with the approving agency and should 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 should be indicated by one or many additional digits. (e.g. the company decides to simply number all studies performed for the product. Thus the 6<sup>th</sup> study has the OID 1.3.6.1.4.1.24263.1.32.1.6). This OID should be used for the "id" element of "StudyOnBatch".

Each report created for this study should have at least one additional digit within this structure (e.g. the third report is identified by 1.3.6.1.4.1.24263.1.32.1.6.3. A company can decide to map its versioning to this numbering schema).

Since one Stability Data File covers only on storage condition, in some cases many file 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 3<sup>rd</sup> report is identified by 1.3.6.1.4.1.24263.1.32.1.6.3.1). This identifier is used as "id" attribute of the "StabilityStudy" element.

All other "id" attributes should 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	1.3.6.1.4.1.24263
Product / Application	1.3.6.1.4.1.24263.1.32
Stability related branch	1.3.6.1.4.1.24263.1.32.1
Study	1.3.6.1.4.1.24263.1.32.1.6
Report	1.3.6.1.4.1.24263.1.32.1.6.3
File of a report	1.3.6.1.4.1.24263.1.32.1.6.3.1
5 <sup>th</sup> Testdefinition of the spec	1.3.6.1.4.1.24263.1.32.1.6.3.1.5
4 <sup>th</sup> parameter of this Testdefinition (i.e. the second level of Testdefinition)	1.3.6.1.4.1.24263.1.32.1.6.3.1.5.4

## 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 to the XML model element by element).

For orientation purposes, an XPath is provided to locate the element described in the table. An XPath is comparable to the well known directorypath of PC systems 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 codevalues 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
<i>Specification</i>	<i>code</i>	<i>Internal specification code</i>
Testdefinition	code	Test Code
StudyOnBatch	code	Study Type
Container	code	Container Code
<i>Storage</i>	<i>code</i>	<i>Storage code</i>
StorageCondition	code	Storage Condition Code
Testing	code	Pause Description Code

### ACTCODE – Elements

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

#### Attributes:

Name	Description	H	F
code	The code value for the given code system.	R	R
codeSystem	The OID of the code system.	R	R
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.	R	M

#### Complex Children:

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

originalText	not used	N	N
translation	not used	N	N

### Sample Code

Suppose "code" being an ACTCODE:

Full example:

```
<code code="34391-3" codeSystem="2.16.840.1.113883.6.1" codeSystemName="LOINC"
displayName="Human prescription drug"/>
```

Mandatory example:

```
<code displayName="Human prescription drug"/>
```

### ACTREASON

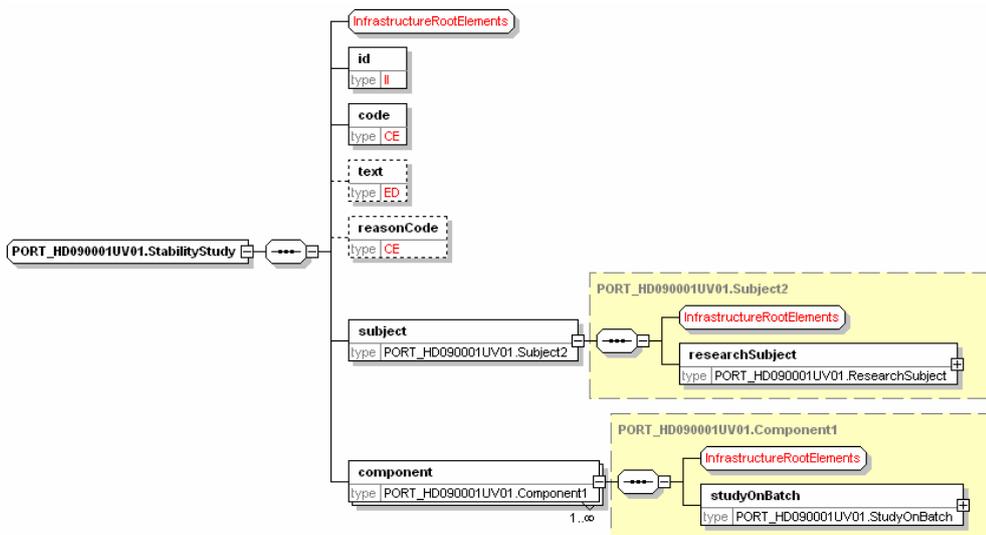
ACTREASON elements in eStability describe codevalues such as:

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

### ACTREASON - Elements

Attributes:			
Name	Description	H	F
code	The code value for the given code system.		R
codeSystem	The OID of the code system.		R
codeSystemName	The name of the code system.		R
codeSystemVersion	The version of the code system used.		R
displayName	A displayable name of the code system code.		M
Complex Children:			
Name	Description	H	F
originalText	not used	N	N
translation	not used	N	N

# StabilityStudy – Element



StabilityStudy						
/stabilityStudy						
<b>Description:</b>						
The root element of the document.						
<b>Simple Children:</b>						
Name	Description	H	F			
id	Is a global unique identifier for the document.	M	M			
	<b>Attributes</b>					
	root			OID for this document	M	M
	extension				N	N
	assigningAuthorityName				N	N
displayable		N	N			
text	Either a text provided by the submitter or an URI to an external document with further annotations for this submission.	O	O			
<b>Complex Children:</b>						
Name	Description	H	F			
code	an ACTCODE which describes the type of document sent.	R	R			
reasonCode	an ACTREASON which describes the reason for this document.	O	M			
Subject2	a complex structure to describe the researchsubject of the study (exactly	M	M			

	one provided).		
Component1	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

### Sample Code

```

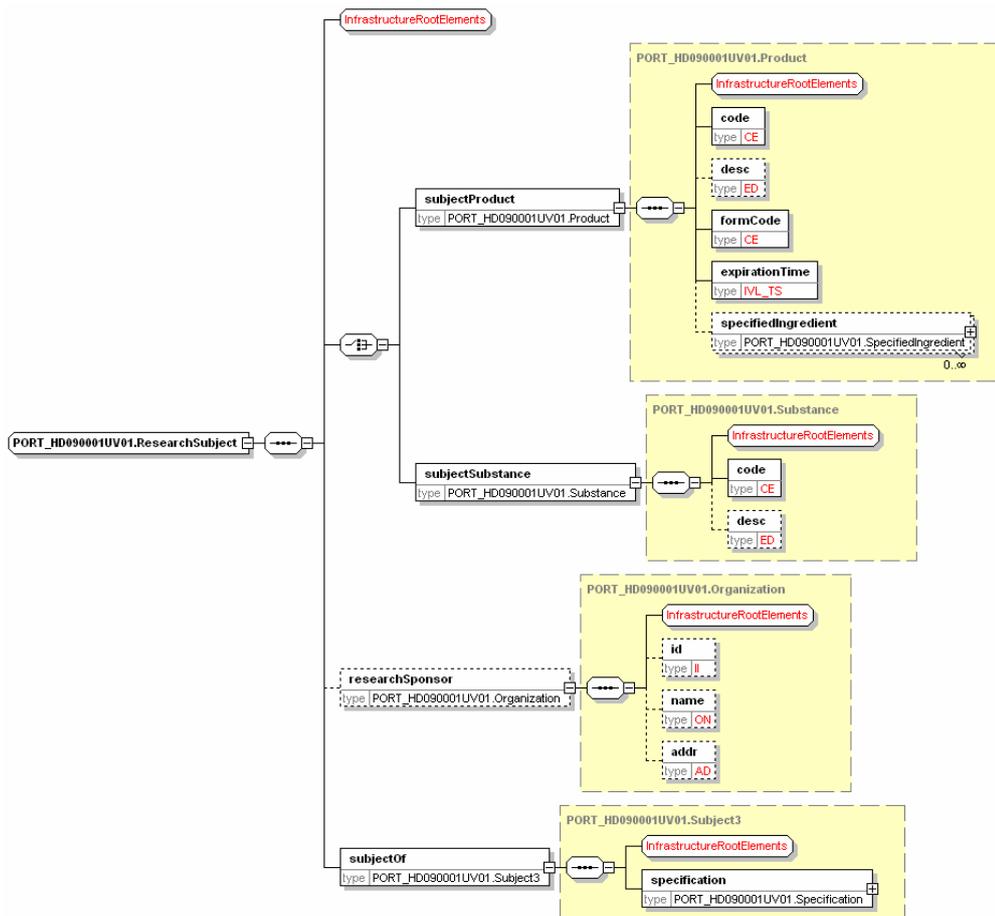
<stabilityStudy>
<id root="1.3.6.1.4.1.24263.4711.1.1"/>
<code displayName="ICH-Type Stability Study"/>
<text>JBE1000-7196</text>
<reasonCode displayName="New Drug Application"/>
<subject>
  <researchSubject>
    ...
  </researchSubject>
</subject>
<component>
  <studyOnBatch>
    ...
  </studyOnBatch>
</component>
</stabilityStudy>

