Digital Imaging and Communications in Medicine (DICOM)

Supplement 192: Instance Approval Storage SOP Class

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VERSION: Post-Public Comment Draft

Developed pursuant to DICOM Work Item 2006-04-E

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Scope and Field of Application

This Supplement defines a storage SOP Class to convey assertions of approval for instances. Specific codes and examples are provided for assertions about CT Protocols stored as DICOM instances.

The assertions are encoded using a macro which is also being used for RT. The macro was originally part of the Supplement 121 and embedded within those instances. A decision was made to make this a separate SOP Class and so it has been moved into a new supplement.

CLOSED ISSUES

Scope	
1	Should the Approval Macro address digital signatures of the Protocol Instances? *A. No.* Assertions are attributed to the Identified person or device, but authenticating the person/device and/or digitially signing the instance in a way to prevent undetected changes go beyond the scope of DICOM services implementers appear willing to support. The vast majority of DICOM instances today are unsigned and the level of forgery is quite small. Systems that manage or host the protocol objects may choose to secure them as they see fit.
2	Do the codes in newcid3 Protocol Assertion Codes cover typical CT Protocol approval practice? *A: Yes.* Several reviewers felt they sufficient for the typical types of approval and protocol management that sites would like to use now and foresee using in the near future.
3	What conditions should void an approval and how should voiding be reflected? *A: Approvals point to an instance, so effectively anything that creates a new instance by default voids approvals. So can approvals be cloned*? Previous conclusion: Invalidate an approval by setting the Assertion Invalidation DateTime. Invalidation is at the discretion of the editing device which is advised, but not mandated, to invalidate approvals when the approved instance is edited other than to add a new approval. IHE might mandate more specific behaviors.

Changes to NEMA Standards Publication PS 3.2

Digital Imaging and Communications in Medicine (DICOM)

Part 2: Conformance

Add new SOP Classes in Table A.1-2

Table A.1-2
UID VALUES

UID Value	UID NAME	Category
…		
1.2.840.10008.5.1.4.1.1.X.0.1	**Instance Approval Storage**	**Transfer**
…		

Changes to NEMA Standards Publication PS 3.3

Digital Imaging and Communications in Medicine (DICOM)

Part 3: Information Object Definitions

Add definitions to 3.8

Assertion An affirmative statement or declaration by a specified entity about a specified or implied subject for a specified or implied purpose.

TODO Revise a Real World Model figure to show relation of Approvals to instances.

Figure 7-3. Model of the Real World for the Purpose of Modality-IS Interface

Add new sections 10.XW1 & 10.XW2 & 10.XW3

10.XW1 ASSERTION MACRO

This Macro may be used to record Assertions made by a person or device about the content of a SOP Instance. The nature of the Assertion is defined by the Assertion Code.

The scope of the Assertion (e.g., whether it applies to the whole instance, to a specific item in a sequence, etc.) is described at the point where the Macro is included. It is also expected that the point of inclusion will constrain the Baseline CID for the Assertion Code Sequence (30xx,50A0).

Table 10.XW1-1
ASSERTION MACRO ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Assertion Code Sequence	(30xx,50A0)	1	The Assertion being made. Only a single Item shall be included in this sequence.
>Include 'Code Sequence Macro' Table 8.8-1			*No Baseline CID defined*
Assertion Source Identification Sequence	(0070,00QQ)	1	The person or device making the Assertion. Only a single Item shall be included in this sequence. Note: Multiple sources wishing to make the same Assertion may be recorded as multiple Assertions, each with a single source.
>Include 'Identified Person or Device Macro' Table C.17-3b			*Baseline CID for Organizational Role is CID 7452 Organizational Roles*
Assertion DateTime	(30xx,50A4)	1	Date and time at which the Assertion was made.

