Status	Letter Ballot
Date of Last Update	2018/11/11
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Submission Date	2018/05/20

Correction Number CP-1826
Log Summary: Specimen De-identification
Name of Standard PS3.15
Rationale for Correction: The PS3.15 Annex E Basic Confidentiality Profile does not include specimen identifiers, i.e., from the Specimen Macro, such as Container Identifier, Specimen Identifier, Specimen UID and related Issuer Attributes. Nor does it include Barcode Value or Label Text (the latter might be cleaned, e.g., to retain the stain type without the identifiers). Also, the retired Attributes from the retired Specimen Identification Module, Specimen Accession Number and Slide Identifier need to be included (and being retired are flagged for removal, rather than replacement with dummy or empty values).
Correction Wording:

*Amend DICOM PS3.15 as follows (changes to existing text are bold and **underlined** for additions and ~~**struckthrough**~~ for removals):*

E.1.1 De-identifier

...

The Attributes listed in Table E.1-1 for each profile are contained in Standard IODs, or may be contained in Standard Extended IODs. An implementation claiming conformance to an Application Level Confidentiality Profile as a de-identifier shall protect or retain all instances of the Attributes listed in Table E.1-1, whether contained in the main dataset or embedded in an Item of a Sequence of Items. The following action codes are used in the table:

- D - replace with a non-zero length value that may be a dummy value and consistent with the VR
- Z - replace with a zero length value, or a non-zero length value that may be a dummy value and consistent with the VR
- X - remove
- K - keep (unchanged for non-sequence attributes, cleaned for sequences)
- C - clean, that is replace with values of similar meaning known not to contain identifying information and consistent with the VR
- U - replace with a non-zero length UID that is internally consistent within a set of Instances
- Z/D - Z unless D is required to maintain IOD conformance (Type 2 versus Type 1)
- X/Z - X unless Z is required to maintain IOD conformance (Type 3 versus Type 2)
- X/D - X unless D is required to maintain IOD conformance (Type 3 versus Type 1)
- X/Z/D - X unless Z or D is required to maintain IOD conformance (Type 3 versus Type 2 versus Type 1)
- X/Z/U* - X unless Z or replacement of contained instance UIDs (U) is required to maintain IOD conformance (Type 3 versus Type 2 versus Type 1 sequences containing UID references)

These action codes are applicable to both Sequence and non-Sequence attributes; in the case of Sequences, the action is applicable to the Sequence and all of its contents. Cleaning a sequence ("C" action) may entail either changing values of attributes within that Sequence when the meaning of the Sequence within the context of its use in the IOD is understood, or recursively applying the profile rules to each Dataset in each Item of the Sequence. Keeping a Sequence ("K" action) requires recursively applying the profile rules to each Dataset in each Item of the Sequence (for example, in order to remap any UIDs contained within that sequence).

...

Table E.1-1. Application Level Confidentiality Profile Attributes

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.
...	...	...	...	...										
Barcode Value	**(2200,0005)**	**N**	**Y**	**X/Z**										
...	...	...	...	...										
Consulting Physician Identification Sequence	(0008,009D)	N	Y	X										
Container Component ID	**(0050,001B)**	**N**	**Y**	**X**										
Container Description	**(0040,051A)**	**N**	**Y**	**X**								**C**		

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.
Container Identifier	**(0040,0512)**	**N**	**Y**	**D**										
Content Creator's Identification Code Sequence	(0070,0086)	N	Y	X										
...	...	...	...	...										
Issuer of Service Episode ID	(0038,0061)	N	Y	X										
Issuer of the Container Identifier Sequence	**(0040,0513)**	**N**	**Y**	**Z**										
Issuer of the Specimen Identifier Sequence	**(0040,0562)**	**N**	**Y**	**Z**										
Large Palette Color Lookup Table UID	(0028,1214)	Y	N	U		K								
Label Text	**(2200,0002)**	**N**	**Y**	**X/Z**								**C**		
...	...	...	...	...										
Slide Identifier	**(0040,06FA)**	**Y**	**N**	**X**										
...	...	...	...	...										
Special Needs	(0038,0050)	N	N	X					C					
Specimen Accession Number	**(0040,0551)**	**Y**	**N**	**X**										
Specimen Detailed Description	**(0040,0602)**	**N**	**Y**	**X**								**C**		
Specimen Identifier	**(0040,0551)**	**N**	**Y**	**D**										
Specimen Preparation Sequence	**(0040,0610)**	**N**	**Y**	**Z**									**C**	
Specimen Short Description	**(0040,0600)**	**N**	**Y**	**X**								**C**		
Specimen UID	**(0040,0554)**	**N**	**Y**	**U**		**K**								
Start Acquisition DateTime	(0018,9516)	N	Y	X/D						K	C			
...	...	...	...											