```

## Subject2 – Element

Subject2 /stabilityStudy/subject			
<b>Description:</b> Intermediate element			
<b>Complex Children:</b>			
Name	Description	H	F
ResearchSubject	a complex structure to describe the researchsubject (exactly one provided).	M	M

# Research Subject – Element



<b>ResearchSubject</b>			
/stabilityStudy/subject			
<b>Description:</b>			
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.			
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Product	Finished dosage form (exactly one).	M	M
Substance	Active ingredient (exactly one).	M	M
Organisation	Research Sponsor.	O	R
Subject3	Reference to the specification used in this study.	M	M

## Sample Code

```

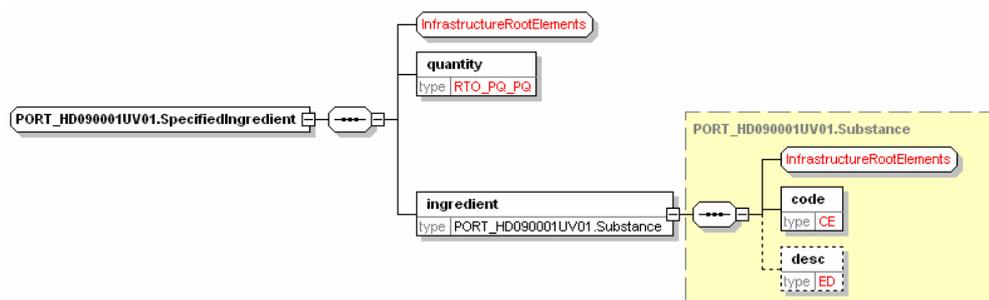
<researchSubject>
  <subjectProduct>
    <code displayName="JBE1000"/>
    <desc>Gummi Bears 100g Bag</desc>
    <formCode displayName="Not provided"/>
    <expirationTime/>
  </subjectProduct>
</researchSponsor>
...
</researchSponsor>
<subjectOf>
  <specification>
    ...
  </specification>
</subjectOf>
</researchSubject>

```

## Product – Element

<b>Product</b>			
/stabilityStudy/subject/researchSubject/subjectProduct			
<b>Description:</b>			
Complex structure to describe a finished dosage form.			
<b>Simple Children</b>			
expirationTime	The “expected” expiration period (e.g. 24 Months) for NDA, or the existing expiration period for ongoing studies.  Either a valid timeperiod (ISO8601, e.g. P24M) or ‘TBD’ (to be determined) for user in IND.	R	M
Desc	A description of the product provided by the submitter or an URI for additional external documentation.	O	O
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Code	an ACTCODE: ProductCode (i.e. a unique identifier of the product).  For FDA implementation, only the “displayName” (i.e. the product name) is mandatory, the code values might be provided if available.  For NDA this is a new identifier.  For ongoing studies the identifier should be identical to an already submitted code.	R	M
formCode	an ACTCODE: Formtype of this product  For FDA implementation, only the “displayName” (i.e. the product name) is mandatory, the code values might be provided if available.	R	M
SpecifiedIngredient	The formulation of this product (many, if necessary).	O	R

## SpecifiedIngredient – Element



<b>SpecifiedIngredient</b>			
/stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient			
<b>Description:</b>			
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.			
<b>Complex Children:</b>			
Name	Description	H	F
Quantity	The quantity of the referenced substance in the product	R	R
Substance	Reference to substance, i.e. active ingredient	M	M

## Substance – Element

<b>Substance</b>			
/stabilityStudy/subject/researchSubject/subjectSubstance or /stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient			
<b>Description:</b>			
When used as a child of “ResearchSubject” this element describes the substance the study is performed on. As child of “SpecifiedIngredient” this element describes a substance as part of a formulation.			
<b>Complex Children:</b>			
Name	Description	H	F
Code	an ACTCODE: code of the substance.  For FDA implementation, only the “displayName” (i.e. the substance name) is mandatory, the code values might be provided if available.	R	M
Desc	URI for additional documentation.	O	O

## Organization - Element

Organization						
/stabilityStudy/subject/researchSubject/researchSponsor						
<b>Description:</b>						
The research sponsor for the study.						
<b>Simple Children:</b>						
Name	Description	H	F			
id	Is a global unique identifier for the sponsoring organization assigned by IANA.	M	M			
	<b>Attributes</b>					
	root			OID for the sponsoring organization	M	M
	extension				N	N
	assigningAuthorityName				N	N
	displayable				N	N
This identifier should be the same for one organization within all submissions of one company.						
name	Name of the organization sponsoring the study.	O	M			
<b>Complex Children:</b>						
Name	Description	H	F			
addr	Address of the organization.	O	M			

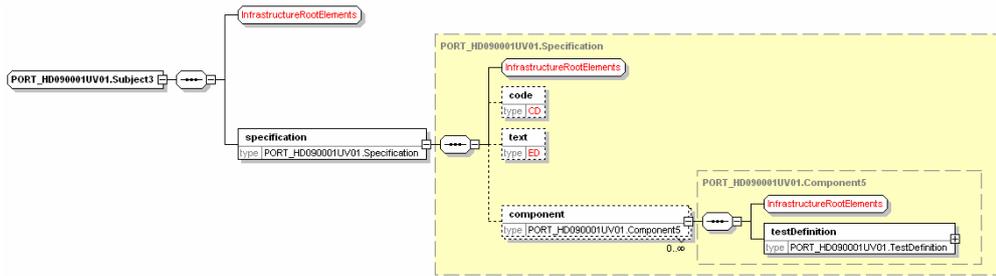
### Sample Code

```

<researchSponsor>
  <id root="1.3.6.1.4.1.24263" />
  <name>up to data professional service GmbH</name>
  <addr>
    <country>Germany</country>
    <city>Wörrstadt</city>
    <postalCode>55286</postalCode>
    <streetAddressLine>Am Pfädchen 4</streetAddressLine>
  </addr>
</researchSponsor>

```

## Subject3 – Element



<b>Subject3</b> /stabilityStudy/subject/researchSubject/subjectOf			
<b>Description:</b> Reference to the specification (intermediate element).			
<b>Complex Children:</b>			
Name	Description	H	F
Specification	(exactly one)	M	M

## Specification - Element

<b>Specification</b> /stabilityStudy/subject/researchSubject/subjectOf/specification			
<b>Description:</b> For this Element the “full” HL7 structure has to be provided for the specification.			
<b>Simple Children:</b>			
Name	Description	H	F
text	URI for additional documentation.	O	R
<b>Complex Children:</b>			
Name	Description		
code	an ACTCODE: Specification identifier. i.e. the name and version of the specification (as displayName).	O	M
Component5	The testdefinition and acceptance criteria for these tests.	O	M