Assertion Expiry DateTime	(30xx,50A8)	3	Date and time at which the Assertion expires. If this Attribute is absent or empty, it means the Assertion does not have a pre-determined date and time at which it expires.
Assertion Invalidation DateTime	(30xx,50AA)	3	Date and time at which something happened that is assumed to have invalidated the Assertion.
Assertion Comments	(30xx,50A6)	3	Comments on the nature, extent or basis of the Assertion.
Pertinent Documents Sequence	(0038,0100)	3	Reference to document(s) that describe the Assertion semantics, or provide the basis for making the Assertion. Items shall not be empty.
>Referenced SOP Class UID	(0008,1150)	3	Unique identifier for the class of the referenced document.
>Referenced SOP Instance UID	(0008,1155)	3	Unique identifier for the referenced document as used in DICOM instance references (see C.12.1.1.6)
>HL7 Instance Identifier	(0040,E001)	3	Instance Identifier of the referenced document, encoded as a UID (OID or UUID), concatenated with a caret (“^”) and Extension value (if Extension is present in Instance Identifier).
>Retrieve URI	(0040,E010)	3	Retrieval access path to the referenced document. Includes fully specified scheme, authority, path, and query in accordance with RFC 2396

10.XW2 APPROVAL MACRO

This Macro may be used to record approvals by a person or device of the content of a SOP Instance.

An approval is modeled as a form of Assertion. The nature of the approval is defined by the Assertion Code in the embedded Assertion Macro.

The scope of an approval (e.g., whether it applies to a whole instance, to a specific item in a sequence, etc.) is described at the point where the Approval Macro is included.

When an approved instance is modified, other than to add more Assertions, it may be appropriate to invalidate existing Assertions by setting their Assertion Invalidation DateTime (30xx,50AA). It may also be informative for users of Assertions to see if the Assertion DateTime (30xx,50A4) is older than the DateTime of the instance contents.

Neither the Approval Macro nor the underlying Assertion Macro address securing the approved instance against tampering (e.g., via a digital hash) or authenticating the identity of the source of the Assertion.

Examples of use:

- An Approval Sequence in a CT Protocol might identify AAPM in the Content Creator's Identification Code Sequence, and have an Assertion Code of "Provided as appropriate or the recorded indications"

Table 10.XW2-1
APPROVAL MACRO ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Include 'Assertion Macro' Table 8.8-1			The Baseline CID for the Assertion Code Sequence is newcid3. The Approver is recorded in the Assertion Source Identification Sequence inside the Assertion Macro.

A number of the Assertion codes in CID newcid3 are associated with information in Attributes of a CT Protocol object. The Attributes associated with each Assertion code are shown in Table 10.XW2-2.

Table 10.XW2-2
Associated Attributes for Protocol Assertion Codes

Code Value	Code Meaning	Associated Attribute
newcode001	Appropriate for the indications	Indications Code Sequence (yym1,m1x6)
newcode002	Consistent with labelling of the device	Model Specification Sequence (yym2,m2x3)
newcode003	Approved for use at the institution	Institution Code Sequence (0008,0082)
newcode004	Approved for use in the clinical trial	Clinical Trial Protocol ID (0012,0020)
newcode006	Approved for use on the patient	Patient ID (0010,0020)
newcode007	Approved for use in the order	Requested Procedure ID (0040,1001)
newcode014	Approved for use in the procedure	Scheduled Procedure Step ID (0040,0009)
newcode008	Appropriate for the device	Model Specification Sequence (yym2,m2x3)
newcode009	Operational for the device	Model Specification Sequence (yym2,m2x3)
newcode010	Optimized for the device instance	Model Specification Sequence (yym2,m2x3) Device Serial Number (0018,1000)
newcode011	Accurate record of what was performed	Contents of the instance

Although an instance may contain a variety of approvals, it is likely that many systems will simply look for the specific approval associated with some local policy and ignore the rest of the approvals. However, in the event the needed approval is missing, it is conceivable that it may be useful to display the other approvals to the system operator.

Add Section A.1.2.QQ with a new IE for Approvals

A.1.2.QQ Approval IE

The Approval IE defines the Attributes that describe an approval of an Instance.

