sup238_pc_AssertionCollection.docx

Digital Imaging and Communications in Medicine (DICOM)

Supplement 238: Assertion Collection

Prepared by: DICOM WG-07 "Radiotherapy"

DICOM Standards Committee, Working Group 7

1300 N. 17th Street

Rosslyn, Virginia 22209 USA

VERSION: Version PC

September 28, 2023

Developed pursuant to DICOM Work Item 2022-09-B

Table of Contents

sup238_pc_AssertionCollection.docx

Foreword

With an increasing number of DICOM Instances from different modalities for a single patient visit and related assertions for them, such as approval, the need to collect these assertions outside the actual Instances arises. The Assertion Collection IOD proposed in this Supplement addresses these issues, along with providing contextual information for the assertion and identification information for the referenced Instances.

Scope and Field of Application

The Assertion Collection IOD provides means to convey a collection of assertions for referenced instances along with the information during which clinical step the assertions were created, and other meta information.

- High-level identification information for the collection
  This may be information from one or more of the referenced Instances so that the Assertion Collection can be easily identified without evaluating referenced Instances
- State definitions for the referenced Instances on Study, Series, Instance or Instance Component level
  States allow to define assertions when e.g. Instances were added or removed, or when they were reviewed and/or approved, along detailed information for which purpose an assertion was made so that the context of an assertion is clear.
- State definitions for the Assertion Collection Instance itself.
  This allows for assertion of the entire Assertion Collection. This may be applicable for e.g. treatment plans that are created in several planning steps, each step providing a set of assertions. A final review of the entire treatment plan by the physician may not include the verification of each asserted Instance, but a high-level assertion (“sign-off”) of the entire collection.
- Means to transfer content that was created during the collection of the assertions.
  This may be information collected e.g. during treatment session and provides additional semantics for the collected references.

The design of the Assertion Collection is agnostic to any clinical domain and any requires domain-specific information that is modeled by codes, by including specific CIDs or TIDs.

Potential use cases of the Assertion Collection IOD include collection of assertions for instance references during post-acquisition/pre-planning, treatment planning, treatment delivery, pre- or post-treatment quality evaluation, and more.

An Assertion Collection Instance may be used as input for sub-sequent workflow steps, whereas the Assertion Collection IOD only represents a current state and does not include any forward-looking statements about further usage. It is not intended to control any workflow steps, just to represent the outcome.

Open Questions

1	Do we need/want to represent references/links between referenced instances, e.g. between an RT Radiation Set and the corresponding segmentations, or a Segmentation and the corresponding image Instances?
2	DSC 16-Sept-2022: Should we include Digital Signatures for the assertions? See PS3.15, Annex C, section C.2, where all the attributes of the Reference Collection State Module are added.
4	WG-06 Nov 2022: Have the right attributes be chosen to be replicated in the Reference Collection Module to present a contextual information for Study/Series/Instance/Instance Component? WG-06 Jan 2023: How much meta information is justified about the Study/Series/Instance/Instance Component in the Collection Module, i.e. list vs. DICOMDIR?
5	The relationship between Reference Collections and Reference Collection States is n-m: - Multiple Assertions (included in the Reference Collection States) can refer to a single Reference Collection. - A single Assertion can be made on multiple Reference Collections. See §§§§.3 for examples. Are there any concerns regarding this n-m relationship?
6	Should the Instance always keep the whole history or should it only keep the current state? Both is currently possible. Should the Standard state anything here? During discussions with WG-06 it was agreed to only include the current state. Including all historic information will lead to lots of references and states where it may become complex to extract the current information. See also Open Issues #14 and #15.
7	Are there potential risks by having the same Reference Collection UID in multiple instances where the content represented by the UID is also duplicated and thus might be different in fact? Note that this is a convenience function. In principle a consumer could compare two Reference Collections in different Instances to observe it's the same list without using the UID.
10	For §§§§.1.1 Post-Acquisition Workflow: is there any concrete example that could be included? Are there any other examples?
11	For additional high-level identification in Assertion Collection Identification Content Item Sequence (gggg,0006), currently TIDs TNNN1 and TNNN2 provide RT-specific parameters. Are there other (non-RT) TIDs that can already be foreseen and should be included?
12	CID NNN2 Reference Collection States provides state codes primarily driven from an RT workflow perspective. Are there other states to support additional (non-RT) use cases?

13	Currently, the Assertion Context UID comes with the Assertion Context Label. Is it necessary to also provide an Assertion Context Code Sequence along with pre-defined codes? E.g. for the example in §§§§.2 where all Assertion Collection Instances share the same Assertion Context UID and have different Assertion Collection Codes, would it be beneficial to introduce a code such as “Treatment Planning Context”?
14	Code (S238022, 99SUP238, “Demoted”): should this code be present? Background: this code includes temporal information and could also be derived by checking the approval state in a predecessor instance of the Assertion Collection. If the state was (S238020, 99SUP238, “Approved”) before and is now (S238023, 99SUP238, “Unapproved”), then this would be the same as a demoted state. See also Open Issues #6 and #15.
15	The Active State Indicator (gggg,0004) allows to annotate a state as historic. With the current decision to recommend to only include the current states, this would not be necessary anymore. Still, there may be use cases where this annotation is helpful. Any comments on this? Any use cases where the annotation of a historic state would be required? See also Open Issues #6 and #14.
16	Do the definitions of the codes in CID NNN5 need to be more specific beyond repeating the name of the state? The state machines for approvals are not standardized or uniform at most healthcare facilities and application. These definitions provide names for the most commonly found state names, but do not provide an interoperable definition. For example, the meaning of "Reviewed" or "Approved" can vary from significantly from facility to facility. The alternative of providing fully specified states and state transition rules will not meet the needs of any system with different rules. Most systems and sites would need to provide their own codes. This could possible conflict with defined codes in a DCID and become confusing rather than adding value. Leaving out these codes completely leaves the users and implementers with no guidance at all regarding codes or state machines. This has been done in some other situations by providing a BCID with no contents beyond a description. That is a potential alternative, and worth comment if viewed as superior to this proposal. Some of the existing BPEL and W3C governance, provenance, and approval standards accommodate this inter facility variability by using a highly complex data structure that incorporates facility specific data elements. Using their approach would increase the complexity of the SOP Class dramatically. The proposed approach provides generally recognized codes, but will require clear coordination and communication of precise meaning between local participants. This is already current practice at most sites. It does increase the risk to interoperability if SOP Instances are exchanged without such coordination.
17	The Assertion Collection allows express states, such as an approval state, see CID NNN5. In order to strengthen the use cases for this new IOD, should the Approval Module be retired? Note, the attributes of a retired Module can still be used.

Closed Questions

1	Why not use existing approval concepts already found in the DICOM Standard? The existing Protocol Approval IOD is specific to protocols and does not allow documenting assertions for the mentioned use case. The existing Content Assessment Results IOD is used to document which observations and corresponding results lead to a specific assessment and may therefore be included as references along the state of an assertion. It is not suited for the use case of collecting the assertions. The existing Approval Module is always part of an IOD and therefore a change of the approval state causes a change of the instance UID which results in an unnecessary proliferation of data and compromises existing references. In addition, this Module has short-comings with respect to granularity, context and multiplicity. Therefore, this Module cannot meet current and foreseen clinical needs.
2	WG-06 November 2022: The Study Instance UID is not suited as a “collection” of Assertion Collection Instances that are part of a specific procedure. WG-06 March 2023: The Assertion Context UID (gggg,0015) was added to address this use case.
3	DSC 16-Sept-2022: Is it ok to just refer to a Study or Series and thus assuming that everything that may happen later is implicitly also e.g. approved? Or is this just up to the business logic of the application creating the assertion what is included and what not? This is now explicitly addressed in Section C.A.2.4.1.2.
8	CID NNN9 has the working title “Devices that can make assertions” – are there any proposals how to call this CID? Proposal WG-07: Automated Assertion Devices
9	CID NNN9 contains a proposal for an AI device. Is an AI device distinct from the other devices? Or is AI rather an aspect of the other devices? WG-07: Any device can to some extent be driven by AI, therefore, there is no differentiation to other devices necessary.

sup238_pc_AssertionCollection.docx

Part 2 Addendum

Add a new SOP Class to PS3.2 Table A.1-2 UID Values:

UID Value	UID Name	Category
1.2.840.10008.5.1.4.1.1.481.XN.1	Assertion Collection Storage	Transfer

Part 3 Addendum

In PS3.3, A.1.2, replace the existing Figure A.1-1 with the one below, where "Content Assessment Result" has been replaced with "Content Assessment".