### Sample Code

```

<specification>
  <code displayName="JBE1000"/>

```

```

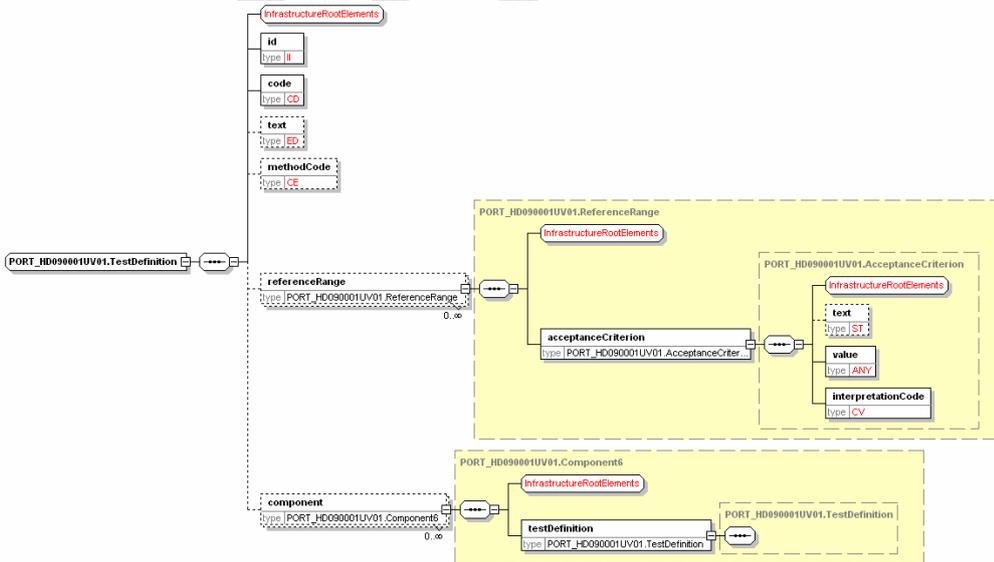
<text>Spec_Gummibears_12345679.pdf</text>
<component>
  <testDefinition>
    ...
  </testDefinition>
</component>
</specification>

```

## Component5 - Element

<b>Component5</b>			
/stabilityStudy/subject/researchSubject/subjectOf/specification/component			
<b>Description:</b>			
Intermediate element			
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
TestDefinition		M	M

## TestDefinition – Element



<b>TestDefinition</b>
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition
<b>Description:</b>

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.

**Simple Children:**

Name	Description	H	F																				
Id	A global unique identifier for this TestDefinition <table border="1" data-bbox="363 405 1098 600"> <thead> <tr> <th colspan="4">Attributes</th> </tr> </thead> <tbody> <tr> <td>Root</td> <td>OID</td> <td>M</td> <td>M</td> </tr> <tr> <td>Extension</td> <td></td> <td>N</td> <td>N</td> </tr> <tr> <td>assigningAuthorityName</td> <td></td> <td>N</td> <td>N</td> </tr> <tr> <td>displayable</td> <td></td> <td>N</td> <td>N</td> </tr> </tbody> </table>	Attributes				Root	OID	M	M	Extension		N	N	assigningAuthorityName		N	N	displayable		N	N	R	M
Attributes																							
Root	OID	M	M																				
Extension		N	N																				
assigningAuthorityName		N	N																				
displayable		N	N																				
text	URI for additional documentation for this test, e.g. SOP or Specification document for this method.	O	R																				

**Complex Children:**

Name	Description	H	F
code	an ACTCODE: Test code.	R	R
methodCode	an ACTREASON: Method type.	O	M
ReferenceRange	The acceptance criterion for this parameter.	O	M
Component6	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 one additional level may be provided.	O	M

**Sample Code**

```

<testDefinition>
  <id root="1.3.6.1.4.1.24263.4711.1.1.1"/>
  <code displayName="ASSAY"/>
  <text>Spec_Gummibears_TD1.pdf</text>
  <methodCode displayName="Assay"/>
  <component>
    <testDefinition>
      <id root="1.3.6.1.4.1.24263.4711.1.1.1"/>
      <code displayName="Sodium"/>
      <text>Spec_Gummibears_TD2.pdf</text>
      <methodCode displayName="Sodium"/>
      <referenceRange>
        ...
      </referenceRange>
      ...
    </testDefinition>
  </component>
  ...
</testDefinition>

```

**ReferenceRange – Element**

<b>ReferenceRange</b>			
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange			
<b>Description:</b>			
The container for the set of acceptance criteria for a TestDefinition.			
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
AcceptanceCriterion	One or many acceptance criteria.	O	M

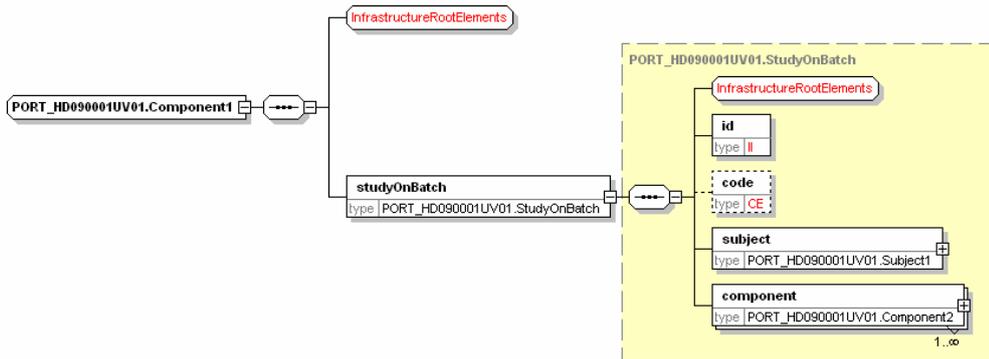
## AcceptanceCriterion – Element

<b>AcceptanceCriterion</b>			
/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange/acceptanceCriteria			
<b>Description:</b>			
Describes one valid specification limit.			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
interpretationCode	e.g. not more than (NMT), not less than (NLT), ...	M	M
Text	URI for additional documentation.	O	O
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Value	The value of the criterion.	M	M

### Sample Code

```
<acceptanceCriterion>
  <value xsi:type="PQ" value="1900" unit="ug"/>
  <interpretationCode displayName="NLT"/>
</acceptanceCriterion>
```

## Component1 – Element



<b>Component1</b> /stabilityStudy/component			
<b>Description:</b> Reference to the batch and result information for one study on one batch. Many of these elements can be provided.			
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
StudyOnBatch		M	M

## StudyOnBatch - Element

<b>StudyOnBatch</b> /stabilityStudy/component/studyOnBatch			
<b>Description:</b> The container for the batch information and results for the study performed on one batch.			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
id	Is a global unique identifier for the study, should be the same in all submitted files for this study.	M	M
<b>Attributes</b>			
Root	OID	M	M
extension		N	N
assigningAuthorityName		N	N

	displayable		N	N		
<b>Complex Children:</b>						
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>			
code	an ACTCODE: study type	O	R			
Subject1	The reference to the information on the material the study is performed on (e.g. a batch).	M	M			
Component2	The reference to the study design and the results section.	M	M			