Add new IOD and Modules to Table A.1-1 by looking at A.??? TODO

Add section to Annex A

A.X1 APPROVAL INFORMATION OBJECT DEFINITIONS

Approval Information Object Definitions (IODs) record the details of an approval of DICOM instances.

A.X1.1 Approval Information Object Definition

A.X1.1.1 Approval IOD Description

The Approval IOD describes approval-related assertions made by people, organizations and devices about Instances.

A.X1.1.2 Protocol Approval IOD Entity-Relationship Model

The E-R model for the Protocol Approval IOD is shown in Figure A.X1.3.2-1.

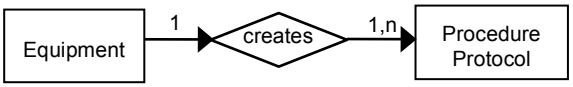

Figure A.X1.3.2-1 APPROVAL IOD E-R MODEL

A.X1.1.3 Approval IOD Module Table

Table A.X1.1.3-1
Approval IOD MODULES

IE	Module	Reference	Usage
Equipment	General Equipment	C.7.5.1	M

	Enhanced General Equipment	C.7.5.2	M
Approval	SOP Common	C.12.1	M
	Approval	C.X4.2	M

154 **A.X1.1.3.1 Approval IOD Content Constraints**

A.X1.1.3.1.1 Modality Attribute

156 The value of Modality (0008,0060) shall be APPROVAL. (Or ASSERTION?)

158 ***Modify C.17.2.4 Identified Person or Device Macro as shown:***

C.17.2.4 Identified Person or Device Macro

160 Table C.17-3b defines the Attributes that identify a person or a device participating as an observer for the context of an SR Instance. This Macro contains content equivalent to TID 1002 (see PS3.16).

162 **Table C.17-3b**
Identified Person or Device Macro Attributes

Attribute Name	Tag	Type	Attribute Description
Observer Type	(0040,A084)	1	Enumerated Values: PSN – Person DEV – Device
Person Name	(0040,A123)	1C	Name of the person observer for this document Instance. Required if Observer Type value is PSN.
Person Identification Code Sequence	(0040,1101)	2C	Coded identifier of person observer. Zero or one Item shall be included in this sequence. Required if Observer Type value is PSN.
>Include 'Code Sequence Macro' Table 8.8-1			*No Baseline Context ID defined*
Organizational Role Code Sequence		**3**	**The organizational capacity in which the person observer is participating**
>Include 'Code Sequence Macro' Table 8.8-1			***No Baseline Context ID defined***
Station Name	(0008,1010)	2C	Name of the device observer for this document instance. Required if Observer Type value is DEV.
Device UID	(0018,1002)	1C	Unique identifier of device observer. Required if Observer Type value is DEV.
Manufacturer	(0008,0070)	1C	Manufacturer of the device observer. Required if Observer Type value is DEV.
Manufacturer's Model Name	(0008,1090)	1C	Model Name of the device observer.

			Required if Observer Type value is DEV.
Device Serial Number	**(0018,1000)**	**3**	**Manufacturer's serial number of the identified device.** **Note: While the serial number will be unique within the scope of the Manufacturer and Model, it might not be universally unique.**
Software Versions	**(0018,1020)**	**3**	**Manufacturer's designation of software version of the identified device.** **See Section C.7.5.1.1.3.**
Institution Name	(0008,0080)	2	Institution or organization to which the identified person is responsible or accountable, or which manages the identified device.
Institution Code Sequence	(0008,0082)	2	Institution or organization to which the identified person is responsible or accountable, or which manages the identified device. Zero or one Item shall be included in this Sequence.
>Include 'Code Sequence Macro' Table 8.8-1			*No Baseline Context ID defined*

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Add section to Annex C

166 **C.X4.2 Approval**

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168 **Table C.X4-2**
APPROVAL CONTEXT MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Approval Subject Sequence			Instances that are the subject of the Approval Sequence.
>Include Table 10-11. SOP Instance Reference Macro			
Approval Sequence	(yym1,m1xa)	2	Recorded approvals of the subject instances. Zero or more items shall be included in this sequence.
>Include 'Approval Macro' Table 10.XW2-1			