See the "supporting" folder for the file "PS3.3_A.1-1_new.svg".

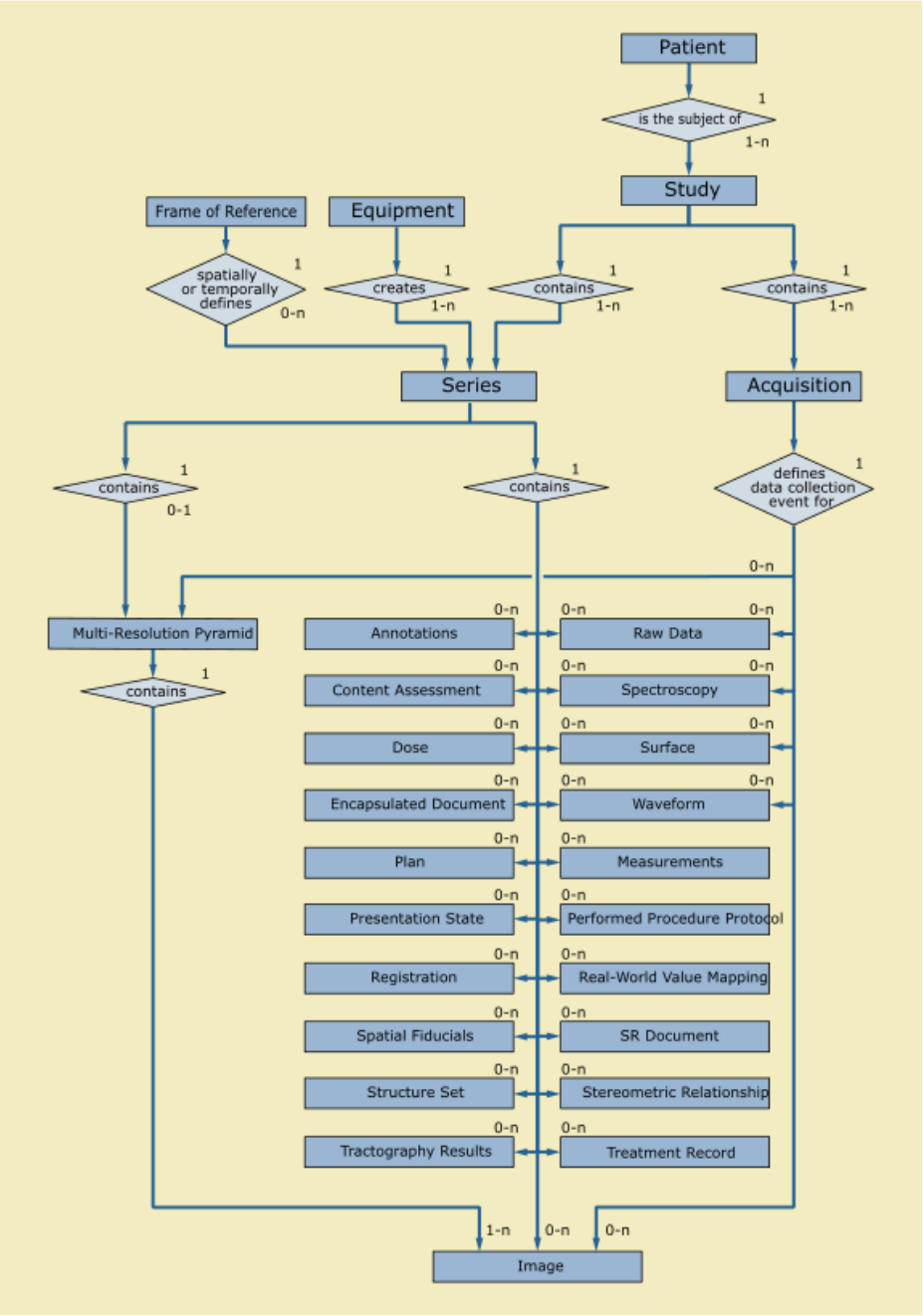

Figure A.1-1. DICOM Composite Instance IOD Information Model

In PS3.3, A.1.2.22, update the text:

A.1.2.22 Content Assessment ~~Result~~ IE

The Content Assessment **~~Result~~** IE contains **~~the results of~~** an assessment of the content of **one or more ~~a~~** SOP Instance**s**.

An assessment is part of a process within a clinical workflow, conducted by users or devices, which have the role of assessing the validity**~~.~~ ~~and~~** suitability**, and characteristics** of the content in question, based on subjective or objective criteria. The specific nature of such a process is outside of the scope of this Standard.

In PS3.3, A.81.3 update the text:

A.81.3 Content Assessment Results IOD Module Table

Table A.81.3-1 specifies the Modules of the Content Assessment Results IOD.

Table A.81.3-1. Content Assessment Results IOD Modules

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	General Series	C.7.3.1	M
	Clinical Trial Series	C.7.3.2	U
Equipment	General Equipment	C.7.5.1	M
	Enhanced General Equipment	C.7.5.2	M
Content Assessment ~~Results~~	Content Assessment Results	C.33.1	M
	SOP Common	C.12.1	M
	Common Instance Reference	C.12.2	M

Add the following to PS3.3 Annex A

See the "supporting" folder for the file "Figure_A.VV.1-N.drawio.svg".

A.VV ASSERTION COLLECTION DOCUMENT INFORMATION OBJECT DEFINITION

A.VV.1 Assertion Collection IOD Description

The Assertion Collection IOD is intended to collect assertions on referenced data including corresponding meta information for high-level identification.

An Assertion Collection IOD may be used in different clinical contexts and workflows. Therefore, it is possible to use this IOD in arbitrary levels of granularity of workflow steps to document outcomes.

A.VV.1.1 Assertion Collection IOD internal entity-relationship model

Figure A.VV.1-N depicts the Entity-Relationship Model of the internal components of the Assertion Collection IOD.