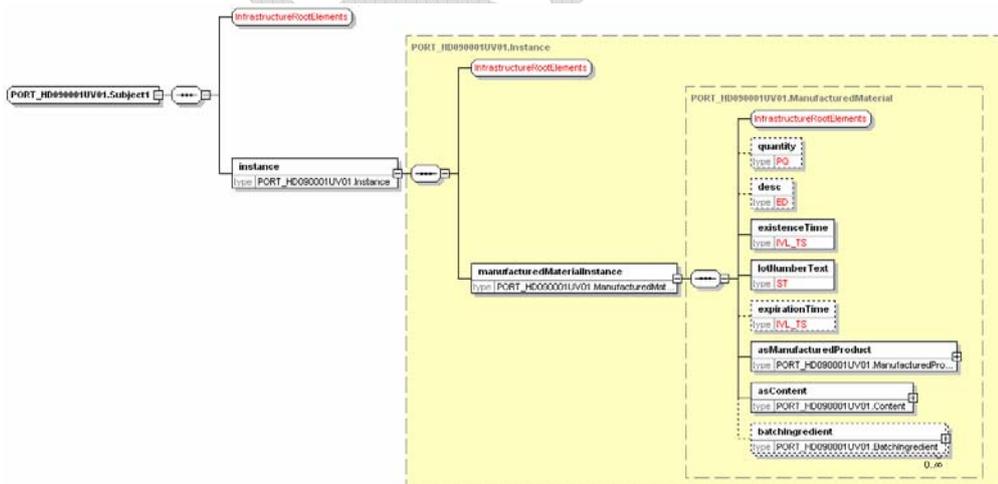
### Sample Code

```

<studyOnBatch>
  <id root="1.3.6.1.4.1.24263.4711.1" />
  <code displayName="Stability" />
  <subject>
    <instance>
      <manufacturedMaterialInstance>
        ...
      </manufacturedMaterialInstance>
    </instance>
  </subject>
  <component>
    ...
  </component>
</studyOnBatch>

```

## Subject1 – Element



<b>Subject1</b> /stabilityStudy/component/studyOnBatch/subject
<b>Description:</b> An intermediate element.

Complex Children:			
Name	Description	H	F
Instance	The Instance of the material.	M	M

## Instance – Element

<b>Instance</b> /stabilityStudy/component/studyOnBatch/subject/instance			
<b>Description:</b> An intermediate element.			
<b>Complex Children:</b>			
Name	Description	H	F
ManufacturedMaterial		M	M

## ManufacturedMaterial – Element

<b>ManufacturedMaterial</b> /stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance			
<b>Description:</b> Describes the produced material used in the stability study.			
<b>Simple Children:</b>			
Name	Description	H	F
quantity	Total amount of material in the batch.	O	R
desc	A textual description or/and external reference to a pdf document describing details of this production.	O	O
lotNumberText	Company internal lot number.	R	M
<b>Complex Children:</b>			
Name	Description	H	F
existenceTime	Date of production (use ISO 8601 format)	R	M
expirationTime	Date of expiration (based on the provided expirationCode of the „Product“ element) or the proposed expiration date or the material. Add P proposed exp. time or A for approved exp. Time. P24M-A, P24M-P Also with Product element.	O	M

ManufacturedProduct	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	R
Content	A reference to the container/closure system.	M	M
BatchIngredient	A reference to a ManufacturedMaterial, so that a „BatchRecord“ can be provided. Using this element leads to a recursive structure.	O	O

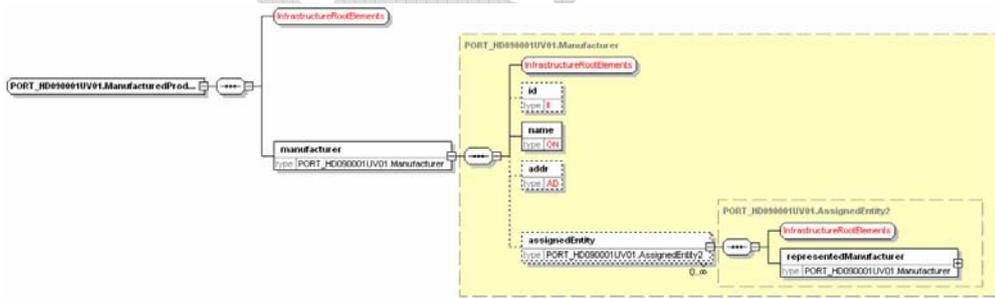
### Sample Code

```

<manufacturedMaterialInstance>
  <quantity value="0" unit=""/>
  <desc>Production from 2003-01-01</desc>
  <existenceTime>
    <high value="20030101"/>
  </existenceTime>
  <lotNumberText>JBE1000_001@BAG_PL</lotNumberText>
  <expirationTime>
    <high value="20050101"/>
  </expirationTime>
  <asManufacturedProduct>
    <manufacturer>
      ...
    </manufacturer>
  </asManufacturedProduct>
  <asContent>
    ...
  </asContent>
</manufacturedMaterialInstance>

```

## ManufacturedProduct– Element



<b>ManufacturedProduct</b>			
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct			
<b>Description:</b>			
Intermediate element, holding the manufacturer of the Manufactured Material.			
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Manufacturer		M	M

## Manufacturer – Element

<b>Manufacturer</b>							
/stabilityStudy/component/study/OnBatch/subject/instance/manufacturedMaterialInstance/asManufacturedProduct/ manufacturer							
<b>Description:</b>							
The details about a manufacturer or a manufacturing site who produced the “ManufacturedMaterial”.							
<b>Simple Children:</b>							
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>				
id	Is a global unique identifier of the manufacturing site.	M	M				
	<b>Attributes</b>						
	root				OID	M	M
	extension					N	N
	assigningAuthorityName					N	N
displayable		N	N				
name	Name of the manufacturer (or manufacturing site).	R	M				
<b>Complex Children:</b>							
addr	Address	O	M				
assignedEntity	One or many references to a “Manufacturer” who produced this product in behalf of the “Manufacturer” or who partial produced the product.	O	O				

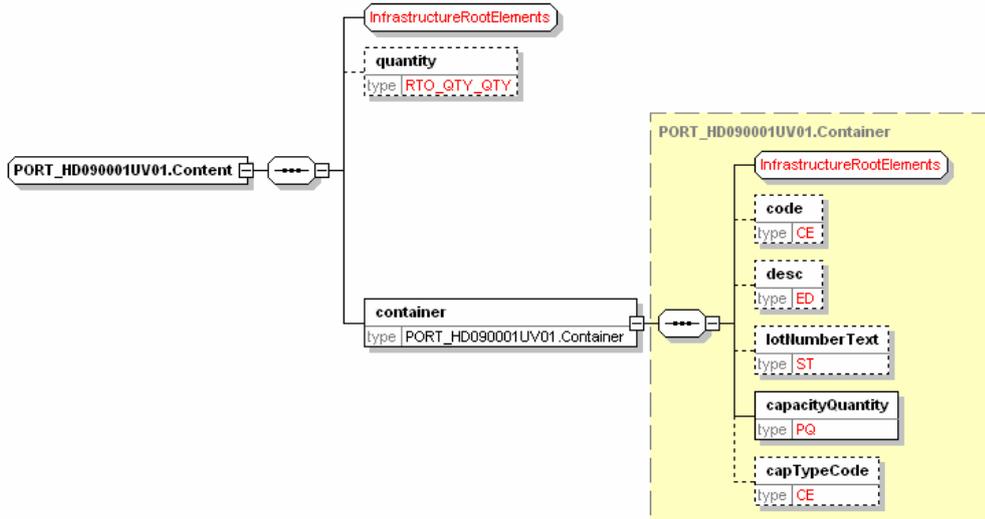
### Sample Code

```

<manufacturer>
  <id root="1.3.6.1.4.1.24263"/>
  <name>up to data professional service GmbH</name>
  <addr>
    <country>Germany</country>
    <city>Wörrstadt</city>
    <postalCode>55286</postalCode>
    <streetAddressLine>Am Pfädchen 4</streetAddressLine>
  </addr>
</manufacturer>

