

DICOM Correction Proposal

STATUS	Letter Ballot
Date of Last Update	2024/01/14
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Correction Number	CP-2320
Log Summary: Add Synthetic Data Flag	
Name of Standard PS 3.3, 3.6	
<p>Rationale for Correction:</p> <p>There is interest in creating, storing, and processing imaging data that has been generated synthetically (e.g. by a generative AI algorithm rather than by reconstructing data acquired from a scanner).</p> <p>Such data objects might be used for machine learning, for system testing, or other non-clinical purposes. Generating synthetic data can make it easier to assemble large training sets with known image characteristics.</p> <p>For some uses, such data should resemble "real" patient data very closely, potentially to the point of being indistinguishable. To avoid potential confusion, an attribute specifically declaring the synthetic nature of the data would be helpful.</p> <p>This attribute is somewhat analogous to Quality Control Subject (0010,0200) in the Patient Module.</p> <p>This flag is not intended to address concerns where synthetic images are inserted into the medical record with intent to misdirect patient care since such bad actors would ignore this flag. Thwarting such behaviors would involve tamper proofing mechanisms not discussed here.</p>	
Correction Wording:	

PS3.3 Modify SOP Common Module as shown

C.12.1 SOP Common Module

Table C.12-1. SOP Common Module Attributes

Attribute Name	Tag	Type	Attribute Description
...			
Instance Creation Time	(0008,0013)	3	Time the SOP Instance was created. This is the time that the SOP Instance UID was assigned, and does not change during subsequent coercion of the Instance.
Instance Coercion DateTime	(0008,0015)	3	Date and time that the SOP Instance was last coerced, corrected or converted by a Storage SCP (see Section B.4.1.3 "Coercion of Attributes" in PS3.4).

Attribute Name	Tag	Type	Attribute Description
Instance Creator UID	(0008,0014)	3	Uniquely identifies device that created the SOP Instance. Note: There is no requirement that the Instance Creator UID (0008,0014) be the same as the Device UID (0018,1002) in the General Equipment Module, though they may be.
Synthetic Data	(xxxx,yyy1)	3	<p><u>Identifies that some or all of the content of this instance was made artificially rather than being a faithful representation of acquired data.</u></p> <p><u>Notes:</u> 1. <u>Since this instance may be intended for use in training or testing, the data may be otherwise indistinguishable from acquired patient data. For example, the value of Manufacturer's Model Name (0008,1090) in the Equipment Module may reflect the model whose output the instance is simulating even though such a model did not create this instance. Similarly, the value of KVP (0018,0060) may reflect the technique being simulated even though no x-rays were involved.</u></p> <p>2. <u>The equipment that synthesized the data may be recorded as additional Item(s) of the Contributing Equipment Sequence (0018,A001) in the SOP Common Module. The Purpose of Reference code value of (newcode1, DCM, "Synthesizing Equipment") can be used.</u></p> <p><u>Enumerated Values:</u> <u>YES</u> <u>NO</u> <u>If data with Synthetic Data (xxxx,yyy1) of YES is used to derive other content then it is expected that this derived content will also have Synthetic Data (xxxx,yyy1) of YES.</u></p>
...			
Content Qualification	(0018,9004)		<p>Content Qualification Indicator</p> <p>Enumerated Values: PRODUCT RESEARCH SERVICE</p> <p>See Section C.8.13.2.1.1 for further explanation.</p>

Included for reference (text about suitability for use)

C.8.13.2.1.1 Content Qualification

Content Qualification (0018,9004) shall have the value PRODUCT if the content (image or Spectroscopy data) was produced with approved hardware and software. It shall have the value RESEARCH or SERVICE if there is any doubt as to whether the content was produced with approved hardware and software.

If data with Content Qualification (0018,9004) of RESEARCH or SERVICE is used to derive other content then it is expected that this derived content will also have Content Qualification (0018,9004) set to RESEARCH or SERVICE.

The intent of this element is to allow annotation of an advisory message that indicates that this content may not be suitable for clinical interpretation.

Add tag to PS3.6 Table 6-1

Tag	Name	Keyword	VR	VM	
<u>(xxxx,yyy1)</u>	<u>Synthetic Data</u>	<u>SyntheticData</u>	<u>CS</u>	<u>1</u>	

PS3.16 Add a new code to CID 7005 as shown

CID 7005 Contributing Equipment Purpose of Reference

Resources: HTML | FHIR JSON | FHIR XML | IHE SVS XML
 Keyword: ContributingEquipmentPurposeOfReference
 FHIR Keyword: dicom-cid-7005-ContributingEquipmentPurposeOfReference
 Type: Extensible
 Version: 20130617
 UID: 1.2.840.10008.6.1.486

Table CID 7005. Contributing Equipment Purpose of Reference

Coding Scheme Designator	Code Value	Code Meaning
DCM	109101	Acquisition Equipment
DCM	109102	Processing Equipment
DCM	109103	Modifying Equipment
DCM	109104	De-identifying Equipment
DCM	109105	Frame Extracting Equipment
DCM	109106	Enhanced Multi-frame Conversion Equipment
DCM	MEDIM	Portable Media Importer Equipment
DCM	FILMD	Film Digitizer
DCM	DOCD	Document Digitizer Equipment
DCM	VIDD	Video Tape Digitizer Equipment
<u>DCM</u>	<u>Newcode1</u>	<u>Synthesizing Equipment</u>

PS3.16 Add a new code definition to Annex D as shown

Code Value	Code Meaning	Definition	Notes
109101	Acquisition Equipment	Equipment that originally acquired the data stored within	

Code Value	Code Meaning	Definition	Notes
		composite instances. E.g., a CT, MR or Ultrasound modality.	
109102	Processing Equipment	Equipment that has processed composite instances to create new composite instances. E.g., a workstation or software component that performs 3D construction, segmentation or applies an AI model.	
<u>Newcode1</u>	<u>Synthesizing Equipment</u>	<u>Equipment that made artificial data.</u>	