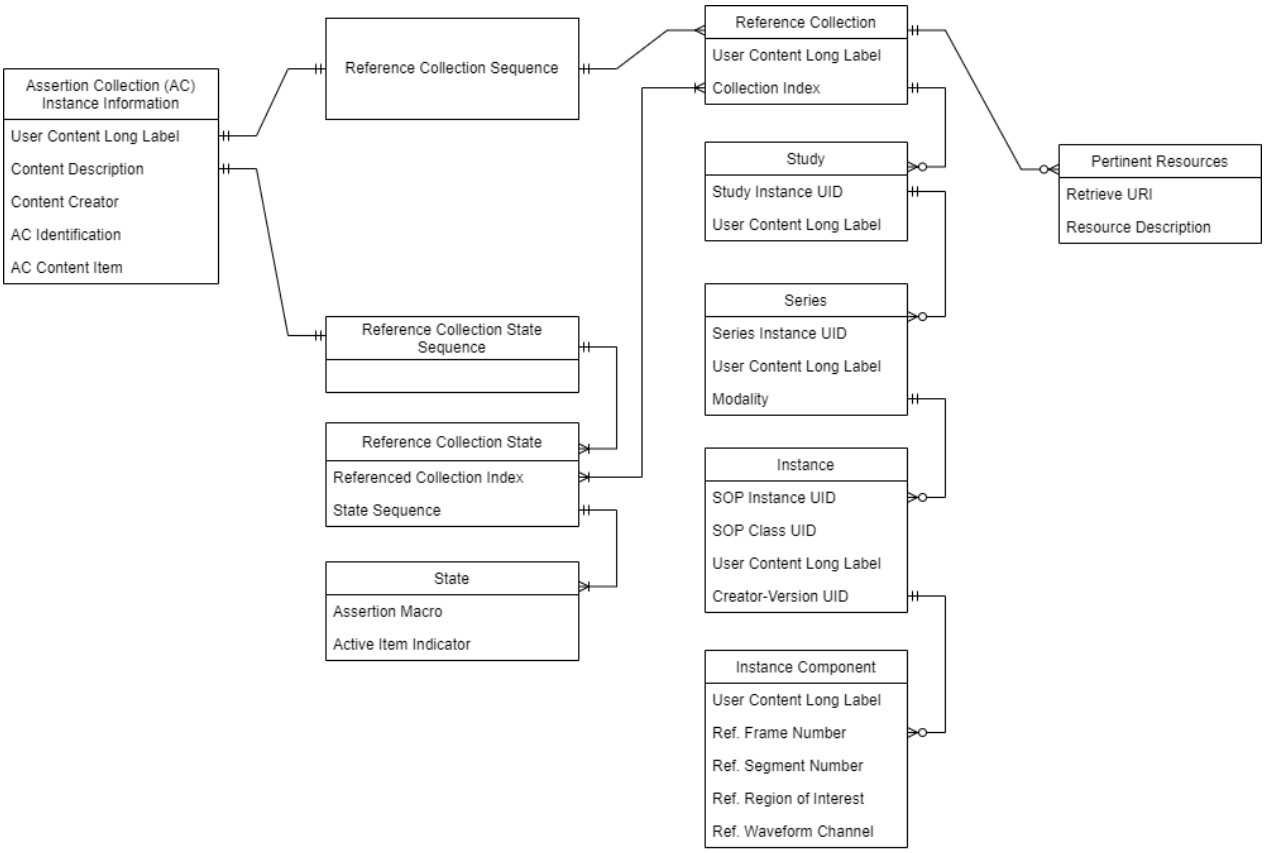

Figure A.VV.1-N
Assertion Collection IOD Entity-Relationship Diagram of the Internal Model

A.VV.2 Assertion Collection IOD entity-relationship model

This IOD uses the E-R Model in Section A.1.2, with only the Content Assessment IE below the Series IE.

A.VV.3 Assertion Collection IOD Module Table

Table A.VV.3-1 specifies the Modules of the Assertion Collection Document IOD.

Table A.VV.3-1
Assertion Collection IOD MODULES

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	Assertion Collection Series	C.A.2.1	M
	Clinical Trial Series	C.7.3.2	U
Equipment	General Equipment	C.7.5.1	M
	Enhanced General Equipment	C.7.5.2	M
Content Assessment	Assertion Collection	C.A.2.2	M
	Reference Collection	C.A.2.3	M
	Reference Collection State	C.A.2.4	M
	Common Instance Reference	C.12.2	M
	SOP Common	C.12.1	M

Add the following to PS3.3 Annex C:

C.A ASSERTION COLLECTION MODULES

C.A.1 Assertion Collection Modules

C.A.1.1 Assertion Collection Series Module

Table C.A.1.1-1 specifies the Attributes of the Assertion Collection Series Module, which identify and describe general information about a collection of Assertions.

Table C.A.1.1-1
Assertion Collection Series Module Table

Attribute Name	Tag	Type	Attribute Description
Modality	(0008,0060)	1	Type of device, process or method that created the Instances in this Series. Enumerated Values: AC – Assertion Collection
Series Instance UID	(0020,000E)	1	Unique identifier of the Series.

Series Number	(0020,0011)	1	A number that identifies this Series
Series Date	(0008,0021)	1	Date the Series started.
Series Time	(0008,0031)	1	Time the Series started.
Series Description	(0008,103E)	3	Description of the Series.
Series Description Code Sequence	(0008,103F)	3	A coded description of the Series. Only a single Item is permitted in this Sequence.
>Include Table 8.8-1 "Code Sequence Macro Attributes"			*No Baseline CID is defined.*
Referenced Performed Procedure Step Sequence	(0008,1111)	2	Uniquely identifies the Performed Procedure Step SOP Instance for which the Series is created. Zero or one Item shall be included in this Sequence. Note 1. The Performed Procedure Step referred to by this Attribute is the Step during which this Document is generated. 2. If this Document is generated during the same Performed Procedure Step as the evidence in the current interpretation procedure, this Attribute may contain reference to that Performed Procedure Step. 3. This Attribute is not used to convey reference to the evidence in the current interpretation procedure. See Current Requested Procedure Evidence Sequence (0040,A375). 4. This Sequence may be zero length if the Performed Procedure Step is unknown.
>Include Table 10-11 "SOP Instance Reference Macro Attributes"			
Treatment Session UID	(3000,0070)	3	A unique identifier of the RT Treatment Session to which Instances in this Series belong.

C.A.1.2 Assertion Collection Module

Table C.A.1.2-1 defines the general Attributes of an Assertion Collection. These Attributes identify and provide context for a collection of Assertions.

Table C.A.1.2-1
Assertion Collection Module Table

Attribute Name	Tag	Type	Attribute Description
Assertion Context UID	(gggg,0015)	2	Identifying Assertion Collection Instances that are in the same context.
Assertion Context Label	(gggg,0017)	1C	User-defined label for the Assertion Context. Required if Assertion Context UID (gggg,0015) has a value.
User Content Long Label	(3010,0034)	1	User-defined label for the content of this SOP Instance. See Section 10.9.2.1.1.
Assertion Collection Code Sequence	(gggg,0018)	2	A coded description of the content of the SOP Instance. Only a single Item shall be included in this Sequence. See C.A.1.2.1.1.
>Include Table 8.8-1 "Code Sequence Macro Attributes"			*Defined CID NNN1 Assertion Collection Concept Names*
Content Date	(0008,0023)	1	The date the document content creation started.
Content Time	(0008,0033)	1	The date the document content creation started.
Content Description	(0070,0081)	2	User-defined description for the content of this SOP Instance. See Section 10.9.2.1.1.
Content Creator's Person or Device Sequence	(gggg,0013)	2	Identification of the person or device who created the content. Only a single Item is permitted in this Sequence.
>Include Table C.17-3b "Identified Person or Device Macro Attributes"			*Defined CID for Organizational Role Code Sequence (0044,010A) is CID NNN7 Assertion Collection Creator Roles.*
Concept Name Code Sequence	(0040,A043)	2	A coded description of the content of the SOP Instance. Only a single Item shall be included in this Sequence. See C.A.1.2.1.1.
>Include Table 8.8-1 "Code Sequence Macro Attributes"			*Defined CID NNN1 Assertion Collection Concept Names*
Assertion Collection Identification Content Item Sequence	(gggg,0006)	2	Properties providing more detailed high-level identification. See C.A.1.2.1.2 Zero or more Items shall be included in this Sequence.

>Include Table 10-2.1-1 "Content Item with Modifiers Macro"			See C.A.2.2.1.2 for Baseline TIDs.
Assertion Collection Content Item Sequence	(gggg,0012)	2	Information created during collection of this Assertion Collection Instance. See C.A.1.2.1.3 Zero or more Items shall be included in this Sequence.
>Include Table 10.2.1-1 "Content Item with Modifiers Macro"			See C.A.2.2.1.3 for Baseline TIDs.
Assertion Collection Predecessor Sequence	(gggg,0010)	2	The direct predecessor Instance of this Assertion Collection Instance. See. C.A.1.2.1.4 One or more Items shall be present in this Sequence.
>Include Table 10-11 "SOP Instance Reference Macro Attributes"			

C.A.1.2.1 Assertion Collection Attribute Description

C.A.1.2.1.1 Concept Name Code Sequence

An Assertion Collection Instance may be used in specific hospital workflows that may vary in granularity depending on clinical procedures and systems in use to document the outcome of these workflow steps. The Assertion Collection Code Sequence (gggg,0018) reflects this outcome.