```

# Content - Element



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

## Sample Code

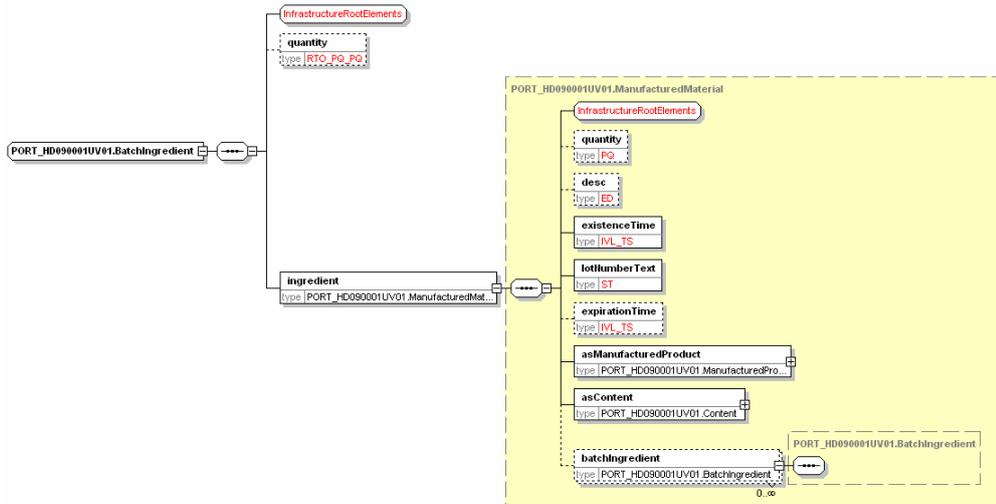
```

<asContent>
  <quantity>
    <numerator xsi:type="PQ" value="0" unit=""/>
    <denominator xsi:type="PQ" value="1" unit=""/>
  </quantity>
  <container>
    <code displayName="BAG_PL"/>
    <desc>Plastic Bag</desc>
    <lotNumberText>BAG_PL</lotNumberText>
    <capacityQuantity xsi:type="PQ" value="" unit=""/>
  </container>
</asContent>
  
```

## Container - Element

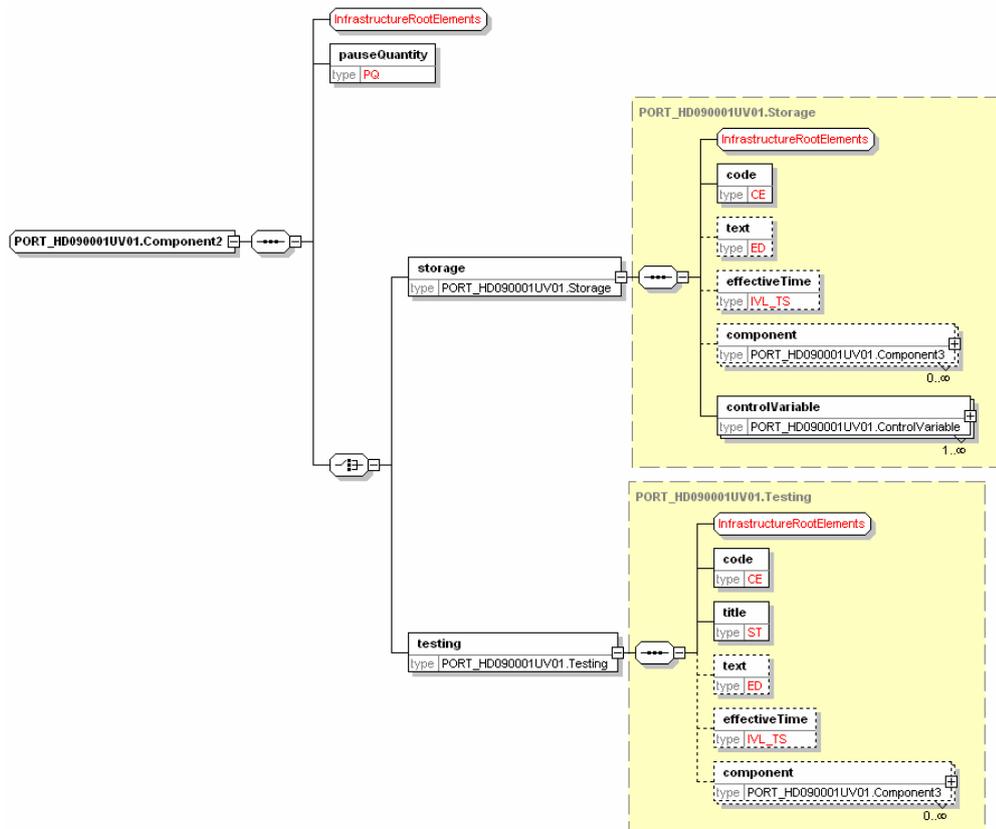
<b>Container</b>			
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container			
<b>Description:</b>			
A simple structure to store the makeup to the container closure system.			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Desc	A verbal description of the container closure system or a reference to an external pdf which holds this description.	O	O
lotNumberText	The lot number of the production lot for this container	O	O
capacityQuantity	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	The code for the used closure system (e.g. plastic cap).	O	O
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Code	an ENTITYCODE – Type of Container (e.g. Bottle).	R	M

# BatchIngredient – Element



<b>BatchIngredient</b>			
/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/batchIngredient			
<b>Description:</b>			
An intermediate element to store a recursive reference to a "ManufacturedMaterial" to provide a kind of batch record for the product.			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Quantity	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	R
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
ManufacturedMaterial	This is a recursive link to ManufacturedMaterial.	M	M

## Component2 – Element



Component2			
/stabilityStudy/component/studyOnBatch/component			
<b>Description:</b>			
For each combination of storage time (pauseQuantity) and “Storage” (storage condition) one Component2 has to be provided.			
<b>Simple Children:</b>			
Name	Description	H	F
pauseQuantity	<p>Storage time of the batch in a climatic chamber.</p> <p>The unit of the pauseQuantity has to be homogenous for all xml files, which are connected to the concerning study, e.g. only months are used throughout the xml files. Fractions of the unit are allowed (e.g. 0.25 months to denote a week).</p> <p>For more than one pauseQuantity, the connection between the storage to the concerning testing section is done by the value of the pauseQuantity.</p>	R	M

Complex Children:			
Name	Description	H	F
Storage	A structure to describe the used storage condition.	M	M
Testing	A structure to store the results of measurement.	M	M

## Sample Code

Only one storage condition is used in one file:

```
<component>
  <pauseQuantity xsi:type="PQ" value="60" unit="days"/>
  <storage>
    <code displayName="25° C 60% RH"/>
    ...
  </storage>
</component>
<component>
  <pauseQuantity xsi:type="PQ" value="60" unit="days"/>
  <testing>
    ...
  </testing>
</component>
<component>
  <pauseQuantity xsi:type="PQ" value="91" unit="days"/>
  <storage>
    <code displayName="25° C 60% RH"/>
    ...
  </storage>
</component>
<component>
  <pauseQuantity xsi:type="PQ" value="91" unit="days"/>
  <testing>
    ...
  </testing>
</component>
```

In the case of cycled studies, multiple “components” may be used.

