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6	Digital Imaging and Communications in Medicine (DICOM)
8	Supplement 222: Whole Slide Microscopy Bulk Annotations Storage SOP Class
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Document History

2020/07/03	01	DAC	Initial version derived from Tractography Results.	
2020/07/07	02	DAC	Working draft at t/con discussion.	
2020/07/17	03	DAC	Factor out Z when possible; add simple geometric shapes; add algorithm identification, open issue about OF/FL precision.	
2020/09/01	04	DAC	Add optical path identifier and applies to all optical paths, add applies to all Z depths, include Leica, Sectra comments,	
2020/09/15	05	DAC	Change Set to Group, don't re-use Segmentation Property data elements but define new similar ones.	
2020/11/09	06	DAC	Prep for WG 6 first read	
2020/11/25	07	DAC	Incorporate WG 6 feedback and assigned number.	
2021/01/04	08	DAC	Clean up measurements text, add annotation group UID, add example with measurements, clean up open issues for public comment	
2021/01/05	09	DAC	Prepare for release by WG 6 for public comment	
2021/01/12	10	DAC	Public comment draft	

TODO

1	Need to flesh out context group listing property types (beyond nucleus, cell, etc.). Add to DICOM SNOMED subset 84640000, 362837007,	
2	Need to test against various bulk annotation use cases (e.g., from the scientific literature).	
3	Need to add log information (provenance, audit trail) prn. or discuss reference from SR containing it.	

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Open Issues

1	Is it sufficient to limit the scope to whole slide imaging (WSI)? What use cases beyond WSI might require such a mechanism? The scope of the work item and the SOP Class is constrained to WSI, but the underlying mechanisms could theoretically be reused for other types of imaging if there were use cases that required large numbers of annotations that could not be readily satisfied by SR. Note that there is a strong desire to avoid proliferation of competing annotation mechanisms that undermine interoperability; specifically, the intent is not to compete with SR for small numbers of annotations.
2	Do we need an explicit definition of "annotation", and if so, what should it be? The supplement (and the existing standard), do not explicitly define what an "annotation" is (as opposed to defining various encoding mechanism that may be used for various purposes). Is there a need for an explicit definition? What should it be? In what ways should it be distinct from an "ROI" or a segment(ation)?
3	Are OF/FL (32-bit IEEE float, i.e., 23-bit mantissa + sign bit) 3D coordinates and parameters sufficiently precise? Or do we need OD/FD (64-bit IEEE float)?
4	Is a 2D coordinate mechanism needed? Currently, only 3D coordinates are specified. It is understood that there are many 2D sources and applications. Should 2D total matrix relative coordinates, +/- 2D frame relative + frame number using the same approach (still floating point to allow sub-pixel resolution)? One reason to do this is to allow lossless transformation from a source of 2D coordinates (such as might be needed for regulatory purposes that cannot tolerate loss during format conversion from 2D to 3D, which might be affected by the 32-bit IEEE float precision). Also, encoding 3D coordinates means that if the annotations are being converted from a 2D image relative source, then the pixel spacing (mm per pixel) needs to be made known to the converter (and needs to be reliable).
5	Should there be a restriction that the planar objects be in the same plane as the acquired images? I.e., in the current draft, they could lie between actual image slices, or be in a different orientation, even perpendicular to the image plane (edge on).
6	Do we want to allow for (possibly optional) tiled frame indices, forward or backward (e.g., which image frames an annotation touches +/- which image tiles contain which numbered annotations)? This would be non-trivial to encode, given that a polyline or polygon may span more than one frame, and if large enough, include an entire frame without actually having any boundary coordinate points that touch the frame. These could be in the same IOD, or a separate IOD that references this one (esp. if produced by a separate indexing system, or created and saved by the recipient, rather than the AI algorithm creating the annotation object). Arguably, this would really only make sense if it were mandatory.

7	Are the measurement capabilities sufficient? Excessive? Compact enough?
	E.g., what about counts of things, or counts per high power field, or overall scores, or is that better left to a separate SR?
	Should measurements all be in the same object or a separate object, and not present in this object at all?
	Does a separate SR have sufficient reference mechanisms? Do we need to add a mechanism to identify an individual annotation (e.g., by a UID)? Currently only the Annotation Group has a UID for this purpose. We presume that the most compact representation is SOP Instance UID or Annotation Group UID + (implicit) numerical offset of the annotation, and this needs to be added to SR templates.
8	Do we need anatomical information in addition to the property category and type? Do we need more than one property at the same time? How descriptive should they be (e.g., pleomorphic nuclei vs. any nuclei, mitotic figures, cell vs. particular type of cell e.g., lymphocyte, very specific, e.g., TILs, cell positive for XYZ antigen)? Look at transitive closure of children of 4421005 Cell Structure in SNOMED for examples (<u>http://snomed.info/id/4421005</u>).
10	Do we need any baseline algorithm identification (or family CIDs) to be defined, and if so, what should they be?
11	Do we need rendering related attributes included other than color? E.g., we did not include the Recommended Line Thickness (0066,0038) from Tractography Results, since it would not seem likely to be useful for WSI. The intent is to communicate the semantics not the appearance in a particular application. A preference has been expressed by some for keeping styling out of this IOD, even color. Others suggest that there are examples where rendering related attributes would be helpful, for example an order of precedence for rendering of annotation groups and annotations within a group (e.g., groups/annotations with lower index are rendered before groups/annotations with higher index). It has been suggested that we add an element for Display Hint. Is there a use case for a display hint for something other than linear interpolation between points? I.e., if needing an outline around a smooth object like a cell, specifying something like a polynomial or spline interpolation might allow a polygon to be defined using fewer points at the cost of increased complexity in the renderer. This approach might handle some of the use cases that would call for smooth shapes like a circle or oval. For polygon annotations, a display hint differentiating an outline from a fill, to allow heatmaps to be explicitly defined. In theory this could be done by convention, where a connected polyline is always an outline and a polygon is always a fill; but it might be better (and less "abusing" to the standard) to be explicit. Must descend en the definition of whet en "more the interpolation"
12	May depend on the definition of what an "annotation" is anyway (as opposed to "markup").
	polygons, e.g., to achieve a consistent derived measurement? In SR, a content item could be added to define this, but no such extensible mechanism is included in this IOD. If, so what would those values be?
13	Do we need an API for DICOMweb to retrieve a subset of annotations on a subset of frames? Also retrieve bulk data coordinate data as raw file. Need examples to show how this can be done. Not within the scope of the work item but could be added as a separate supplement.