The Assertion Collection Code Sequence (gggg,0018) is not intended to make forward-looking statements, as it is not in the scope of this SOP Class to control a workflow.

C.A.1.2.1.2 Assertion Collection Identification Content Item Sequence

The content items included in the Assertion Collection Identification Content Item Sequence (gggg,0006) are intended to provide a high-level identification of included references. This may be for example a single prescription dose value or an anatomic region. It is not intended to just duplicate information in the referenced Instances, but to actively pick information that supports identification.

For a detailed analysis it is expected that the referenced SOP Instances are evaluated accordingly.

The following TIDs are be used for the corresponding Concept Name Codes:

Table C.A.1.2-2
Assertion Collection Identification Content Item TIDs

Assertion Collection Code Sequence (gggg,0018)	TID
(128189, DCM, RT Planning Result)	Defined TNNN1 RT Treatment Planning Assertion Collection Identification
(128192, DCM, RT Treatment Session Result)	Defined TNNN11 RT Treatment Positioning Assertion Collection Identification
	No other DTIDs defined.

C.A.1.2.1.3 Assertion Collection Content Item Sequence

The content items included in the Assertion Collection Content Item Sequence (gggg,0012) are providing information that was created during collection of this Assertion Collection Instance but cannot be located in any of the referenced Instances.

The following TIDs are be used for the corresponding Concept Name Codes:

Table C.A.1.2-2
Assertion Collection Content Item TIDs

Assertion Collection Code Sequence (gggg,0018)	TID
(128189, DCM, RT Planning Result)	Defined TNNN2 RT Treatment Planning Annotation
(128192, DCM, RT Treatment Session Result)	Defined TNNN3 Treatment Session Annotation
	No other DTIDs defined.

C.A.1.2.1.4 Assertion Collection Predecessor Sequence

An Instance is considered a predecessor when the content of such an Instance changes, but the semantic scope and context does not change. For example, an Assertion Collection defined during a contouring session may be appended with additional segments but stays semantically the same. If such a contouring Assertion Collection is utilized in a next step as input in treatment plan creation, the contouring Assertion Collection shall not be the predecessor of a planning result Assertion Collection, as the scope changed. The contouring Assertion Collection Instance may or may not be included in the planning result Assertion Collection Instance as a referenced content.

As an example, a predecessor is created if for any of the referenced Studies, Series or Instances an State is changed, e.g. an Assertion that approves is added.

C.A.1.3 Reference Collection Module

Table C.A.1.3-1 defines the Collection of hierarchical references, along with identifying information for a Collection.

Table C.A.1.3-1
Reference Collection Module Table

Attribute Name	Tag	Type	Attribute Description
Reference Collection Sequence	(gggg,0001)	1	Collection of hierarchical references to Studies/Series/Instances/Instance Components. One or more Items shall be included in this Sequence.
>User Content Long Label	(3010,0034)	3	User-defined label for this Collection.
>Reference Collection Index	(gggg,0008)	1	The index of the Reference Collection. The value shall start at 1 and increase monotonically by 1 within this Sequence.
>Reference Collection UID	(gggg,0016)	3	Unique identifier of the Reference Collection across Instances.
>Pertinent Resources Sequence	(0038,0101)	1C	Resources that contain information that are part of this Reference Collection. Required if Referenced Study Sequence (0008,1110) is absent. May be present otherwise. One or more Items shall be included in this Sequence.
>>Retrieve URI	(0040,E010)	1	Retrieval access path to resource. Includes fully specified scheme, authority, path, and query in accordance with [RFC3986].
>>Resource Description	(0038,0102)	3	Description or title of the resource.
>Referenced Study Sequence	(0008,1110)	1C	Studies that are part of this Reference Collection. Required if Pertinent Resources Sequence (0038,0101) is absent. May be present otherwise. One or more Items shall be included in this Sequence.
>>Study Instance UID	(0020,000D)	1	Uniquely identifies the referenced Study.
>>Study Date	(0008,0020)	2	Date the Study started.
>>Study Time	(0008,0030)	2	Time the Study started.
>>User Content Long Label	(3010,0034)	3	User-defined label for this Study.
>>Referenced Series Sequence	(0008,1115)	1C	Series that are part of this Reference Collection. Required if only specific Series are associated with the Reference Collection. One or more Items shall be included in this Sequence.
>>>Series Instance UID	(0020,000E)	1	Uniquely identifies the referenced Series.
>>>Series Date	(0008,0021)	2	Date the Series started.
>>>Series Time	(0008,0031)	2	Time the Series started.

>>>User Content Long Label	(3010,0034)	3	User-defined label for this Series.
>>>Modality	(0008,0060)	1	Modality of the referenced Series.
>>>Referenced Instance Sequence	(0008,114A)	1C	Instances that are part of this Reference Collection. Required if only specific Instances are associated with the Reference Collection. One or more Items shall be included in this Sequence.
>>>>Include Table 10-11 "SOP Instance Reference Macro Attributes"			
>>>>Content Date	(0008,0023)	1	The date the document content creation started.
>>>>Content Time	(0008,0033)	1	The date the document content creation started.
>>>>User Content Long Label	(3010,0034)	3	User-defined label for this Instance.
>>>>Creator-Version UID	(0008,9123)	1C	Unique identification of the equipment and version of the software that has created the Raw Data information. The UID allows one to avoid attempting to interpret raw data with an unknown format. Required if Referenced SOP Class UID (0008,1150) equals 1.2.840.10008.5.1.4.1.1.66 ("Raw Data Storage").
>>>>Instance Component Sequence	(gggg,0014)	1C	Items of an Instance that are part of this Reference Collection. Required if only specific Instance Components are associated with the Reference Collection. One or more Items shall be included in this Sequence.
>>>>>Referenced Frame Number	(0008,1160)	1C	Identifies the frame numbers within the Referenced SOP Instance to which the reference applies. The first frame shall be denoted as frame number 1. Required if the Referenced SOP Instance is a multi-frame image and the reference does not apply to all frames.
>>>>>Referenced Segment Number	(0062,000B)	1C	Identifies the segments to which the reference applies identified by Segment Number (0062,0004). Required if the Referenced SOP Instance is a Segmentation or Surface Segmentation and the reference does not apply to all segments.
>>>>>Referenced Regions of Interest	(gggg,0011)	1C	Identifies the ROIs to which the reference applies identified by ROI Number (3006,0022). Required if the Referenced SOP Instance is an RT Structure Set and the reference does not apply to all ROIs.

>>>>>Referenced Waveform Channels	(0040,A0B0)	1C	List of channels in Waveform to which the reference applies. Required if the Referenced SOP Instance is a Waveform that contains multiple Channels and the reference does not apply to all Channels of all Multiplex Groups. See Section C.18.5.1.1.
>>>>>User Content Long Label	(3010,0034)	3	User-defined label for this Instance Component.

C.A.1.4 Reference Collection State Module

Table C.A.1.4-1 defines the Collection of hierarchical references, along with identifying information for a Collection.

Table C.A.1.4-1
Collection State Module Table

Attribute Name	Tag	Type	Attribute Description
Reference Collection State Sequence	(gggg,0007)	1	State of a Reference Collection in Reference Collection Sequence (gggg,0001). One or more Items shall be included in this Sequence. See C.A.1.4.1.1.
>Referenced Reference Collection Index	(gggg,0009)	1	References to one or more values of Reference Collection Index (gggg,0008) in the Reference Collection Sequence (gggg,0001) to which this Collection State applies. See C.A.1.4.1.2.
>State Sequence	(gggg,0003)	1	States associated with the Reference Collection referenced by Referenced Reference Collection Index(gggg,0009). One or more Items shall be included in this Sequence. See C.A.1.4.1.3.
>>Include Table 10-30-1 'Assertion Macro'			*Baseline CID for Assertion Code Sequence (0044,0101) is CID NNN2 "Reference Collection States"* *See C.A.1.4.1.4.*
>>Assertion Purpose Code Sequence	(gggg,0005)	2	The purpose for which this assertion is made and valid. Only a single Item shall be present in this Sequence. See C.A.1.4.1.5.
>>>Include Table 8.8-1 "Code Sequence Macro Attributes"			*Defined CID NNN8 Assertion Purposes*

>>Active State Indicator	(gggg,0004)	1	Indicator of the active versus historic status of this state. Enumerated Values: ACTIVE HISTORIC See C.A.1.4.1.6.