In this case the samples have been stored at “-10° C” for 5 days, then for 2 weeks and finally at 25° C 60% RH for three months. Results of testing can be provided in both cases.

```
<component>
  <pauseQuantity xsi:type="PQ" value="0,17" unit="month"/>
  <storage>
    <code displayName="-10° C"/>
    ...
  </storage>
</component>
<component>
  <pauseQuantity xsi:type="PQ" value="0,17" unit=" month "/>
  <testing>
    ...
  </testing>
</component>
<component>
  <pauseQuantity xsi:type="PQ" value="0.5" unit=" month "/>
  <storage>
    <code displayName="-10° C"/>
    ...
  </storage>
</component>
```

```

<component>
  <pauseQuantity xsi:type="PQ" value="0.5" unit=" month "/>
  <testing>
    ...
  </testing>
</component>
...
<component>
  <pauseQuantity xsi:type="PQ" value="3" unit=" month "/>
  <storage>
    <code displayName="25° C 60% RH"/>
    ...
  </storage>
</component>
<component>
  <pauseQuantity xsi:type="PQ" value="3" unit=" month "/>
  <testing>
    ...
  </testing>
</component>

```

## Storage – Element

<b>Storage</b> /stabilityStudy/component/studyOnBatch/component/storage			
<b>Description:</b>			
Reference to one or many predefined storage condition (e.g. one reference to "25°/60%" and one to "upright" – or alternatively one reference to "25°/60% upright").			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Text	A textual description of this storage condition or an external reference to pdf to describe this storage condition.	O	O
effectiveTime	The Time the product is put on stability. The date the stability storage is started for this condition.	O	R
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Code	an ACTCODE: fixed code value, may be used for other purposes in future versions.	M	M
ControlVariable	Reference to the predefined storage conditions (one or many may be used).	M	M
Component3	not used	N	N

### Sample Code

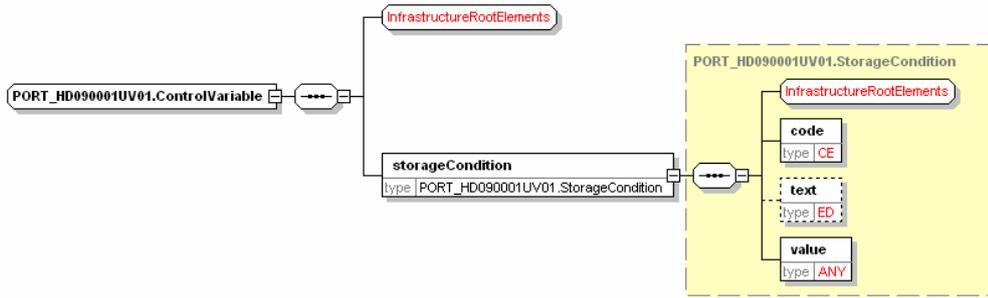
```

<storage>
  <code displayName="ICH25_60"/>
  <controlVariable>
    <storageCondition>
      <code displayName="ICH25_60"/>
      <text>Storagecondition according ICH Q1A: 25°C / 60% r.h.</text>
      <value xsi:type="ST">25°C / 60% r.h.</value>
    </storageCondition>
  </controlVariable>
</storage>

```

</controlVariable>  
</storage>

## ControlVariable– Element



<b>ControlVariable</b> /stabilityStudy/component/studyOnBatch/component/storage/controlVariable			
<b>Description:</b> Intermediate element			
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
StorageCondition		M	M

## StorageCondition– Element

<b>StorageCondition</b> /stabilityStudy/component/studyOnBatch/component/storage/controlVariable/storageCondition			
<b>Description:</b> 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 "ControlVariable"s referencing simple "StorageConditions".			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Text	A textual description or an external reference.	O	O
Value	e.g. "25°" or "25°/60%" or "25°/60% upright"	M	M
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Code	an ACTCODE: Storagecondition code	M	M

## Testing – Element

<b>Testing</b>			
/stabilityStudy/component/studyOnBatch/component/testing			
<b>Description:</b>			
This is a representation of “pulling a sample from the climatic chamber”.			
<b>Simple Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Title	A title that labels a collection of related tests across “pauseQuantities”, e.g. “Batch Release”.	M	M
Text	A textual description or an external reference.	O	O
effectiveTime	Pulldate (use ISO 8601 notation).	O	R
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>		
Code	an ACTCODE: pauseDescription. Something done with the sample, e.g. freeze sample.	M	R
Component3	A reference to the tests performed with this sample.	M	M

### Sample Code

```

<testing>
  <code displayName="ICH25_60"/>
  <title/>
  <component>
    <test>
      ...
    </test>
  </component>
</testing>

```



	level, if Component4 has no child elements.		
effectiveTime	Testing date, mandatory on the first level, omitted on the second level (ISO8601).	M	M
<b>Complex Children:</b>			
<b>Name</b>	<b>Description</b>	<b>H</b>	<b>F</b>
Performer	A reference to a testing site.	M	M
Definition	Reference to a specification for this test.	O	M
Component4	Recursive reference to a "Test".	R	R

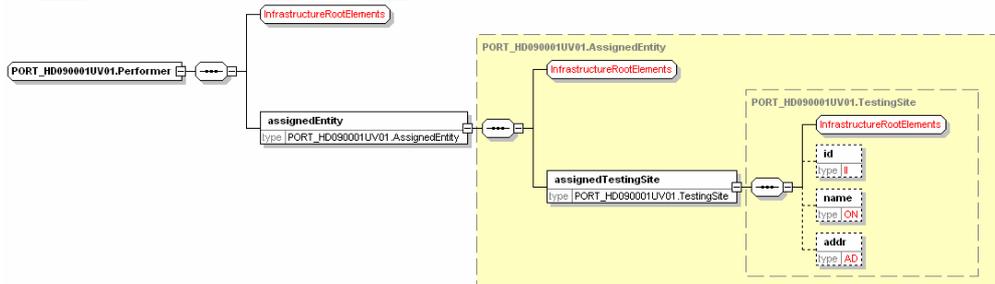
### Sample Code

```

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

```

## Performer – Element



<b>Performer</b> /stabilityStudy/component/studyOnBatch/component/testing/component/test/performer or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/performer
<b>Description:</b> Intermediate element

Complex Children:			
Name	Description	H	F
AssignedEntity		M	M

### Sample Code

```

<performer>
  <assignedEntity>
    <assignedTestingSite>
      <id root="1.3.6.1.4.1.24263"/>
      <name>up to data professional service GmbH</name>
      <addr>
        <country>Germany</country>
        <city>Wörrstadt</city>
        <postalCode>55286</postalCode>
        <streetAddressLine>Am Pfädchen 4</streetAddressLine>
      </addr>
    </assignedTestingSite>
  </assignedEntity>
</performer>

```

## AssignedEntity – Element

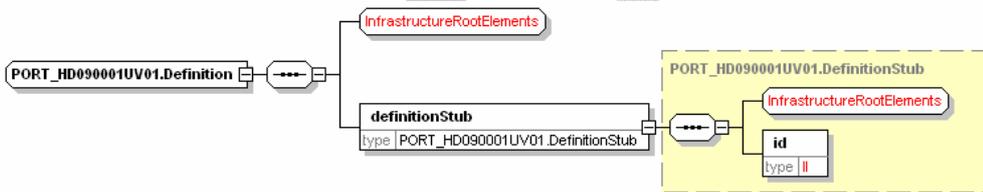
<b>AssignedEntity</b> /stabilityStudy/component/studyOnBatch/component/testing/component/test/performer/assignedEntity or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/performer/ assignedEntity			
<b>Description:</b>			
Intermediate element, a reference to a TestingSite who is performing the test on behalf of the ResearchSponsor.			
<b>Complex Children:</b>			
Name	Description	H	F
TestingSite		M	M

## TestingSite – Element

<b>TestingSite</b> /stabilityStudy/component/studyOnBatch/component/testing/component/test/performer/assignedEntity/ assignedTestingSite or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/performer/ assignedEntity/assignedTestingSite			
<b>Description:</b>			
The details about a tester who performs the tests on behalf of the ResearchSponsor.			
<b>Simple Children:</b>			

Name	Description	H	F			
Id	Is a global unique identifier of the testing site.	M	M			
	<b>Attributes</b>					
	root			OID of the testing site company	M	M
	extension				N	N
	assigningAuthorityName				N	N
	displayable	N	N			
Name	The name of the testing site.	O	M			
<b>Complex Children:</b>						
Addr	The address of the testing site.	O	M			