14	Do we need a compact JSON representation of the entire object +/- subsets for a DICOMweb API? This would entail float to decimal string conversions, which might raise round trip full fidelity (and overall size) issues. Currently it is thought not, and there has been little interest in the JSON representation of SR in Supplement 219. The data volume also mitigates against this.
15	Do we need an image and frame reference mechanism? Annotations typically apply to an entire set of image instances constituting a pyramid representing a single scan of a slide. A polygon enclosing a tissue section is just as interesting when rendering a subsampled pyramid level as when rendering the base level. Using the slide coordinate system in mm relative defined by a Frame of Reference UID instead of pixel offsets solves this.
	There is still a question of whether references to individual instances or series by their UID are necessary, since theoretically multiple scans of a slide, or processed images, may be transformed into the same frame of reference, and the annotations might or might not apply to all images in the same frame of reference, or some defined subset of those images. There is probably a need for a Segmentation IOD like method of specifying the "Source"
	Image/Series to which the annotation applies, if not to all images in the same frame of reference. Note that one should not assume that there is a 1:1 scan:series relationship. Scans can span a series, and a series may contain more than 1 scan. The appropriate "entity" for a "scan" of a slide (and hence all its pyramidal levels) is the "Acquisition", but that doesn't (currently) have a UID (only a number, and a date/time). Is there a need to more formally define an Acquisition entity (for the WSM Image IOD) and a means to reference it? We need to keep any mechanism consistent with existing or new SR approaches.
16	Do we need to add constraints to the WSM Image IOD to assure that all images in the same frame of reference (UID) identify the optical paths with the same identifiers, since that is assumed by the construction of the annotations? Probably need a CP to WSM Image IOD.
17	Is the definition of a RECTANGLE sufficient or correct (e.g., in the edge case of a coronal or sagittal plane relative to the slide orientation) or over-specified (i.e., would a clockwise winding rule with an arbitrary start point be sufficient)?

Closed Issues

1	We need a mechanism for specifying geometric shapes. These only need to be 2D rather than 3D (rectangle, not cuboid).
2	For the very common no Z-stack single "slice" WSI, every coordinate tuple will be 33% larger than necessary, since the Z value is always the same. Factor it out of the Point Coordinates Data (0066,0016) and send only X,Y pairs, and the constant Z in a separate attribute.
3	Z coordinates Assume most annotations are relevant for all focal planes; the need to specify focal plane
	probably is an exception to use only when the scanned volume is really thick with overlapping cells. The draft does not allow for the common case of specifying that an annotation applies to all focal planes, unless one duplicates the data in one annotation group for each plane. If Z coordinate is really required (omitting it would be simplifying things), maybe it should be possible to omit it somehow to indicate that it is not relevant. Resolution: Need a means for indicating that an annotation applies to all Z planes.
4	Coplanar annotations
	Points for polylines are not required to be coplanar according to the draft. How would one render such a polyline when rendering a specific focal plane? If a two-point line has one point in focal plane 1 and the other in plane 2, is it rendered for both or for none or would some interpolation be required?
	SR SCOORD3D requires POLYGON points be coplanar (wrt., the slide coordinate system, regardless of reality); true, but not POLYLINE points; resolve all to be coplanar, but do not require plane be same as Z plane.
5	Z coordinates related to the Z offset of frames Z Offset in Slide Coordinate System (0040,074A). The Z offset is only nominal and only has local meaning, according to Supplement 145. They can only be used as identifiers for focal planes to know which tiles belong to the same focal plane. If Z coordinates of annotations are actual Z positions in the slide coordinate system, I think we have a problem since the pixel data's Z offset value "should not be used as an absolute depth measurement" according to e.g., http://dicom.nema.org/dicom/dicomwsi/.
	Resolution: Regardless of reality, the slide coordinates system defined by a frame of reference is nominally Cartesian and usable for reference purposes.
6	Negative annotations (holes) are powerful for IA. Strictly speaking, we didn't need to associate the negative annotations with the positive ones, but simply took the intersection as the area for analysis. However, it seems likely that logical regions would be defined as enclosed by a polygon with other interior polygons being marked as not part of the region. Resolution: Boolean relationships should be handled in a separate object, perhaps using the RTR-style composite volume method
7	Measurements Sequence may need more than just a flat list, as some measurements are linked to others. You could just encode it in the name, but that requires understanding the convention to figure out the association. If we add "sub-measurements" or similar tied to each measurement, this may be helpful for related measurements.
	complexity of SR within the bulk annotation object.
8	Recommended Display CIELab Value: Consider sRGB color space as this could make life easier when rendering in viewer.