C.A.1.4.1 Collection State Attribute Description

C.A.1.4.1.1 Collection State Sequence

Multiple Instances of the Assertion Collection IOD may define different states for the same Reference Collection. This may be intended as the clinical workflow for which the Assertion Collection IOD is used requires different steps of e.g. review and/or approval to represent different clinical states. However, this may also result in a consumer receiving Assertion Collection Instances with conflicting states.

In case it is important to document whether the change of a state was made in awareness of a prior defined state, then this can be expressed by utilizing the Referenced Assertion UID (0044,0108) of the Related Assertion Sequence (0044,0107).

Another form of this process issue can occur when an Assertion Collection Instance defines a state for referenced SOP Instance, e.g. an RT Plan IOD, and the referenced SOP Instance also contains an attribute for its own state and those two states may differ. For example, the Approval Status (300E,0002) with a value UNAPPROVED within an RT Plan IOD and the code (99SUPNNNSUP238, SNNNS238020, “Approved”) in the Assertion Collection IOD.

C.A.1.4.1.2 Referenced Reference Collection Index

The Referenced Reference Collection Index associates a set of assertions in the State Macro with a Reference Collection.

Referencing components and resources in a Reference Collection limits the components and resources for which the Assertions encoded in the included State Sequence (gggg,0003) are made and valid. If specific Instance UIDs are referenced, then the assertions are only valid for those specific Instances. If a specific Series Instance UID (0020,000E) is referenced but no specific Instances are referenced, then the assertions are not limited to specific Instances, but instead are valid for all Instances in the referenced Series. Similarly, if a Study Instance UID (0020,000D) is referenced, but no Series or Instances are referenced, then the Assertion is valid for all Instances and Series in the Study.

It is important for creators of Assertions to recognize that Images may be added to Series and Series may be added to Studies even after an Assertion has been made. If the creator’s intention is that the Assertion should be limited and not apply to those future Instances, then the creator is obliged to enumerate, in the Reference Collection, the “current” Instances to which they intend the Assertion apply. If the creator’s intention is that the Assertion should apply to those “future” Instances, then they should not include references that limit the scope at a given level.

C.A.1.4.1.3 State Sequence

The State Sequence (gggg,0100) contains a Sequence of Items which define an Assertion. The CIDs which define the codes to be used in Assertion Code Sequence (0044,0101) attribute of the Assertion Macro are defined at the invocation of the macro.

C.A.1.4.1.4 Pertinent Documents Sequence

The Pertinent Documents Sequence (0038,0100) shall contain Content Assessment Results SOP Instances that provide the basis for making the Assertion if available.

C.A.1.4.1.5 Assertion Purpose Code Sequence

The Assertion Purpose Code Sequence shall have a value if the assertion is made for a specific purpose. E.g. a coarsely segmented anatomy may only be used in a diagnostic context, but not for treatment planning. This intention may then be conveyed using this Sequence.

Whether this information is actually used in a subsequent step is out of scope as this only documents the intent at the time of creation of the Assertion Collection SOP Instance.

C.A.1.4.1.6 Active State Indicator

The Active State Indicator (gggg,0004) attribute is used to specify which state definition items in the State Sequence (gggg,0003) are active and which items do only convey an audit trail of states having been in place in the past.

This indication additionally allows conveying more than one state entry of different persons as being active. E.g. if the department requires approvals by more than one person, several items having an approved state can be marked as active, indicating the list of persons having provided approval.

The semantics of the states are defined in the code definition and may be further specialized at invocation of that macro. Which state transitions are allowed and which are the pre-conditions to perform a state transition is outside of the scope of the standard.

Update in PS3.3, Annex F, F.5.45:

F.5.45 Content Assessment Results Directory Record Definition

The Directory Record is based on the specification of Section F.3. It is identified by a Directory Record Type of Value "ASSESSMENT". Table F.5-45 lists the set of keys with their associated Types for such a Directory Record Type. The description of these keys may be found in the Modules related to the Content Assessment Results IOD. This Directory Record shall be used to reference a Content Assessment Results SOP Instance **or Assertion Collection SOP Instance**. This type of Directory Record may reference a Lower-Level Directory Entity that includes one or more Directory Records as defined in Table F.4-1.

Table F.5-45. Content Assessment Results Directory Record Results Keys

Key	Tag	Type	Attribute Description
Specific Character Set	(0008,0005)	1C	Required if an extended or replacement character set is used in one of the keys.
Instance Number	(0020,0013)	1	
Instance Creation Date	(0008,0012)	1	
Instance Creation Time	(0008,0013)	2	
Any other Attribute of the Content Assessment ***~~Results~~*** *IE Modules*		3	

Note

Because Referenced SOP Instance UID in File (0004,1511) may be used as a "pseudo" Directory Record Key (see Table F.3-3), it is not duplicated in this list of keys.

Add the following data elements to PS3.6:

Part 6 Addendum

Table 6-1. Registry of DICOM Data Elements

Tag	Name	Keyword	VR	VM
(gggg,0001)	Reference Collection Sequence	ReferenceCollectionSequence	SQ	1
(gggg,0003)	State Sequence	StateSequence	SQ	1
(gggg,0004)	Active State Indicator	ActiveStateIndicator	CS	1
(gggg,0005)	Assertion Purpose Code Sequence	AssertionPurposeCodeSequence	SQ	1
(gggg,0006)	Assertion Collection Identification Content Item Sequence	AssertionCollectionIdentificationContentItemSequence	SQ	1
(gggg,0007)	Reference Collection State Sequence	ReferenceCollectionStateSequence	SQ	1
(gggg,0008)	Referenced Collection Index	ReferenceCollectionIndex	US	1
(gggg,0009)	Referenced Reference Collection Index	ReferencedReferenceCollectionIndex	US	1-n
(gggg,0010)	Assertion Collection Predecessor Sequence	AssertionCollectionPredecessorSequence	SQ	1
(gggg,0011)	Referenced Regions of Interest	ReferencedRegionsofInterest	IS	1-n
(gggg,0012)	Assertion Collection Content Item Sequence	AssertionCollectionContentItemSequence	SQ	1
(gggg,0013)	Content Creator's Person or Device Sequence	ContentCreatorsPersonOrDeviceSequence	SQ	1
(gggg,0014)	Instance Component Sequence	InstanceComponentSequence	SQ	1
(gggg,0015)	Assertion Context UID	AssertionContextUID	UI	1
(gggg,0016)	Reference Collection UID	ReferenceCollectionUID	UI	1
(gggg,0017)	Assertion Context Label	Assertion Context Label	SH	1
(gggg,0018)	Assertion Collection Code Sequence	AssertionContextCodeSequence	SQ	1

Add to Part 6 Annex A

Annex A Registry of DICOM unique identifiers (UID) (Normative)

Table A-1
UID VALUES

UID Value	UID Name	UIDKeyword	UID Type	Part
1.2.840.10008.5.1.4.1.1.N	Assertion Collection Storage	AssertionCollectionStorage	SOP Class	PS 3.4

Table A-3
CONTEXT GROUP UID VALUES

Context UID	Context Identifier	Context Group Name
1.2.840.10008.6.1.NNN.1	NNN1	Assertion Collection Concept Names
1.2.840.10008.6.1.NNN.2	NNN2	Reference Collection States
1.2.840.10008.6.1.NNN.3	NNN3	Reference Inclusion States
1.2.840.10008.6.1.NNN.4	NNN4	Review States
1.2.840.10008.6.1.NNN.5	NNN5	Approval States
1.2.840.10008.6.1.NNN.7	NNN7	Assertion Collection Creastor Roles
1.2.840.10008.6.1.NNN.8	NNN8	Assertion Purposes
1.2.840.10008.6.1.NNN.9	NNN9	Automated Assertion Devices
1.2.840.10008.6.1.NNN.10	NNN10	Treatment Session Checks