For reference DICOM PS3.3 :

C.7.6.22 Specimen Module

Table C.7.6.22-1 specifies the Attributes that identify one or more Specimens being imaged.

Table C.7.6.22-1. Specimen Module Attributes

Attribute Name	Tag	Type	Attribute Description
Include Table C.7.6.22-2 "Specimen Macro Attributes"			

Table C.7.6.22-2. Specimen Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Container Identifier	(0040,0512)	1	The identifier for the container that contains the specimen(s) being imaged. See Section C.7.6.22.1.1.
Issuer of the Container Identifier Sequence	(0040,0513)	2	Organization that assigned the Container Identifier. Zero or one Item shall be included in this Sequence.
>*Include ???*			
Alternate Container Identifier Sequence	(0040,0515)	3	Sequence of alternate identifiers for the container that contains the specimen(s) being imaged. These may have been assigned, e.g., by the manufacturer, or by another institution that collected the specimen. One or more Items are permitted in this Sequence.
>Container Identifier	(0040,0512)	1	The identifier for the container that contains the specimen(s) being imaged.
>Issuer of the Container Identifier Sequence	(0040,0513)	2	Organization that assigned the Container Identifier. Zero or one Item shall be included in this Sequence.
>>*Include ???*			
Container Type Code Sequence	(0040,0518)	2	Type of container that contains the specimen(s) being imaged. Zero or one Item shall be included in this Sequence.
>*Include ???*			*Baseline ????.*
Container Description	(0040,051A)	3	Description of the container.
Container Component Sequence	(0040,0520)	3	Description of one or more components of the container (e.g., description of the slide and of the coverslip). One or more Items are permitted in this Sequence.
>Container Component Type Code Sequence	(0050,0012)	1	Type of container component. Only a single Item shall be included in this Sequence.
>>*Include ???*			*Baseline ????.*
>Manufacturer	(0008,0070)	3	Manufacturer of the container component.
>Manufacturer's Model Name	(0008,1090)	3	Manufacturer's model name of the container component.
>Container Component ID	(0050,001B)	3	Manufacturer's identifier of the container component, e.g., Lot Number and/or Version.
>Container Component Length	(0050,001C)	3	Length in mm of container component.
>Container Component Width	(0050,0015)	3	Width in mm of container component.
>Container Component Diameter	(0050,001D)	3	Diameter in mm of container component for cylindrical or circular components.
>Container Component Thickness	(0050,0013)	3	Thickness in mm of container component
>Container Component Material	(0050,001A)	3	Material of container component. **Defined Terms:** **GLASS** **PLASTIC** **METAL**
>Container Component Description	(0050,001E)	3	Container component text description.

Attribute Name	Tag	Type	Attribute Description
Specimen Description Sequence	(0040,0560)	1	Sequence of identifiers and detailed description of the specimen(s) being imaged. One or more Items shall be included in this Sequence. Each specimen imaged in the Pixel Data shall be identified by an Item in this Sequence. Other specimens in/on the container, but not imaged in the Pixel Data, may also be identified by Items in this Sequence.
>Specimen Identifier	(0040,0551)	1	A departmental information system identifier for the Specimen. See Section C.7.6.22.1.1 and Section C.7.6.22.1.2. If a single specimen is present in a container, the value of the Specimen Identifier and the value of the Container Identifier are typically the same.
>Issuer of the Specimen Identifier Sequence	(0040,0562)	2	The name or code for the institution that has assigned the Specimen Identifier. Zero or one Item shall be included in this Sequence.
>>Include ???			
>Specimen UID	(0040,0554)	1	Unique Identifier for Specimen. See Section C.7.6.22.1.2.
>Specimen Type Code Sequence	(0040,059A)	3	Specimen Type. Only a single Item is permitted in this Sequence.
>>Include ???			*Baseline ????.*
>Specimen Short Description	(0040,0600)	3	Short textual specimen description (may include ancestor specimen descriptions).
>Specimen Detailed Description	(0040,0602)	3	Detailed textual specimen description (may include ancestor specimen descriptions).
>Specimen Preparation Sequence	(0040,0610)	2	Sequence of Items identifying the process steps used to prepare the specimen for image acquisition. This includes description of all processing necessary to interpret the image. Zero or more Items shall be included in this Sequence. This Sequence includes description of the specimen sampling step from an ancestor specimen, potentially back to the original part collection. See Section C.7.6.22.1.3.
>>Specimen Preparation Step Content Item Sequence	(0040,0612)	1	Sequence of Content Items identifying the processes used in one preparation step to prepare the specimen for image acquisition. One or more Items shall be included in this Sequence.
>>>Include ???			*Baseline ????*
>Include ???			Original anatomic location in patient of specimen. This location may be identical to that of the parent specimen, may be further refined by modifiers depending on the sampling procedure for this specimen, or may be a distinct concept.