	Resolution: By policy, all colors specified are in CIELab ICC Profile Connection Space (PCS) to allow them to be color managed.
9	Wrt. reusing the same attributes that are used in the Segmentation IOD. The term "segmented" is misleading, because the encoded geometries may not be regions or segments (e.g., POINT, POLYLINE).Resolution: Create new attributes for property category, etc. rather than reusing those from SEG.
10	Annotation Group Sequence: Can one of these attributes be used to organize groups? It might be helpful to be able to logically organize the annotations groups into groups. Each group of annotations belongs to particular logical groups: tumor, stroma, lymphocyte, etc. You could have hundreds of annotations, but fewer groups. Resolution: Yes, the items of the sequence can be used to logically group common annotations, not just based on geometric shape but also properties.
11	Avoid the term "set", which has an explicit meaning in computer science in the context of abstract data types. It assumes for example that there is no order, but then the items are included in a "Sequence" and assigned a "Number". What about the term "group"? Resolution: Replaced Set with Group.

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Scope and Field

This Supplement to the DICOM Standard specifies a new DICOM Information Object and Storage SOP Class for storing Whole Slide Microscopy Bulk Annotations (points, open polylines, closed polygons and simple geometric shapes), which is referred to as Whole Slide Microscopy Bulk Annotations IOD.

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Whole Slide Microscopy Bulk Annotations are usually created by machine algorithms from high resolution images of entire tissue sections. These are distinct from alternative representations, such as segmented

- bit planes (which can be encoded in Segmentation Images), and more tractable size human or machine
 generated contour-based annotations on selected high-power fields or lower resolution or gross specimen
 images (which can be encoded in Structured Reports using standard templates like TID 1500).
- ⁷⁰ No new image encoding mechanism is introduced. The annotations are in a 3D Frame of Reference that is shared with a Whole Slide Microscopy Image Storage instance.

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DICOM PS 3.2 Conformance

74 Item: Add SOP Class to Table A.1-2

Table A.1-2 UID VALUES		
UID Value	UID NAME	Category
<u>1.2.840.10008.5.1.4.1.1.sss</u>	Whole Slide Microscopy Bulk Annotations Storage	Transfer

78

DICOM PS 3.3: Information Object Definitions

Item: Change Figure 7-1a. DICOM Model of the Real World:

80 Add "Whole Slide Microscopy Bulk Annotations" to be contained in the Series.

Item: Change Figure A.1-1 DICOM Composite Instance IOD Information Model:

82 Add "Whole Slide Microscopy Bulk Annotations" to the same level as Surface.

Item: Add in Section A.1.4, rows and column to Table A.1-2

84 A.1.4 Overview of the Composite IOD Module Content

IODs Modules	<u>WS Bulk</u> <u>Ann</u>
Patient	M
Specimen	<u>U</u>
Clinical Trial Subject	<u>U</u>
General Study	M
Patient Study	<u>U</u>
Clinical Trial Study	<u>U</u>
General Series	М
<u>Whole Slide</u> <u>Microscopy Bulk</u> <u>Annotations</u> <u>Series</u>	M
Clinical Trial Series	<u>U</u>
Frame of Reference	M
Whole Slide Microscopy Bulk Annotations	M
General Equipment	M
Enhanced General Equipment	M
ICC Profile	<u>C</u>
Common Instance Reference	M
SOP Common	M

88 Item: Add in the following new section in Annex A

A.X1 WHOLE SLIDE MICROSCOPY BULK ANNOTATIONS IOD

90 A.X1.1 Whole Slide Microscopy Bulk Annotations IOD Description

The Whole Slide Microscopy Bulk Annotations IOD encodes Whole Slide Microscopy Bulk Annotations into a collection of points, closed polygons, open polylines and simple geometric shapes. Polygons and

polylines are defined by the x, y and z coordinates of each point. Simple geometric shapes are defined by parameters.

Numeric quantities and color may be associated with polygons or points.

96 A.X1.2 Whole Slide Microscopy Bulk Annotations IOD Entity-Relationship Model

The E-R Model in Section A.1.2 depicts those components of the DICOM Information Model that directly reference the Whole Slide Microscopy Bulk Annotations IOD.

A.X1.3 Whole Slide Microscopy Bulk Annotations IOD Module Table

100

Table A.X1-1. Whole Slide Microscopy Bulk Annotations IOD Modules

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	М
	Specimen	C.7.1.2	U
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	М
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	General Series	C.7.3.1	М
	Whole Slide Microscopy Bulk Annotations Series	C.8.Y1.1	М
	Clinical Trial Series	C.7.3.2	U
Frame of Reference	Frame of Reference	C.7.4.1	М
Equipment	General Equipment	C.7.5.1	М
	Enhanced General Equipment	C.7.5.2	М
Whole Slide Microscopy Bulk	Whole Slide Microscopy Bulk Annotations	C.8.Y1.2	М
Annotations	ICC Profile		C - Required if Recommended Display CIELab Value (0062,000D) is present
	Common Instance Reference	C.12.2	М
	SOP Common	C.12.1	М

102 Item: Amend Section C.7.3.1.1 to add new modality

C.7.3.1.1 General Series Attribute Descriptions

104 C.7.3.1.1.1 Modality

Defined Terms:

106 ANN Annotation

108 Item: Add in the following new sections in C

110 C.8.Y1 Whole Slide Microscopy Bulk Annotations Modules

This Section describes Whole Slide Microscopy Bulk Annotations Modules.