In PS 3.15, Section E.1.1. De-identifier update Table E.1-1 as follows:

Attribute Name	Tag	Retd. (from PS3.6)	In Std. Comp. IOD (from PS3.3)	Basic Prof.	Rtn. Safe Priv. Opt.	Rtn. UIDs Opt.	Rtn. Dev. Id. Opt.	Rtn. Inst. Id. Opt.	Rtn. Pat. Chars. Opt.	Rtn. Long. Full Dates Opt.	Rtn. Long. Modif. Dates Opt.	Clean Desc. Opt.	Clean Struct. Cont. Opt.	Clean Graph. Opt.
…														
Assertion Context UID	(gggg,0015)	N	Y	X		K								
Reference Collection UID	(gggg,0016)	N	Y	X		K								

Attribute Name	Tag	Retd. (from PS3.6)	In Std. Comp. IOD (from PS3.3)	Basic Prof.	Rtn. Safe Priv. Opt.	Rtn. UIDs Opt.	Rtn. Dev. Id. Opt.	Rtn. Inst. Id. Opt.	Rtn. Pat. Chars. Opt.	Rtn. Long. Full Dates Opt.	Rtn. Long. Modif. Dates Opt.	Clean Desc. Opt.	Clean Struct. Cont. Opt.	Clean Graph. Opt.
Assertion Context Label	**(gggg,0017)**	**N**	**Y**	**D**								**C**		

Add the following to PS3.15 Annex C:

Part 15 Addendum

C.2 CREATOR RSA DIGITAL SIGNATURE PROFILE

…

As a minimum, an implementation shall include the following Attributes in generating the Creator RSA Digital Signature:

a. the SOP Class and Instance UIDs
b. the SOP Creation Date and Time, if present

…

$$. Any Attributes of the Reference Collection State Module.

Update in Part 16, Annex B

Part 16 Addendum

Annex B DCMR Context Groups (Normative)

CID 32 NON-ACQUISITION MODALITY

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: NonAcquisitionModality
FHIR Keyword: dicom-cid-32-NonAcquisitionModality
Type: Extensible
Version: YYYYMMDD

UID: **1.2.840.10008.6.1.1282**

Table CID 32 Non-Acquisition Modality

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	ASMT	Content Assessment Result
DCM	**AC**	**Assertion Collection**
DCM	AU	Basic Voice Audio
…		

Add to Part 16, Annex B

CID NNN1 ASSERTION COLLECTION CONCEPT NAMES

Resources: **HTML | FHIR JSON | FHIR XML | IHE SVS XML**
Keyword: **AssertionCollectionConceptNames**
FHIR Keyword: **dicom-cid-NNN1-AssertionCollectionConceptNames**
Type: **Extensible**
Version: **YYYYMMDD**
UID: **1.2.840.10008.6.1.NNN.1**

Table CID NNN1 Assertion Collection Concept Names

Coding Scheme Designator	Code Value	Code Meaning
Include CID 7023 "RT Process Output"		

CID NNN2 REFERENCE COLLECTION STATES

Resources: **HTML | FHIR JSON | FHIR XML | IHE SVS XML**
Keyword: **ReferenceCollectionStates**
FHIR Keyword: **dicom-cid-NNN2- ReferenceCollectionStates**
Type: **Extensible**
Version: **YYYYMMDD**
UID: **1.2.840.10008.6.1.NNN.2**

Table CID NNN2 Reference Collection States

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
Include CID NNN3 Reference Inclusion States		
Include CID NNN4 Review States		
Include CID NNN5 Approval States		

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
Include CID NNN8 Assertion Purposes		
Include CID 7004 "Waveform Purposes of Reference"		
Include CID 7022 "Radiotherapy Purposes of Reference"		
Include CID 7202 "Source Image Purposes of Reference"		
Include CID 7013 "Non-Image Source Instance Purposes of Reference"		

CID NNN3 REFERENCE INCLUSION STATES

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: ReferenceInclusionStates
FHIR Keyword: dicom-cid-NNN3-ReferenceInclusionStates
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.3

Table CID NNN3 Reference Inclusion States

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238001	Reference Added to Collection
99SUP238	S238002	Reference Removed from Collection
99SUP238	S238003	Reference Not Added to Collection

CID NNN4 REVIEW STATES

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: ReviewStates
FHIR Keyword: dicom-cid-NNN4-ReviewStates
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.4

Table CID NNN4 Review States

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238010	Unreviewed
99SUP238	S238011	Reviewed

CID NNN5 APPROVAL STATES

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: ApprovalStates
FHIR Keyword: dicom-cid-NNN5-ApprovalStates
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.5

Table CID NNN5 Approval States

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238023	Unapproved
99SUP238	S238020	Approved
99SUP238	S238021	Rejected
99SUP238	S238022	Demoted

CID NNN7 ASSERTION COLLECTION CREATOR ROLES

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: AssertionCollectionCreatorRoles
FHIR Keyword: dicom-cid-NNN7-AssertionCollectionCreatorRoles
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.7

Table CID NNN7 Assertion Collection Creator Roles

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
Include CID NNN9 "Automated Assertion Devices"		
Include CID 7452 "Organizational Roles"		

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
Include CID 9555 "Radiotherapy Treatment Planning Person Roles"		

CID NNN8 ASSERTION PURPOSES

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: AssertionPurposes
FHIR Keyword: dicom-cid-NNN8-AssertionPurposes
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.8

Table CID NNN8 Assertion Purposes

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238030	For Contouring
99SUP238	S238031	For Registration
99SUP238	S238032	For Positioning
99SUP238	S238033	For Planning
99SUP238	S238034	For Treatment
99SUP238	S238035	For Treatment Continuation

CID NNN9 AUTOMATED ASSERTION DEVICES

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: AutomatedAssertionDevices
FHIR Keyword: dicom-cid-NNN9-AutomatedAssertionDevices
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.9

Table CID NNN9 Automated Assertion Devices

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238040	Automated Segmentation Device
99SUP238	S238041	Automated Registration Device
99SUP238	S238042	Automated Image Collection Device
99SUP238	S238043	Automated Plan Optimization Device

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238044	Automated Dose Calculation Device

CID NNN10 TREATMENT SESSION CHECKS

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
Keyword: TreatmentSessionChecks
FHIR Keyword: dicom-cid-NNN10-TreatmentSessionChecks
Type: Extensible
Version: YYYYMMDD
UID: 1.2.840.10008.6.1.NNN.10

Table CID NNN10 Treatment Session Checks

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
99SUP238	S238020	Vacuum Cushion Position Verified
99SUP238	S238021	Headrest Position Verified

Add to Part 16, Annex C

Annex C Acquisition Context Module, Protocol and Workflow Context Templates (Normative)

TID TNNN1 RT TREATMENT PLANNING ASSERTION COLLECTION IDENTIFICATION

TID TNNN1

RT Treatment Planning Assertion Collection Identification

Type: Extensible Order: Non-Significant

	NL	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint	Notes
1		NUMERIC	EV (S238500, 99SUP238, "Nominal Prescription Radiation Dose")	1	U		Units = EV (Gy,UCUM,"Gray")	
2		CODE	EV (123014 , DCM, "Target Region")	1	U		BCID CID 4030 "CT, MR and PET Anatomy Imaged"	
3		NUMERIC	EV (121386, DCM, "Number of Fractions Planned")	1	U		Units= EV (1, UCUM, "no units")	

TID TNNN11 RT TREATMENT POSITIONING ASSERTION COLLECTION IDENTIFICATION

TID TNNN1

RT Treatment Positioning Assertion Collection Identification

Type: Extensible Order: Non-Significant

	NL	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint	Notes
1		NUMERIC	EV (S238519, 99SUP238, “Delivered Fraction”)	1	U		Units= EV (1, UCUM, “no units”)	
2		NUMERIC	EV (121386, DCM, “Number of Fractions Planned”)	1	U		Units= EV (1, UCUM, “no units”)	