Attribute Name	Tag	Type	Attribute Description
>Specimen Localization Content Item Sequence	(0040,0620)	1C	Sequence of Content Items identifying the location of the specimen in the container and/or in the image. See Section C.7.6.22.1.4. One or more Items shall be included in this Sequence. Required if multiple specimens present in the image. May be present otherwise.
>>Include ???			Defined TID is ????.

C.7.6.22.1 Specimen Module Attributes

C.7.6.22.1.1 Container Identifier and Specimen Identifier

"Specimen" is the role played by a discrete physical object (or a collection of objects that are considered as a unit) that is the subject of pathology examination.

A specimen is a physical object (or a collection of objects) when the laboratory considers it a single discrete, uniquely identified unit that is the subject of one or more steps in the laboratory (diagnostic) workflow. This includes objects at all levels of processing, including fresh tissue, dissected organs, tissue embedded in paraffin, sections made from embedded tissue, and liquid preparations.

Specimens are physically managed by being placed in or on a container. The concept of container includes buckets, cassettes, vials, and slides. While there is usually one specimen per container, it is possible, in some laboratory workflows, for multiple specimens to be in/on a container.

Both specimens and specimen containers have logical identifiers for workflow management. The logical identifier of a container is usually conveyed on a label on the container. The specimen itself will typically not be physically labeled with its identifier. For the usual case of a single specimen in/on a container, the logical identifiers may be identical. However, when there are multiple specimens in/on a container, each specimen receives a distinct logical identifier. These identifiers are encoded in the SOP Instance using Attributes Container Identifier (0040,0512) and Specimen Identifier (0040,0551).

Note

1. This definition of "specimen" extends the common definition beyond the part or parts that were submitted for examination (e.g., from surgery) to include any derivative piece that may be separately analyzed or examined, such as a block or slide preparation.

2. Although many Pathology Information Systems use a hierarchical system for identifying parts, blocks and slides, there should be no assumption made that this will be the case and in particular, there should be no attempt to parse a given Specimen Identifier to retrieve an accession number or other higher level identifier.

C.7.6.22.1.2 Specimen Identifier and Specimen UID

Specimen Identifier (0040,0551) must be unique at least within the Study; the actual scope of uniqueness is determined by the departmental information system that assigns the IDs. Each specimen shall also be assigned a globally unique Specimen UID (0040,0554) that allows referencing beyond the scope of a Study. This UID may be used, for instance, if a specimen is delivered to another institution for further analysis.

C.7.6.22.1.3 Specimen Preparation Sequence and Specimen Preparation Step Content Item Sequence

Interpretation of specimen images requires information about the source of the specimen and its preparation (e.g., sampling, fixation, staining). The processing steps used to prepare a specimen are recorded in the Specimen Preparation Sequence (0040,0610). This Sequence may include one Item for each processing step (as defined in the laboratory workflow) in the history of the specimen, and those Items are composed of a set of Content Items in the Specimen Preparation Step Content Item Sequence (0040,0612).

The Specimen Preparation Sequence may include description of the original part collected from the patient, the processing of that part, the sampling of tissue from the part and the preparation of that sample, and the further sub-sampling and processing of the tissue. In other words, the description of a specific specimen may include descriptions of the specimen's ancestors.

The Specimen Preparation Sequence Items shall be in ascending chronological order.

C.7.6.22.1.4 Specimen Localization Content Item Sequence

When there are multiple specimens in/on a container, the Specimen Localization Content Item Sequence (0040,0620) is used to identify the location of the specimen in the container, as there is no physical label with the Specimen Identifier. This Content Item Sequence, in accordance with ????, allows the specimen to be localized by a distance in one to three dimensions from a reference point on the container, by an identified physical description such as a colored ink, or by its location as shown in a referenced image of the container. The referenced image may use an overlay, burned-in annotation, or an associated Presentation State SOP Instance to specify the location of the specimen.

C.8.12.8 Slide Label Module

Table C.8.12.8-1 specifies the Attributes that describe the interpretation of a scanned Slide Label.

Table C.8.12.8-1. Slide Label Module Attributes

Attribute Name	Tag	Type	Attribute Description
Barcode Value	(2200,0005)	2	Barcode interpreted from the scanned slide label. **Note** This may be the same as Container Identifier (0040,0512).
Label Text	(2200,0002)	2	Label text interpreted from the scanned slide label, e.g., by optical character recognition.