112 C.8.Y1.1 Whole Slide Microscopy Bulk Annotations Series Module

114 Table C.8.Y1-1 specifies the Attributes that identify and describe general information about a Whole Slide Microscopy Bulk Annotations Series.

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Table C.8.Y1-1 WHOLE SLIDE MICROSCOPY BULK ANNOTATIONS SERIES MODULE ATTRIBUTES

Attribute Name	Tag	Туре	Attribute Description
Modality	(0008,0060)	1	Type of equipment that originally acquired the data used to create the instances in this Series.
			Enumerated Values:
			ANN
			See Section C.7.3.1.1.1 for further explanation.
Series Number	(0020,0011)	1	A number that identifies this Series.
Referenced Performed Procedure Step Sequence	(0008,1111)	1C	Uniquely identifies the Performed Procedure Step SOP Instance to which the Series is related. Only a single Item shall be included in this Sequence.
			Required if a Performed Procedure Step SOP Class was involved in the creation of this Series.

>Include Table 10-11 "SOP Instance Reference Macro Attributes"

118

120 C.8.Y1.2 Whole Slide Microscopy Bulk Annotations Module

Table C.8.Y1-2 specifies the Attributes that describe the Whole Slide Microscopy Bulk Annotations.122

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Table C.8.Y1-2 WHOLE SLIDE MICROSCOPY BULK ANNOTATIONS MODULE ATTRIBUTES

Attribute Name	Tag	Туре	Attribute Description
Include Table 10-12 "Content Identification Mac			
Content Date	(0008,0023)	1	The date the content creation started.
Content Time	(0008,0033)	1	The time the content creation started.
Annotation Group Sequence	(gggg,eee1)	1	Groups of annotations sharing common characteristics, such as graphic type, properties or measurements.
			One or more Items shall be included in this Sequence.
>Annotation Group UID	(gggg,ee19)	1	Unique identifier of the Annotation Group.
>Annotation Group Number	(gggg,eee2)	1	Identification number of the Annotation Group. Uniquely identifies a Annotation Group within this SOP Instance. Shall start at a value of 1, and increase monotonically by 1.
>Annotation Group Label	(gggg,eee3)	1	User-defined label identifying this Annotation Group. This may be the same as Code Meaning (0008,0104) of Annotation Group Anatomical Type Code Sequence (0066,0108).
>Annotation Group Description	(gggg,eee4)	3	User-defined description for this Annotation Group.
>Annotation Group Generation Type	(gggg,ee13)	1	Type of algorithm used to generate the Annotations.
			Enumerated Values:
			AUTOMATIC - generated by algorithm without human user assistance
			SEMIAUTOMATIC - generated by algorithm with human user assistance
			MANUAL - generated by human user
>Annotation Algorithm Identification Sequence	(gggg,ee12)	1C	The algorithms used to create the annotations in this group.
			One or more Items shall be included in this Sequence.
			Required if Annotation Generation Type (gggg,ee13) is AUTOMATIC or SEMIAUTOMATIC.
>>Include Table 10-19 "Algorithm Identification	No Baseline CIDs are defined.		

>Annotation Property Category Code Sequence	(gggg,ee16)	1	Sequence defining the general category of the property the Annotation Group represents.
>>Include Table 8.8-1 "Code Sequence Macro Attributes"			BCID 7150 "Segmentation Property Categories".
>Annotation Property Type Code Sequence (gggg,ee17		1	Sequence defining the specific property the Annotation Group represents. Only a single Item shall be included in this Sequence.
>>Include Table 8.8-1 "Code Sequence Macro Attributes"			BCID ccc1 "Slide Microscopy Annotation Property Types".
>>Annotation Property Type Modifier Code Sequence	(gggg,ee18)	3	Sequence defining the modifier of the property type of this Annotation Group. One or more Items are permitted in this Sequence.
>>Include Table 8.8-1 "Code Sequence Macro Attributes"			No Baseline CID is defined.
>Number of Annotations	(gggg,eee5)	1	The number of Annotations in this Annotation Group. Each point, open polyline or closed polygon, circle, ellipse or rectangle is counted as one Annotation.

>Graphic Type	(0070,0023)	1	The shape of the Annotations in this Annotation Group. See Section C.8.Y1.2.1.1.
			Enumerated Values:
			POINT a single location denoted by a single coordinate
			POLYLINE a series of connected line segments with ordered vertices denoted by coordinates forming an open polyline; the points shall be coplanar
			POLYGON a series of connected line segments with ordered vertices denoted by coordinates, where the first and last vertices are not the same but are implicitly joined to form a closed polygon; the points shall be coplanar
			CIRCLE a circle defined by two coordinates. The first point is the central pixel. The second point is a pixel on the perimeter of the circle
			ELLIPSE an ellipse defined by four coordinates, the first two points specifying the endpoints of the major axis and the second two points specifying the endpoints of the minor axis of an ellipse; the points shall be coplanar
			RECTANGLE a rectangle defined by four coordinates, the first being the top left hand corner (when viewed from the top surface of the slide towards the bottom), then the top right hand corner, then the bottom right hand corner and finally the bottom left hand corner; the points shall be coplanar Notes: Individual annotations in the same group are not required to be in the same plane.
>Annotation Applies to All Optical Paths	(gggg,ee15)	1	The annotations in in this Annotation Group apply to all the optical paths within the images to which this annotation applies.
			Enumerated Values:
			YES the annotations apply to all optical paths
			NO the annotations apply only to the specified optical path