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Changes to NEMA Standards Publication PS 3.4

Digital Imaging and Communications in Medicine (DICOM)

Part 4: Service Class Specifications

Add SOP Classes to Table B.5-1

B.5 STANDARD SOP CLASSES

Table B.5-1
Standard SOP Classes

SOP Class	SOP Class UID	IOD Specification (defined in PS 3.3)
…		
Approval Storage	**1.2.840.10008.5.1.4.1.1.X.0.1**	
…		

Add SOP Classes to Table I.4-1

I.4 MEDIA STORAGE SOP CLASSES

Table I.4-1
Media Storage Standard SOP Classes

SOP Class	SOP Class UID	IOD Specification
…		
Approval Storage	**1.2.840.10008.5.1.4.1.1.X.0.1**	**IOD defined in PS 3.3**
…		

Changes to NEMA Standards Publication PS 3.6

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Part 6: Data Dictionary

Add the following rows to Section 6

Tag	Name	Keyword	VR	VM
(30xx,50A0)	Assertion Code Sequence		SQ	1
(0070,00QQ)	Assertion Source Identification Sequence		SQ	1
(30xx,50A4)	Assertion DateTime		DT	1
(30xx,50A8)	Assertion Expiry DateTime		DT	1
(30xx,50AA)	Assertion Invalidation DateTime		DT	1
(30xx,50A6)	Assertion Comments		LT	1
(0012,m7x5)	Ethics Committee Approval Start Date		DA	1
(0012,m7x6)	Ethics Committee Approval End Date		DA	1
(0008,mx04)	Responsible Service Code Sequence			

Add the following rows to Table A-1

Table A-1
UID Values

UID Value	UID Name	UID Type	Part
…			
1.2.840.10008.5.1.4.1.1.X.0.1	**Approval Storage**	**SOP Class**	**PS 3.4**
…			

Changes to NEMA Standards Publication PS 3.16

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Part 16: Content Mapping Resource

CID newcid3 Protocol Assertion Codes

Context ID newcid3
Protocol Assertion Codes
Type : Extensible Version : 20yymmdd

Coding Scheme Designator	Code Value	Code Meaning
DCM121	newcode001	Appropriate for the indications
DCM121	newcode002	Consistent with labelling of the device
DCM121	newcode003	Approved for use at the institution
DCM121	newcode004	Approved for use in the clinical trial
DCM121	newcode006	Approved for use on the patient
DCM121	newcode007	Approved for use in the order
DCM121	newcode014	Approved for use in the procedure
DCM121	newcode015	Approved for experimental use
DCM121	newcode016	Eligible for reimbursement
DCM121	newcode008	Appropriate for the device
DCM121	newcode009	Operational for the device
DCM121	newcode010	Optimized for the device instance
DCM121	newcode011	Accurate record of what was performed
DCM121	newcode012	Disapproved for any use
DCM121	newcode017	Disapproved for pregnant females
DCM121	newcode013	Not approved for any use

Modify CID 7452 as shown

CID 7452 Organizational Roles

Type: Extensible
Version: 20~~14111~~0yymmdd

Table CID 7452. Organizational Roles

Coding Scheme Designator	Code Value	Code Meaning	SNOMED-CT Concept ID	UMLS Concept Unique ID
SRT	J-0016E	Medical Practitioner	158965000	C1306754
SRT	J-004E8	Physician	309343006	C0031831
DCM121	**newcode070**	**Head of Radiology**		
DCM121	**newcode071**	**Chair of Protocol Committee**		
DCM121	**newcode072**	**Head of Radiology Section**		
DCM121	**newcode073**	**Administrator of Imaging Department**		
SRT	J-07100	Nurse	106292003	C0028661
SRT	J-00187	Radiologic Technologist	159016003	C0402007
DCM121	**newcode074**	**Lead CT Technologist**		
SRT	J-00187	Radiographer	159016003	C0402007
DCM121	**newcode074**	**Lead CT Radiographer**		
UMLS	C1144859	Intern		C1144859
SRT	J-005E6	Resident	405277009	C1320928
SRT	J-00172	Registrar	158971006	C0401974
DCM	121088	Fellow		
SRT	J-005E8	Attending	405279007	C1320929
SRT	J-0050A	Consultant	309390008	C0586911
SRT	J-0714A	Scrub nurse	415506007	C1531952
SRT	J-00556	Surgeon	304292004	C0582175
DCM	121092	Sonologist		
UMLS	C1954848	Sonographer		C1954848
UMLS	C2985483	Radiation Physicist		C2985483
UMLS	C1708969	Medical Physicist		C1708969