## Definition - Element



Definition		H	F
or /component/studyOnBatch/component/testing/component/test/definition or /component/studyOnBatch/component/testing/component/test/component/test/definition			
<b>Description:</b>			
Intermediate element which reference the testdefinition.			
<b>Complex Children:</b>			
Name	Description	H	F
DefinitionStub		M	M

## Sample Code

```

<definition>
  <definitionStub>
    <id root="1.3.6.1.4.1.24263.4711.1.1.1"/>
  </definitionStub>
</definition>

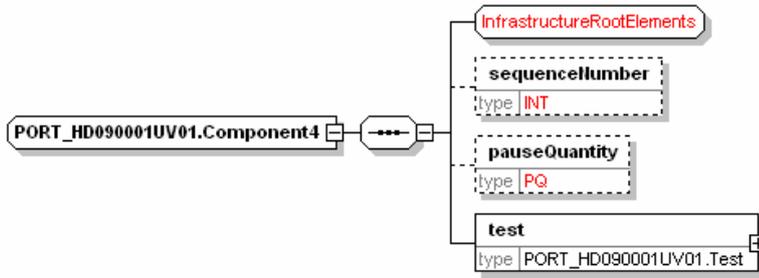
```

## DefinitionStub - Element

DefinitionStub

/stabilityStudy/component/studyOnBatch/component/testing/component/test/definition/definitionStub or /stabilityStudy/component/studyOnBatch/component/testing/component/test/component/test/definition/ definitionStub						
<b>Description:</b>						
<b>Simple Children:</b>						
Name	Description	H	F			
Id	Is the unique identifier (id) of the referenced specification (TestDefinition).	M	M			
	<b>Attributes</b>					
	root			OID of the referenced specification.	M	M
	extension				N	N
	assigningAuthorityName				N	N
displayable		N	N			

## Component4 - Element



<b>Component4</b>			
/stabilityStudy/component/studyOnBatch/component/testing/component/test/component			
<b>Description:</b>			
If a test has parameters (e.g. Assay and ingredients) this structure is used to store the parameters (sequenceNumber)			
or			
Use this structure to indicate the point in time after the sample was drawn from the chamber, when the test was performed (pauseQuantity).			
<b>Simple Children:</b>			
Name	Description	H	F
sequenceNumber	The sequence of parameters of the test.	O	R
pauseQuantity	To use e.g. with growth of bacteria, etc.	O	R

Complex Children:			
Name	Description	H	F
test		O	M

DRAFT

# Code Lists

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

For those values defined (Test, Method, Container and Closure) the NCI Thesaurus will be used to map the defined code to an OID.

Companies are free to define or use their own coding system. The values submitted should be consistent throughout all submitted files of the same "ResearchSponsor" but at least for the same product.

## Type of Data File

Element Name / Attribute	/stabilityStudy - code	
Code System Name	StabilityDataFileType	
Code System (OID)		
This code should reflect if the file in hand is a standard data file for one storage condition or a partial file as part of a cycled study. Other filetypes may be possible.		
Code	Display Name	Description

Example:

```

<stabilityStudy>
  <id root="1.3.6.1.4.1.24263.4711.1.1"/>
  <code displayName="Standard"/>
  ...
</stabilityStudy>

<stabilityStudy>
  <id root="1.3.6.1.4.1.24263.4711.1.2"/>
  <code displayName="Cycled Study"/>
  ...
</stabilityStudy>

```

## Reason for Data File

Element Name	/stability	
Code System Name	Stabilit	
Code System (OID)		
This code should reflect the reason why this data file was sent originally. An example would be "NDA" (New Drug Appli filetypes may be possible		
<b>Code</b>	<b>Display Name</b>	
Element Name	/stabilityStudy/subject/researchSubject/subjectProduct - code	
Code System Name		
Code System (OID)		
<p>This is the code for the official product name. For FDA implementation, only the "displayName" (i.e. the product name) is mandatory, the code values might be provided if available (e.g. when used in other submissions like SPL).</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 relation can be established.</p>		
<b>Code</b>	<b>Display Name</b>	<b>Description</b>
<p>Example:</p> <pre> &lt;researchSubject&gt;   &lt;subjectProduct&gt;     &lt;code displayName="JBE1000"/&gt;     &lt;desc&gt;Gummi Bears 100g Bag&lt;/desc&gt;     ...   &lt;/subjectProduct&gt; </pre>		
Example:		

```

<stabilityStudy>
  <id root="1.3.6.1.4.1.24263.4711.1.1" />
  ....
  <reasonCode displayName="New Drug Application" />
  ...
</stabilityStudy>

```

## Product Code

## Product Form Code

Element Name	/stabilityStudy/subject/researchSubject/subjectProduct - formCode	
Code System Name		
Code System (OID)		
This code describes the form of the reported product.		
Code	Display Name	Description
Example:		
<pre> &lt;researchSubject&gt;   &lt;subjectProduct&gt;     ...     &lt;formCode displayName="Coated Tablet" /&gt;     ...   &lt;/subjectProduct&gt; </pre>		

## Substance Code

Element Name	/stabilityStudy/subject/researchSubject/subjectSubstance - code or /stabilityStudy/subject/researchSubject/subjectProduct/specifiedIngredient - code
Code System Name	
Code System (OID)	
As reported entity or as part of a reported packaged product, this is the official code for a referenced substance (e.g. "acetylsalicylic acid"). For FDA implementation, only the "displayName" (i.e. the product name) is mandatory, the code values might be provided if available.	
This code should be identical in all submissions, when referencing the same substance.	

Code	Display Name	Description
Example:		

## Test Code

Element Name	/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition - code or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/ testDefinition - code	
Code System Name	- to be provided	
Code System (OID)	- to be provided	
This code describes the test performed during a study within the specification section.		
Code	Display Name	Description
physical	Physical or a textual reference to the actual test or parameter	Physical measurement or determination.
chemical	chemical or a textual reference to the actual test or parameter	Chemical measurement or determination.
biological	Biological or a textual reference to the actual test or parameter	Biological measurement or determination.
other	Other or a textual reference to the actual test or parameter	Any other measurement or determination
Example:		
<pre> &lt;testDefinition&gt; &lt;id root="1.3.6.1.4.1.24263.4711.1.1.1"/&gt; &lt;code code="chemical" codeSystem="- to be provided" displayName="Assay" /&gt; &lt;methodCode code="proprietary" codeSystem="- to be provided" displayName="Internal Company Code XYZ" /&gt; &lt;component&gt;   &lt;testDefinition&gt;     &lt;id root="1.3.6.1.4.1.24263.4711.1.1.1"/&gt;     &lt;code code="chemical" codeSystem="- to be provided" displayName="Sodium"/&gt;     &lt;methodCode code="proprietary" codeSystem="- to be provided" displayName="Internal Company Code XYZ" /&gt;     &lt;referenceRange&gt;       ...     &lt;/referenceRange&gt;     ...   &lt;/testDefinition&gt; &lt;/component&gt; ... &lt;/testDefinition&gt; </pre>		

--

## Method Type Code

Element Name	/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition - methodCode or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition - methodCode	
Code System Name		
Code System (OID)		
A classification of the methods used in stability testing.		
Code	Display Name	Description
compendial	Compendial	Offical compendial method
proprietary	Proprietary	Company method
CFR Regulation	CFR Regulation	Method dictated by CFR
other	Other	
Example: See. Test Code		

## Interpretation Code

Element Name	/stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/referenceRange/acceptanceCriterion - interpretationCode or /stabilityStudy/subject/researchSubject/subjectOf/specification/component/testDefinition/component/testDefinition/referenceRange/acceptanceCriterion - interpretationCode	
Code System Name		
Code System (OID)		
<p>For a single acceptance criterium (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) – if the value should not be greater than the given value</p> <p>NLT (not less than) – if the value should not be smaller than the given value</p> <p>COMPLIES – if the limit has a textual structure (e.g. Colour).</p>		