>Optical Path Identifier	(0048,0106)	1C	Identifies the optical path to which this annotation applies.
			Refers to the same value in Optical Path Identifier (0048,0106) within the Optical Path Sequence (0048,0105) in the images to which this annotation applies.
			Required if Annotation Applies to All Optical Paths (gggg,ee15) is NO.
>Annotation Applies to All Z Planes	(gggg,ee14)	1	The annotations in in this Annotation Group apply to the full thickness of the tissue on the slide. I.e., they are applicable regardless of the focal plane, in the case that images were acquired with multiple focal planes (Z-stacks).
			Enumerated Values:
			YES the annotations apply to the full thickness
			NO the annotations apply only to the specified Z depth
			Note: When the value is NO, the Z plane will be specified either in Common Z Coordinate Value (gggg,eee7) if all the coordinates are in the same Z plane, or Point Coordinates Data (0066,0016) if not.
>Common Z Coordinate Value	(gggg,eee7)	1C	The Z coordinate common to all points in Point Coordinates Data (0066,0016), in mm in the Slide Coordinate System (Section C.8.12.2.1.1) associated with the Frame of Reference.
			Required if all points in Point Coordinates Data (0066,0016) are in the same Z plane.
			Note: This requirement means that it is mandatory to factor out the commonality, i.e., it is not permitted to send Point Coordinates Data (0066,0016) with (X, Y, Z) triplets where all the Z values are the same. For annotations of images that only have a single Z plane, or where all the points in an annotation group are coplanar and in the same Z plane, this condition will always be satisfied. Annotations in different Z planes can be separated into separate Annotation Groups in order to allow this condition to be satisfied, but using separate Annotation Groups is not required.
			See Section C.8.Y1.2.1.1.

>Point Coordinates Data	(0066,0016)	1	The coordinates of one or more points that define the annotations (whether single points or polygons), encoded in (X, Y) or (X, Y, Z) order, in mm, in the Slide Coordinate System (Section C.8.12.2.1.1) associated with the Frame of Reference. For each point, two coordinates (X, Y) shall be encoded if Common Z Coordinate Value (gggg,eee7) is present, otherwise three coordinates (X, Y, Z) shall be encoded. See Section C.8.Y1.2.1.1.
>Long Primitive Point Index List	(0066,0040)	1C	A list of point indices. See Section C.8.Y1.2.1.1. Required if Graphic Type (0070,0023) is POLYLINE or POLYGON.
>Recommended Display CIELab Value	(0062,000D)	3	Default triplet value in which it is recommended that the Annotation Group be rendered. The units are specified in PCS-Values, and the value is encoded as CIELab. See Section C.10.7.1.1.
>Measurements Sequence	(0066,0121)	3	Measurements for some or all Annotations in the Annotation Group. Each Item describes one type of measurement. See Section C.8.Y1.2.1.2. One or more Items shall be included in this Sequence.
>>Concept Name Code Sequence	(0040,A043)	1	Defines the type of measurement stored in this Item. Only a single Item shall be included in this Sequence.
>>>Include Table 8.8-1 "Code Sequence Macro Attributes"			DCID ccc2 "Slide Microscopy Measurement Types"
>>Measurement Units Code Sequence	(0040,08EA)	1	Units of measurement for the value in this Item. Only a single Item shall be included in this Sequence.
>>>Include Table 8.8-1 "Code Sequence Macro	Attributes"		DCID 82 "Units of Measurement".
>>Measurement Values Sequence	(0066,0132)	1	The measurement values for the Annotation Group. Only a single Item shall be included in this Sequence.

>>>Floating Point Values	(0066,0125)	1	Measurement values for annotations stored in this Annotation Group.
			If Annotation Index List (gggg,eee6) is present, measurement values are stored for a subset of annotations, and the number of values shall match the number and order of indices in Annotation Index List (gggg,eee6).
			If Annotation Index List (gggg,eee6) is absent, measurement values are stored for every annotation in Long Primitive Point Index List (0066,0040), if present, and the number of values shall match the number and order of annotations in Long Primitive Point Index List (0066,0040).
			If Annotation Index List (gggg,eee6) and Long Primitive Point Index List (0066,0040) are absent, measurement values are stored for every annotation stored in Point Coordinates Data (0066,0016), and the number of values shall match the value of Number of Annotations (gggg,eee5).
			See Section C.8.Y1.2.1.2.
>>>Annotation Index List	(gggg,eee6)	1C	List of indices referencing annotations identified in Long Primitive Point Index List (0066,0040) or successive points stored in Point Coordinates Data (0066,0016) for which measurement values shall be stored.
			Required if Measurement Values stored in Floating Point Values (0066,0125) are associated with only a subset of annotations.
			See Section C.8.Y1.2.1.2.

126 C.8.Y1.2.1 Whole Slide Microscopy Bulk Annotations Module Attributes

C.8.Y1.2.1.1 Type, Points, Polygons, Parametrized and Rotated Shapes and Indices

- 128 All the Annotations in a single Item of Annotation Group Sequence (gggg,eee1) share the same value for Graphic Type (0070,0023).
- 130 If the Annotations are points, then
 - Graphic Type (0070,0023) shall have a value of POINT.
- All the points in the group shall be encoded in Point Coordinates Data (0066,0016), with Z factored out into Common Z Coordinate Value (gggg,eee7), if common.
- There is no need for a separate index of each annotation, so Long Primitive Point Index List (0066,0040) shall not be present.
- Number of Annotations (gggg,eee5) will contain the number of points, which shall also be the number of coordinate tuples in Point Coordinates Data (0066,0016).