Note

1. The distinction between a "physician" and a "surgeon" and a "medical practitioner" is subject to regional variation. In the US, "physician" is often equated with "medical practitioner", and a "surgeon" is considered

to be a "physician". In the UK, a "surgeon" is a "medical practitioner" but is not a "physician". In SNOMED, "physician" and "surgeon" are distinct siblings with no direct relationship, and both are children of "medical practitioner". It is recomended that "medical practitioner" be used rather than "physician" when there is uncertainty over whether the person is or is not a "surgeon".

2. There is no distinction between a "radiographer" and a "radiologic technologist", hence the same SNOMED concept is used for both, and "radiologic technologist" is provided as a synonym for use in the US.

3. In the US, the medical practitioner not in training responsible for the care of a hospital patient is referred to as an "attending". In the UK they are referrered to as a "consultant". Though these two concepts are essentially the same, they are separate concepts in SNOMED, which defines no explicit relationship between them.

Add the following rows to Annex D

DICOM Code Definitions (Coding Scheme Designator "DCM" Coding Scheme Version "01")

Code Value	Code Meaning	Definition	Notes
newcode001	Appropriate for the indications	The protocol is appropriate for the indications recorded in the protocol instance. AAOS defines an appropriate procedure as one for which the expected health benefits exceed the expected health risks by a wide margin.	
newcode002	Consistent with labelling of the device	The protocol is consistent with the regulatory product labelling of the device recorded in the protocol instance.	
newcode003	Approved for use at the institution	The protocol is approved for use at the institution recorded in the protocol instance.	
newcode004	Approved for use in the clinical trial	The protocol is approved for use in the clinical trial recorded in the protocol instance.	
newcode006	Approved for use on the patient	The protocol is approved for use on the patient recorded in the protocol instance.	
newcode007	Approved for use in the order	The protocol is approved for use in the order recorded in the protocol instance.	
newcode014	Approved for use in the procedure	The protocol is approved for use in the procedure recorded in the protocol instance.	
newcode015	Approved for	The protocol is approved for use in	

	experimental use	experimental procedures??	
newcode016	Eligible for reimbursement	The protocol is eligible for reimbursement.	
newcode008	Appropriate for the device	The protocol is appropriate for execution on the device recorded in the protocol instance. I.e. the protocol has incorporated model-specific parameters and optimizations as necessary.	
newcode009	Operational for the device	The protocol is within the operational parameters of the device recorded in the protocol instance. I.e. execution of the protocol is not expected to damage or exceed the operational limits of the device.	
newcode010	Optimized for the device instance	The protocol is optimized for the characteristics of the specific instance of the device recorded in the protocol instance. I.e. the protocol has incorporated device specific calibration parameters as of the timestamp of the signature the protocol has incorporated model-specific parameters and optimizations as necessary.	
newcode011	Accurate record of what was performed	The protocol is an accurate record of the protocol performed.	
newcode012	Disapproved for any use	The protocol is explicitly disapproved, or approval of the protocol has been withdrawn.	
newcode013	Not approved for any use	No approval Assertions have been made about the protocol.	
newcode017	Disapproved for pregnant females	The protocol is explicitly disapproved for use on pregnant female patients.	
newcode070	Head of Radiology	The senior ranking radiologist in the organization	
newcode071	Chair of Protocol Committee	The chair of a committee tasked with reviewing and approving CT protocols in the organization.	
newcode072	Head of Radiology Section	The senior ranking radiologist in a radiology section.	
newcode073	Administrator of Imaging Department	The administrative head of a department which provides imaging services.	
newcode074	Lead CT Technologist	The senior ranking CT	

		technologist in the organization.	