Code	Display Name	Description

Example:

```

<acceptanceCriterion>
  <value xsi:type="PQ" value="1900" unit="ug"/>
  <interpretationCode displayName="NLT"/>
</acceptanceCriterion>

<acceptanceCriterion>
  <value xsi:type="PQ" value="Yellow" />
  <interpretationCode displayName="COMPLIES"/>
</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".

## Study Type

Element Name	/stabilityStudy/component/studyOnBatch - code	
Code System Name		
Code System (OID)		
This code classifies the type of study performed on the given ResearchSubject, e.g. regulatory study for NDA (Stability), stability for clinical samples (Clinical), exploratory studies (Development), ...		
Code	Display Name	Description

Example:

```

<studyOnBatch>
  <id root="1.3.6.1.4.1.24263.4711.1"/>
  <code displayName="Stability"/>
  <subject>
    <instance>
      <manufacturedMaterialInstance>
        ...
      </manufacturedMaterialInstance>
    </instance>
  </subject>
</component>
...
</component>
</studyOnBatch>

```

## Closure System Code

Element Name	/stabilityStudy/component/studyOnBatch/subject/instance/manufacturedMaterialInstance/asContent/container - capTypeCode	
Code System Name	to be provided	
Code System (OID)	to be provided	
The closure system of the container.		
Code	Display Name	Description
	Child-resistant, Metal	Metal closure that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly.
	Child-resistant, Plastic	Plastic closure that is designed or constructed to be significantly difficult for children under five years of age to open and not difficult for normal adults to use properly.
	Continuous Thread, Metal	Metal closure turned onto a corresponding thread on the top or mouth of a container, whether it be glass, plastic or metal.
	Continuous Thread, Plastic	Plastic closure turned onto a corresponding thread on the top or mouth of a container, whether it be glass, plastic or metal.
	Tamper-evident, Metal	A closure/finish of a closure/container system designed to make it difficult to achieve the first removal of a closure from a container without it being detectable by subsequent users that the package seal has been breached.
	Tamper-evident, Plastic	A closure that shows the package has been opened and the product has been exposed to the outside environment.
	Tamper-evident, Composite	Composite tamper-evident closures usually consists of a metal disk with a plastic skirt. The plastic skirt is perforated or weakened in some manner so that when the closure is removed, this section is designed to break and either remain on the container or attached to the closure to indicate the package has been opened.
	Vacuum, Metal	Metal closures used on packages where the pressure inside the package is less than atmospheric.
	Vacuum, Plastic	Plastic closures used on packages where the pressure inside the package is less than atmospheric.
	Vacuum, Composite	Metal/Plastic closures used on packages where the pressure inside the package is less than atmospheric.
	Press-on/Twist-off, Metal	Closure with a stepped, skirted drawn shell with an inside curl. The closure is lined with an annular plastisol material designed to provide a proper seal along the top and side surfaces of the glass container finish. The closure uses a special plastisol material that, following application, takes a permanent impression of the glass threads ensuring cam-off and reseal.
	Press-on, Composite	A metal/plastic composite cap composed of a plastisol lined metal disk, assembled to a plastic band. The closure requires a simple glass bead finish common on bowls, tumblers and carafes.
	Crown, Metal	A non-threaded shallow draw metal closure that normally has 21 corrugations on the outer edge, which function to engage the container when applied. The crown is only 1/4" high when manufactured and does not have a rolled edge or wire. The crown is manufactured in 26mm worldwide and can be applied to either a threaded finish or a solid ring pry-off finish.

	Lug, Metal	Closure with an ability to be applied and removed with a partial turn. The closure can also be produced with vacuum buttons that can clearly indicate to the packer if a vacuum has been effectively drawn following the closure application.
	Roll-on, Metal	A tamper-evident closure produced as an unthreaded shell containing a liner. It is applied to the proper finish on a plastic or glass container by the bottler, using a roll-on capping machine that forms a thread in the closure matching the bottle thread.
	Flip-Top (Dispensing), Plastic	A hinged single or dual flap closure for controlled product dispensing.
	Hinged (Dispensing), Plastic	A closure with a lid that is hinged to the top of a closure and opens to expose a dispensing orifice
	Linerless, Plastic	A closure that incorporates a specific molded-in feature such as rings, plugs or flexible sections. These features achieve a seal by conforming to one or more of the sealing surfaces on the container neck finish.
	Pump (Dispensing), Plastic	Closure dispensing pumps are used to dispense product from containers
	Push-pull (Dispensing), Plastic	A two-piece dispensing closure that includes a base member the lower portion of which is designed to attach and seal securely to a container finish and the upper portion of which is designed to receive a dispensing spout member. The spout member may be moved upward and downward to open and close the dispensing passageway.
	Snap-on Cap, Plastic	A non-threaded closure that is pressed onto the package finish with a protruding feature that mates with a similar protruding feature on the closure to secure the closure to the package.
	Snip-tip (Dispensing), Plastic	Conical closure that is turned onto a container. The tip is cut off to open the container.
	Toggle-swing (Dispensing), Plastic	A closure with a lower part attaches securely and seals the container. The upper part provides a second movable portion which functions in a rocker-like pivotal motion between an open and a closed position.
	Trigger Sprayer (Dispensing), Plastic	Closures designed to dispense product from containers by spraying the product when a trigger is pulled.
	Twist Open/Close (Dispensing), Plastic	Two-piece dispensing closure that has a lower portion designed to attach and seal securely to a container finish and the upper portion of which is designed to receive a dispensing spout member. Rotating the spout member opens and closed the container.
	Valved (Dispensing), Plastic	Dispensing closure incorporating a product-flow controlling valve within the orifice. Product will not dispense from the package until sufficient squeezing pressure is applied to the flexible container to cause the valve to open.
	Stopper	Object used to plug opening of container.
	Tie	Line, ribbon or cord used of fastening, or drawing the container closed.
	Other	
<p>Example:</p> <p>To be provided when codes are available</p>		

## Container Code

### Storage Condition Code

Element Name	/stabilityStudy/component/studyOnBatch/component/storage/controlVariable/storageCondition - code	
Code System Name		
Code System (OID)		
The code provided represents a 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).		
Code	Display Name	Description
Example: <pre>&lt;storageCondition&gt;   &lt;code displayName="__TIMEZERO"/&gt;   &lt;text&gt;Release Samples&lt;/text&gt; &lt;/storageCondition&gt;  &lt;storageCondition&gt;   &lt;code displayName="25_60u"/&gt;   &lt;text&gt;25°C / 60% r.h., upright storage&lt;/text&gt; &lt;/storageCondition&gt;</pre> as shown in this example, it's recommended to provide a "human readable" <text> element for better readability.		

### Pause Description Code

Element Name	/stabilityStudy/component/studyOnBatch/component/testing - code	
Code System Name		
Code System (OID)		
This code describes any „delay“ that happend during testing, e.g. none or freeze sample		
Code	Display Name	Description

Example:

```
<component>
  <pauseQuantity xsi:type="PQ" value="0" unit="MONTHS"/>
  <testing>
    <code displayName="NONE"/>
    <title xsi:type="ST">Normal Testing</title>
    <component>
      <test>
        <effectiveTime>
          <high value="20051115"/>
        </effectiveTime>
        <value xsi:type="PQ" nullFlavor="NA"/>
        <definition>
          <definitionStub>
            <id root="1.3.6.1.4.1.24263.4711.1.1.1"/>
          </definitionStub>
        </definition>
      </test>
    </component>
  </testing>
</component>
...
```

**Comment [NB1]:** I can not see any use for the <title> element.