- 138 If the Annotations are open polylines, then
 - Graphic Type (0070,0023) shall have a value of POLYLINE.
- The points of each polyline shall be encoded in Point Coordinates Data (0066,0016), concatenated one after another, with Z factored out into Common Z Coordinate Value (gggg.eee7), if common.
 - The order of the encoded points is from the first point to the last point of the polyline.
- The index in Point Coordinates Data (0066,0016) of each successive polyline is encoded in Long Primitive Point Index List (0066,0040), which shall contain Number of Annotations (gggg,eee5) values.

If the Annotations are closed polygons, then

- Graphic Type (0070,0023) shall have a value of POLYGON.
- The points of each polygon shall be encoded in Point Coordinates Data (0066,0016),
- 150 concatenated one after another, with Z factored out into Common Z Coordinate Value (gggg,eee7), if common.
- The order of the encoded points is from the first point to the last point of the polygon. The first point and the last point shall not be the same, but rather they are implicitly joined to close the polygon.
- The index in Point Coordinates Data (0066,0016) of each successive polygon is encoded in Long Primitive Point Index List (0066,0040), which shall contain Number of Annotations (gggg,eee5) values.
- Note: This closed polygon representation differs from that used in Presentation States (C.10.5.1.2 Graphic Data and Graphic Type) and Structured Reports (C.18.6.1 Spatial Coordinates Macro Attribute Descriptions and C.18.9.1 3D Spatial Coordinates Macro Attribute Descriptions), none of which are implicitly closed, and required replication of the first point as the last point.

If the Annotations are circles, then

- Graphic Type (0070,0023) shall have a value of CIRCLE.
 - All the center and perimeter points of the circles in the group shall be encoded in Point
- 166 Coordinates Data (0066,0016), with Z factored out into Common Z Coordinate Value (gggg,eee7) if common.

• The index of each annotation can be computed, so Long Primitive Point Index List (0066,0040) shall not be present. Number of Annotations (gggg,eee5) will contain the number of circles, which about a long be helf of the number of coordinate tuples in Point Coordinates Data (0066,0016)

shall also be half of the number of coordinate tuples in Point Coordinates Data (0066,0016).

If the Annotations are ellipses, then

- Graphic Type (0070,0023) shall have a value of ELLIPSE.
 - The end points of the major and minor axes of the ellipses in the group shall be encoded in Point
- 174 Coordinates Data (0066,0016), with Z factored out into Common Z Coordinate Value (gggg,eee7) if common.
- The index of each annotation can be computed, so Long Primitive Point Index List (0066,0040) shall not be present. Number of Annotations (gggg,eee5) will contain the number of ellipses, which shall also be one quarter of the number of coordinate tuples in Point Coordinates Data (0066,0016).

180 If the Annotations are rectangles, then

- Graphic Type (0070,0023) shall have a value of RECTANGLE.
- All the corner points of the rectangles in the group shall be encoded in Point Coordinates Data (0066,0016), with Z factored out into Common Z Coordinate Value (gggg,eee7) if common.
- The index of each annotation can be computed, so Long Primitive Point Index List (0066,0040) shall not be present. Number of Annotations (gggg,eee5) will contain the number of rectangles, which shall also be one quarter of the number of coordinate tuples in Point Coordinates Data (0066,0016).
- Note: This rectangle representation is the same as if the rectangle were encoded as an implicitly closed polygon, except that the number of points is fixed and Long Primitive Point Index List
 (0066,0040) is absent.

The index used in Long Primitive Point Index List (0066,0040) of the first value of the first coordinate tuple in Point Coordinates Data (0066,0016) shall be 1.

The polylines and polygons encoded in Point Coordinates Data (0066,0016) shall be in the same order as Long Primitive Point Index List (0066,0040). I.e., the values of Long Primitive Point Index List (0066,0040) are strictly increasing.

196 Note: This means that the first value of Long Primitive Point Index List (0066,0040) is always 1.

Open polylines and implicitly closed polygons shall have their vertices encoded in Point Coordinates Data (0066,0016) in clockwise winding order when viewed from the top surface of the slide towards the bottom,

- per C.8.12.2.1 Slide Coordinates Attribute Descriptions. The line segments shall not cross (i.e., shall be
- simple polygons, not complex polygons), and shall not contain holes (i.e., the keyhole technique described for RT Structure Sets (C.8.8.6.3 Representing Inner and Outer Contours on an Image) shall not be used).
- 202 Coplanar points used to construct objects are not required to be in the same plane as any image plane, only coplanar in a geometric sense (e.g., they need not all have the same Z coordinate value).

204 C.8.Y1.2.1.2 Measurements

For each Annotation Group, optionally one or more measurements may be defined, either for every Annotation or a subset of Annotations. Measurements are described by coded type and unit.

When a measurement (i.e., an Item of Measurements Sequence (0066,0121)) is encoded for every Annotation, then Floating Point Values (0066,0125) contains the corresponding values for every

- Annotation. When a measurement is encoded for a subset of Annotations, then Floating Point Values
- 210 (0066,0125) contains measurement values for the Annotations that are referenced in Annotation Index List (gggg,eee6).
- 212 More than one Measurements Sequence (0066,0121) Item may be used, for example to encode different types of measurements, or to encode different components of a measurement that is a tuple.
- 214 Within one Annotation Group the types of measurements are the same for all Annotations within that group.