TID TNNN2 RT TREATMENT PLANNING ANNOTATION

TID TNNN2

RT Treatment Planning Annotation

Type: Extensible Order: Non-Significant

	NL	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint	Notes
1		TEXT	EV (130025, DCM, “Special Procedure Note”)	1	U			
2		TEXT	EV (130026, DCM, “Patient Positioning Note”)	1	U			
3		TEXT	EV (130028, DCM, “Patient Setup Note”)	1	U			
4		TEXT	EV (130031, DCM, “Delivery Verification Note”)	1	U			
5		CODE	DT (130035, DCM, “Patient Positioning Procedure Note”)	1	U			
6		TEXT	EV (130027, DCM, “4D Radiation Treatment Note”)	1	U			
7		TEXT	EV (130039, DCM, “Adaptive Radiation Therapy Note”)	1	U			

TID TNNN3 TREATMENT SESSION ANNOTATION

TID TNNN3

Treatment Session Annotation

Type: Extensible Order: Non-Significant

	NL	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint	Notes
1		UID	EV (S238510, 99SUP238, “Treatment Session UID”)	1	U			
2		DATETIME	EV (S238511, 99SUP238, “Treatment Session Start DateTime”)	1	U			

3		**DATETIME**	EV (S238512, 99SUP238, "Treatment Session End DateTime")	**1**	**U**			
4		**INCLUDE**	DTID 1002 "Observer Context"	**1-n**	**U**			
5		**TEXT**	EV(S238513, 99SUP238, "Treatment Device Name")	**1**	**U**			
6		**TEXT**	EV (S238514, 99SUP238, "Treatment Session Notes")	**1**	**U**			
7		**CODE**	EV(S238515, 99SUP238, "Performed Check")	**1-n**	**U**		DCID NNN10 "Treatment Session Checks"	
8	**>**	**DATETIME**	EV(S238516, 99SUP238, "Performed Check DateTime")	**1**	**M**			
9	**>**	**CODE**	EV(S238517, 99SUP238, "Performed Check Outcome")	**1**	**M**		DCID 6042 "Status of Results"	
10	**>**	**INCLUDE**	DTID 1002 "Observer Context"	**1-n**	**U**			
11	**>**	**TEXT**	EV (S238518, 99SUP238, "Performed Check Note")	**1**	**U**			

TID TNNN4 PRE-TREATMENT QUALITY EVALUATION ANNOTATION

TID NNN3

Treatment Session Annotation

Type: Extensible Order: Non-Significant

	NL	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint	Notes
1		**COMPOSITE**	EV (S238530, 99SUP238, "Content Assessment Result Instance")	**1**	**U**			
2		**DATETIME**	EV (S238531, 99SUP238, "Pre-Treatment Quality Evaluation Session Start DateTime")	**1**	**U**			
3		**DATETIME**	EV (S238532, 99SUP238, "Pre-Treatment Quality Evaluation Session End DateTime")	**1**	**U**			

TID TNNN5 POST-TREATMENT QUALITY EVALUATION ANNOTATION

TID NNN3

Treatment Session Annotation

Type: Extensible Order: Non-Significant

	NL	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint	Notes
1		COMPOSITE	EV (S238530, DCM, "Content Assessment Result Instance")	1	U			

2		TEXT	EV (S238400, DCM, “Treatment Delivery Note”)	1	U			
3		TEXT	EV (130026, DCM, “Patient Positioning Note”)	1	U			
4		NUMERIC	EV (S238401, DCM, “Treatment Position Shift”)	1-n	U			
5	>	INCLUDE	TID 15302. “Patient Support Position Parameters”	1	M			

Row 5	The parameters of Row 4 are to be applied as delta values to the Treatment Position specified for the future Fractions to be treated. The Treatment Position specified are contained in the RT Radiation SOP Instances or, if present, in the RT Radiation Set Delivery Instruction SOP Instance as provided for the Treatment Fraction.

sup238_pc_AssertionCollection.docx

Add the following to the table in PS3.16, Annex D:

Annex D Dicom controlled terminology definitions (normative)

Code Value	Code Meaning	Definition	Notes
AC	Assertion Collection	A device, process or method that creates Assertion Collection objects.	
S238001	Reference Added to Collection	A DICOM SOP Instance or another pertinent resource was added to the list of entities that constitute a Reference Collection.	
S238002	Reference Removed from Collection	A DICOM SOP Instance or another pertinent resource was removed from the list of entities that constitute a Reference Collection.	
S238003	Reference Not Added to Collection	A DICOM SOP Instance or another pertinent resource was available but deliberately not added to the list of entities that constitute a Reference Collection.	
S238010	Unreviewed	The subject matter has not been reviewed.	
S238011	Reviewed	The subject matter has been reviewed.	
S238023	Unapproved	The subject matter is not approved.	
S238020	Approved	The subject matter has been approved.	
S238021	Rejected	The subject matter has been rejected.	
S238022	Demoted	The subject matter has been demoted from an approved state.	
S238030	For Contouring	Instances available for creating contours such as the patient anatomy based on information acquired from e.g. imaging modalities.	
S238031	For Registration	Instances available for performing spatial registration.	
S238032	For Positioning	Instances available for positioning the patient for treatment.	
S238033	For Planning	Instances available for creating a plan for a treatment of a patient.	
S238034	For Treatment	Instances available for patient treatment.	
S238035	For Treatment Continuation	Instances available for continuation of a patient treatment.	
S238040	Automated Segmentation Device	A device that creates segmentations without user interaction.	

Code Value	Code Meaning	Definition	Notes
S238041	Automated Registration Device	A device that creates registrations between Frame of References without user interaction.	
S238042	Automated Image Collection Device	A device that collects image data without user interaction.	
S238043	Automated Plan Optimization Device	A device that optimizes a treatment plan without user interaction.	
S238044	Automated Radiation Dose Calculation Device	A device that calculates treatment dose for a radiotherapeutic treatment plan without user interaction.	
S238400	Treatment Delivery Note	Free text note describing the treatment session.	
S238401	Treatment Position Shift	Shift to the treatment position as a result of a patient position verification procedure.	
S238500	Nominal Prescription Radiation Dose	The prescribed radiation dose. The value is only nominal.	
S238510	Treatment Session UID	UID uniquely identifying a treatment session.	
S238511	Treatment Session Start DateTime	Start DateTime of a treatment session.	
S238512	Treatment Session End DateTime	End DateTime of a treatment session.	
S238513	Treatment Device Name	User-defined name identifying the device used for treatment of a patient.	
S238514	Treatment Session Notes	Notes taken during a treatment session.	
S238515	Performed Check	Check that was performed before, during or after a treatment session.	
S238516	Performed Check DateTime	DateTime a check was performed.	
S238517	Performed Check Outcome	Result of a check that was performed.	
S238518	Performed Check Note	Note taken during performance of a check.	
S238519	Clinical Fraction Number	Count of the RT Treatment Fractions that have been delivered.	
S238520	Vacuum Cushion Position Verified	The position of the vacuum cushion on which the patient is placed during treatment has been verified, either manually or automatically.	
S238521	Headrest Position Verified	The position of the headrest on which the patient is placed during treatment has been verified, either manually or automatically.	
S238530	Content Assessment Result Instance	Reference to a Content Assessment Result Instance.	
S238531	Pre-Treatment Quality Evaluation Session Start DateTime	DateTime of the start of evaluation prior to treatment of the plan quality.	

Code Value	Code Meaning	Definition	Notes
S238532	Pre-Treatment Quality Evaluation Session End DateTime	DateTime of the end of evaluation prior to treatment of the plan quality.	