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Changes to NEMA Standards Publication PS 3.17

Digital Imaging and Communications in Medicine (DICOM)

Part 17: Explanatory Information

Add the following New Annex to Part 17 (WW is a placeholder)

Annex WW Protocol Storage Examples and Concepts (Informative)

The following examples are provided to illustrate the usage of various features of the CT Defined and Performed Procedure Protocol IODs. They do NOT represent recommended practice. In some cases they have been influenced by published protocols, but the examples here may not fully encode those published protocols and no attempt has been made to keep them up-to-date.

WW.1 AAPM ROUTINE ADULT HEAD PROTOCOL

This section includes Defined Protocol examples of the AAPM Routine Adult Head Protocol for serveral different scanner models.

Table WW-1a is basically the same for each model so it is shown here rather than duplicating it. The second half for two models is then shown below in Table WW-1b and WW10c.

Table WW-1a AAPM Routine Adult Head - Context

Attribute	Tag	Value
Modality	(0008,0060)	CT
Protocol Name	(0018,1030)	AAPM Routine Adult Head (Brain)
Indications	(yym1,m1x4)	Acute head trauma; Suspected acute intracranial hemorrhage; Immediate postoperative evaluation following brain surgery; Suspected shunt malfunctions, or shunt revisions; Mental status change; Increased intracranial pressure; Headache; Acute neurologic deficits; Suspected hydrocephalus; Evaluating psychiatric disorders; Brain herniation; Drug toxicity; Suspected mass or tumor;

		Seizures; Syncope; Detection of calcification; When magnetic resonance imaging (MRI) imaging is unavailable or contraindicated, or if the supervising physician deems CT to be most appropriate. **Diagnostic Tasks** Detect collections of blood; Identify brain masses; Detect brain edema or ischemia; Identify shift in the normal locations of the brain structures including in the cephalad or caudal directions; Evaluate the location of shunt hardware and the size of the ventricles; Evaluate the size of the sulci and relative changes in symmetry; Detect abnormal collections; Detect calcifications in the brain and related structures; Evaluate for fractures in the calvarium (skull); Detect any intracranial air.
Content Creator's Name	(0070,0084)	Joe Contributor
Protocol Design Comments	(yym1,m1x2)	Tube Current Modulation (or Automatic Exposure Control) may be used, but is often turned off; According to ACR CT Accreditation Program guidelines: - The diagnostic reference level (in terms of volume CTDI) is 75 mGy. - The pass/fail limit (in terms of volume CTDI) is 80 mGy. - These values are for a routine adult head scan and may be significantly different (higher or lower) for a given patient with unique indications. NOTE: All volume CTDI values are for the 16-cm diameter CTDI phantom. Additional Resources ACR–ASNR Practice Guideline For The Performance Of Computed Tomography (CT) Of The Brain, http://www.acr.org/Quality-Safety/Standards-Guidelines/Practice-Guidelines-by-Modality/CT. ACR CT Accreditation Program information, including Clinical Image Guide and Phantom Testing Instructions, http://www.acr.org/Quality-Safety/Accreditation/CT.
Protocol Planning Notes	(yym1,m1x1)	Contrast use as indicated by radiologist
Approval Sequence	(yym1,m1xa)	
>Assertion Code Sequence	(30xx,50A0)	(newcode002,DCM121,"Provided as appropriate for the indications")