216

Amend DICOM PS 3.3 Annex F.3.2.2 Directory Information Module:

218

222

Table F.3-3. Directory Information Module Attributes

Attribute Name	Tag	Туре	Attribute Description
>Directory Record Type	(0004,1430)	1	
			Enumerated Values:
			ANNOTATION

Amend DICOM PS 3.3 F.4 Basic Directory IOD Information Model as follows:

Т	able F.4	-1. Relationship Between Directory Records

Directory Record Type	Section	Directory Record Types that may be included in the next lower-level directory Entity
(Root Directory Entity)		PATIENT, HANGING PROTOCOL, PALETTE, IMPLANT, IMPLANT ASSY, IMPLANT GROUP, PRIVATE
PATIENT	F.5.1	STUDY, HL7 STRUC DOC, PRIVATE
STUDY	F.5.2	SERIES, PRIVATE
SERIES	F.5.3	IMAGE, RT DOSE, RT STRUCTURE SET, RT PLAN, RT TREAT RECORD, PRESENTATION, WAVEFORM, SR DOCUMENT, KEY OBJECT DOC, SPECTROSCOPY, RAW DATA, REGISTRATION, FIDUCIAL, ENCAP DOC, VALUE MAP, STEREOMETRIC, PLAN, MEASUREMENT, SURFACE, <u>ANNOTATION,</u> PRIVATE
SURFACE	F.5.42	PRIVATE
SURFACE SCAN	F.5.43	PRIVATE
ANNOTATION	F.5.44	PRIVATE

224 Item: Change Figure F.4-1 Basic Directory IOD Information Model:

Add "Annotation DR" to the same level as Surface Scan.

226 Item: Add in the following new sections in F.5

F.5.44 Whole Slide Microscopy Bulk Annotations Directory Record Definition

- 228 The Directory Record is based on the specification of Section F.3. It is identified by a Directory Record Type of Value "ANNOTATION". Table F.5-42 lists the set of keys with their associated Types for such a Directory Record Type. The
- 230 description of these keys may be found in the Modules related to the Whole Slide Microscopy Bulk Annotations IE of the Whole Slide Microscopy Bulk Annotations IOD. This Directory Record shall be used to reference a Whole Slide
- Microscopy Bulk Annotations 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.

234

Table F.5-44. Whole Slide Microscopy Bulk Annotations Keys

Key	Tag	Туре	Attribute Description
Specific Character Set (0008,0005)		1C	Required if an extended or replacement character set is used in one of the keys.
Content Date	(0008,0023)	1	The date the content creation started.
Content Time (0008,0033)		1	The time the content creation started.
Include Table 10-12 "Cont	tent Identification Ma	acro Attributes"	
Any other Attribute of the Microscopy Bulk Annotatio	Whole Slide ons IE Modules		

236 Note

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

DICOM PS3.4: Service Class Specifications

242 Amend DICOM PS 3.4 Annex B.5 Standard SOP Classes as follows:

SOP Class Name	SOP Class UID	IOD Specification (defined in PS3.3)
Whole Slide Microscopy Bulk Annotations Storage	<u>1.2.840.10008.5.1.4.1.1.sss</u>	Whole Slide Microscopy Bulk Annotations IOD

Table B.5-1. Standard SOP Classes

246

DICOM PS 3.6: Data Dictionary

248

Amend DICOM PS 3.6 – Data Dictionary – Section 6 Registry of DICOM Data Elements as follows:

250

Table 6-1. Registry of DICOM Data Elements

Тад	Name	Keyword	VR	VM	
(gggg,eee1)	Annotation Group Sequence		SQ	1	
(gggg,eee2)	Annotation Group Number		UL	1	
(gggg,eee3)	Annotation Group Label		LO	1	
(gggg,eee4)	Annotation Group Description		UT	1	
(gggg,eee5)	Number of Annotations		UL	1	
(gggg,eee6)	Annotation Index List		OL	1	
(gggg,eee7)	Common Z Coordinate Value		FL	1	
(gggg,ee12)	Annotation Group Algorithm Identification Sequence		SQ	1	
(gggg,ee13)	Annotation Group Generation Type		CS	1	
(gggg,ee14)	Annotation Applies to All Z Planes		CS	1	
(gggg,ee15)	Annotation Applies to All Optical Paths		CS	1	
(gggg,ee16)	Annotation Property Category Code Sequence		SQ	1	
(gggg,ee17)	Annotation Property Type Code Sequence		SQ	1	
(gggg,ee18)	Annotation Property Type Modifier Code Sequence		SQ	1	
(gggg,ee19)	Annotation Group UID		UI	1	

252

Amend DICOM PS 3.6 - Data Dictionary - Annex A - Registry of DICOM Unique Identifiers (UIDs) as follows:

256

Table A-1. UID Values

UID Value	UID Name	UID Type	Part
<u>1.2.840.10008.5.1.4.1.1.sss</u>	Whole Slide Microscopy Bulk Annotations Storage	SOP Class	<u>PS 3.3</u>

258

Table A-3. Context Group UID Values

Context UID	Context Identifier	Context Group Name
<u>1.2.840.10008.6.1.uuu1</u>	CID ccc1	Slide Microscopy Annotation Property Types
1.2.840.10008.6.1.uuu2	CID ccc2	Slide Microscopy Measurement Types

DICOM PS 3.15: Security and System Management Profiles

Amend: C.2 Creator RSA Digital Signature Profile:

262 ...

xx. any attributes of the Whole Slide Microscopy Bulk Annotations module that are present

264 ..