Add to Part 17 as an Annex

Part 17 Addendum

§§§§ ASSERTION COLLECTION EXAMPLES

§§§§.1 CLINICAL WORKFLOWS

§§§§.1.1 Post-Acquisition Workflow

<No text yet. Any input from Public Comment? See Open Issue #10.>

§§§§.1.2 Radiotherapy Treatment Planning

A radiotherapeutic treatment planning process is typically performed in multiple steps, depending on the clinical process and the used applications. The following steps are considered in this example:

- Prescription
- Pre-Planning (image collection, image registration, segmentation)
- Plan creation/optimization

§§§§.1.2.1 Prescription

Based on a performed diagnosis, an oncologist reviews the diagnostic image data set and creates a prescription. The prescription along with the image data is approved for the treatment planning process.

§§§§.1.2.2 Pre-Planning

A physician (resident) collects available and suited image data for the creation of a draft patient model that may be used in an RT treatment planning procedure. Along with this, image registrations and segmentations of the patient's anatomy and lesion regions are created.

An attending physician reviews the draft patient model approves it as the basis for planning.

In a different hospital, this step could also be performed entirely by an automated software.

§§§§.1.2.3 Plan Creation/Optimization

A dosimetrist or physicist takes the approved prescription and the approved patient model and starts the treatment planning process. The outcome may be one or more potential treatment plans that will be reviewed by the physician. Once, either the physician or both, the physician and the medical physicist, have reviewed and approved one treatment plan, this plan is then ready for patient treatment.

§§§§.1.3 Radiotherapy Treatment

Before a radiotherapeutic treatment session is started, typically the position of the patient with respect to the treatment machine isocenter is checked and corrected. This can be done by either acquisition of surface scan, of fiducial positions, of stereoscopic X-ray images or the of a cone-beam CT, which are then compared against the reference image data set from treatment planning and the planned patient treatment position. Also during the treatment the position may be continuously checked to verify correct treatment.

Therapists perform the actual check based on the acquired artifacts and decide whether the treatment can start/continue or whether a re-positioning procedure is required. The acquired artifacts along the decisions are documented and may later be reviewed and approved by a physician.

§§§§.1.4 Approving the Assertion Collection

In cases the Assertion Collection requires to have an assertion on its own Instance, a Reference Collection in the Instance may reference the own SOP Instance UID. An Assertion for the Instance is to be interpreted independently from the States defined in other Reference Collection States and does not override them. No further business logic is implied and shall not be derived.

Examples

During a post-acquisition/pre-planning step, references to different Instances are added to an Assertion Collection Instance along with States defined by multiple individuals participating in this clinical workflow step. Once the Assertion Collection Instance is finalized an Attending Physician will review the collection and approve it for subsequent use in treatment. This may or may not include detailed review of specific Instances.

In a radiotherapeutic workflow it may be the case that Physician A approved the contouring of the anatomy, Radiologist B approved the registration of the image data sets, Medical Physicist C approved the RT Plan and the RT Dose. The responsible Physician D may then review the DVH information which is derived from the RT Dose and the contours, as well as the contours overlayed on different image data sets, thus relying on former approvals. Once the review is done and successful, the responsible Physician D will the approve the entire Instance for radiotherapeutic treatment.

§§§§.2 ACCESSING ASSERTION COLLECTIONS

Based on the example in §§§§.1.2 Radiotherapy Treatment Planning, a set of Assertion Collection Instances is created, e.g.

- One Instance during the Prescription process:
  Based on the indication it is clear which clinical protocol to follow and therefore, an image data set and a corresponding RT Physician Intent Instance are included in a Reference Collection and approved by an assertion of the physician (Assertion Collection Instance 1 – AC Instance 1).
- Three Instances during the Pre-Planning process:
  Image Data sets are collected (AC Instance 2), Registration and Segmentation Instances are created (AC Instance 2') and approved for treatment planning (AC Instance 2").
- Four Instances during the Plan Creation/Optimization process:
  An initial treatment plan is created (AC Instance 3), but due to potential treatment options, plan alternatives (AC3 Instance a and AC3 Instance b) are created and reviewed and one plan is eventually approved for treatment (AC3 Instance a').

See Figure §§§§.2-n.

See the "supporting" folder for the file "Figure_§§§§.2-n.drawio.svg ".

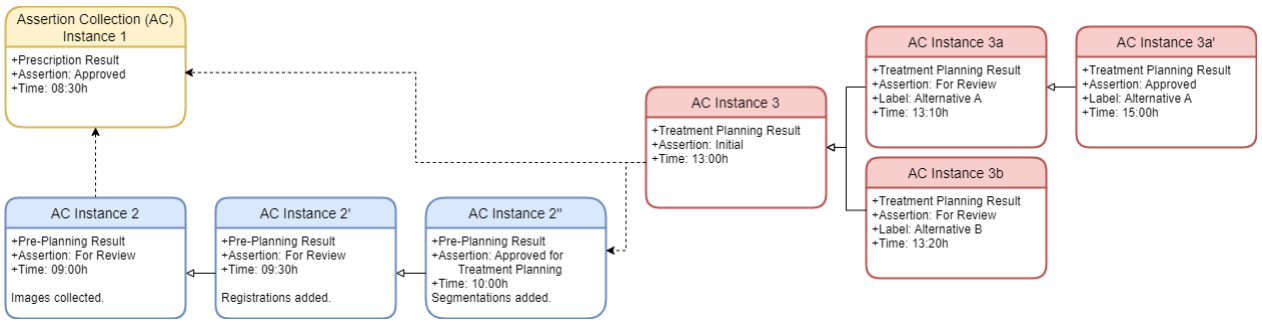

Figure §§§§.2-n Example of Assertion Collection Instances during a Radiotherapy Treatment Planning Process

The eight Assertion Collection Instances in the example in Figure §§§§.2-n all share the same Assertion Context UID (gggg,0015) as they represent a single treatment planning course.

In order to retrieve the Assertion Collection Instance of which the content is approved and intended for a treatment session of a given patient, the following options are possible:

- Query based on Assertion Context UID
  In order to retrieve all Instances defined in a specific context, e.g. a treatment planning session, the Assertion Context UID (gggg,0015) can be queried.
- Query based on time-stamps:
  As typically the time range when the treatment planning process was performed can be limited, it is possible to query for all Assertion Collection Instances of a given range, and then pick the Instance with the latest time stamp to retrieve it and evaluate the content.
- Query for all Instances and retrieve them:
  Retrieve all Assertion Collection Instances of a patient and evaluate the contents in order to determine which Instance is the one intended for treatment.

§§§§.3 REFERENCE COLLECTION AND REFERENCE STATE COLLECTION MULTIPLICITIES

The entity relationship of the Reference Collection and the Reference State Collection is n-m, see Figure §§§§.3-n.

See the "supporting" folder for the file "Figure_§§§§.3-n.drawio.svg ".

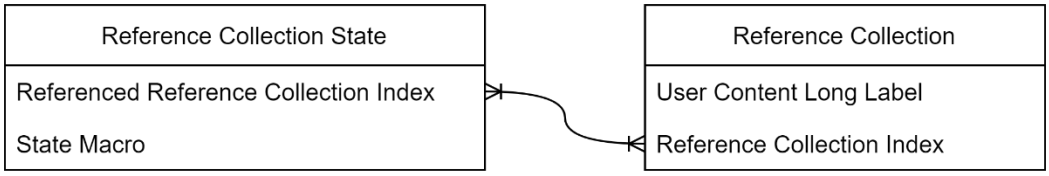

Figure §§§§.3-n n-m Relationship

§§§§.3.1 Multiple Assertions on a single Reference Collection

For a Segmentation Instance, first a resident physician creates an Assertion, e.g. that the Segmentation Instance was added to the Assertion Collection for further evaluation. In a next step the attending makes another Assertion where the Segmentation Instance is approved. Both Assertions defined in the Reference Collection State refer to the same Reference Collection indicated by the same Referenced Reference Collection Index (gggg,0009).

§§§§.3.2 A Single Assertion on multiple Reference Collections

During a treatment planning process multiple individuals participated in creating, reviewing and approving, see §§§§.1.2, resulting in several Reference Collection Sequence (gggg,0001) Items. A final approval by the attending physician may then reference all Reference Collections at once, e.g with a purpose that this set of Reference Collections is now valid for treatment.