Amend: E.1 Application Level Confidentiality Profiles:

266

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

Attribute Name	Тад	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.
Annotation Group Label	(gggg,eee3)	N	Y	D								С		
Annotation Group Description	(gggg,eee4)	N	Y	X								С		
Annotation Group UID	(gggg, ee19)	N	Y	D		К								

268

270

DICOM PS 3.16: Content Mapping Resource

Item: Add in Section B DCMR Context Groups (Normative)

²⁷² CID ccc1 Slide Microscopy Annotation Property Types

Type: 274 Version:

Extensible yyyymmdd

Table CID ccc1. Slide Microscopy Annotation Property Types

Coding Scheme Designator	Code Value	Code Meaning
SCT	84640000	Nucleus
SCT	362837007	Entire cell

Coding Scheme Designator	Code Value	Code Meaning

276

Ed. Note. Add to DICOM SNOMED subset 84640000, 362837007, ...

278

CID ccc2 Slide Microscopy Measurement Types

280 Type: Version: Extensible yyyymmdd

282

Table CID ccc2. Slide Microscopy Measurement Types

Coding Scheme Designator	Code Value	Code Meaning					
SCT	42798000	"Area"					

284 Item: Add +/- update definitions in Annex D

Code Value	Code Meaning	Definition	Notes
ANN	Annotation	A device, process or method that produces annotations.	
RTSTRUCT	Radiotherapy Structure Set	A device, process or method that produces Radiotherapy Structure Sets.	
RWV	Real World Value Map	A device, process or method that produces mappings between image pixel values and some real-world values.	
SEG	Segmentation	An image processing device, process or method that performs segmentation.	
SM	Slide Microscopy	An acquisition device, process or method that performs slide microscopy.	

288

DICOM PS 3.17: Explanatory Information

Item: Add the following Section

290

XXXX Whole Slide Microscopy Bulk Annotations (Informative)

292 XXXX.1 Introduction

....

294

298

An annotation algorithm produces individual annotations that are either:

296	•	single points	(e a	centroids)	۱
290	•	Single points	(e.g.,	Centrolus	

- open polylines
- closed polylines entirely enclosing a structure, or
- circles, ellipses or rectangles.

300 ...

XXXX.2 Encoding Example

- ³⁰² This section illustrates the usage of the Whole Slide Microscopy Bulk Annotations Module (PS 3.3 C.8.Y1.2) in the context of the Whole Slide Microscopy Bulk Annotations IOD.
- 304 The example consists of:
- Group of Polygons "A" outlining nuclei, consisting of: 306 86 points 0 308 Point Coordinates Data (0066,0016) => describes the coordinates for all points in the polygon. 310 Measurement for each polygon 312 0 On how the values are stored, see description in "Encoding of Measurement 314 -Values" below. 316 **Encoding of Measurement Values** 318 320 0 For storing measurement values like area values on specific polygons Measurements Sequence (0066,0121) ... 322 0
- 324 o Measurement Values Sequence (0066,0132) ...

326

The table XXXX-1 shows the encoding of the Whole Slide Microscopy Bulk Annotations module for the example above. In addition to the polygons the table XXXX-1 also encodes the following information:

330

• ...

Name	Tag	Value	Comment
Frame of Reference UID	(0020,0052)	1.2.3.4	
Annotation Group Sequence	(gggg,eee1)		
>Annotation Group UID	(gggg,ee19)	1.2.3.4.5	
> Annotation Group Number	(gggg,eee2)	1	
> Annotation Group Label	(gggg,eee3)	NUCLEI	
> Annotation Group Description	(gggg,eee4)	Nuclei detected on H&E	
> Number of Annotations	(gggg,eee5)	0x0000056	
> Common Z Coordinate Value	(gggg,eee7)	0	
> Annotation Group Generation Type	(gggg,ee13)	AUTOMATIC	
> Annotation Applies to All Z Planes	(gggg,ee14)	NO	
> Annotation Applies to All Optical Paths	(gggg,ee15)	YES	
> Annotation Property Category Code Sequence	(gggg,ee16)	(4421005, SCT, "Cell Structure")	
> Annotation Property Type Code Sequence	(gggg,ee17)	(84640000, SCT, "Nucleus")	
> Point Coordinates Data	(0066,0016)	0.66675,0.032,0.6665,0.03 225,0.6665,0.03275,0.666 75,0.033,0.66725,0.033,0. 66725,0.03275,0.6675,0.0 325,0.6675,0.03225,0.667 25,0.032,	
> Long Primitive Point Index List	(0066,0040)	0x0000000,0x00000012, 0x0000008c,	
> Measurements Sequence	(0066,0121)		
>> Measurement Units Code Sequence	(0040,08EA)	({pixels}, UCUM, "pixels")	
>> Concept Name Code Sequence	(0040,A043)	(42798000, SCT, "Area")	
>> Measurement Values Sequence	(0066,0132)		
>>>Floating Point Values	(0066,0125)	20.0,559.0,24.0,	
> Graphic Type	(0070,0023)	POLYGON	

Table XXXX-1. Example of the Whole Slide Microscopy Bulk Annotations Module