>Assertion Source Identification Sequence	(0070,00QQ)	
>>Observer Type	(0040,A084)	PSN
>>Person Name	(0040,A123)	Working Group Chair?
>>Person Identification Code Sequence	(0040,1101)	(12345,NPI?,"Who?")
>>Institution Name	(0008,0080)	AAPM
>>Institution Code Sequence	(0008,0082)	(dummyOrg456,AAPM,"American Association of Physcists in Medicine")
>Assertion DateTime	(30xx,50A4)	20120601145327
>Assertion Expiry DateTime	(30xx,50A8)	20170601000000 *(based on a 5 yearly review plan)*
>Assertion Comments	(30xx,50A6)	DISCLAIMER: TO THE EXTENT ALLOWED BY LOCAL LAW, THIS INFORMATION IS PROVIDED TO YOU BY THE AMERICAN ASSOCIATION OF PHYCISISTS IN MEDICINE, A NON-PROFIT ORGANISATION ORGANIZED TO PROMOTE THE APPLICATION OF PHYSICS TO MEDICINE AND BIOLOGY, ENCOURAGE INTEREST AND TRAINING IN MEDICAL PHYSICS AND RELATED FIELDS ("AAPM"), 'AS IS' WITHOUT WARRANTIES OR CONDITIONS OF ANY KIND, WHETHER ORAL OR WRITTEN, EXPRESS OR IMPLIED. […]
>Pertinent Documents Sequence	(0038,0100)	
>>Retrieve URI	(0040,E010)	http://www.aapm.org/pubs/CTProtocols/documents/AdultRoutineHeadCT.pdf

WW.2 ACRIN 6678 CT PROTOCOL FOR TUMOR VOLUMETRIC MEASUREMENTS

This section includes a Defined Protocol example of the ACRIN 6678 CT Protocol for Tumor Volumetric Measurements. ACRIN 6678 provided parameter mappings to several models. The Philips mapping is shown here.

Table WW-2a is basically the same for each model so it is shown here rather than duplicating it. The second half for two models is then shown below in Table WW-1b and WW10c.

Table WW-2a ACRIN 6678 CT Tumor Volumetric Measurement - Context

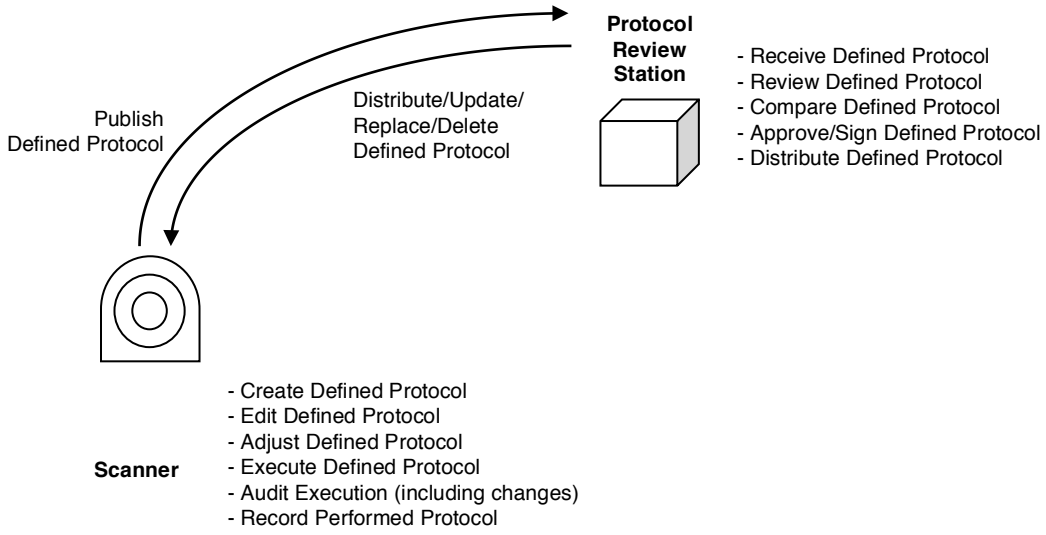
Attribute	Tag	Value

Clinical Trial Name	(0012,m7x1)	ACRIN 6678
Clinical Trial UID	(0012,m7x2)	a.b.c.d.e.f.ggg.hh.yyy
Clinical Trial Sponsor Name	(0012,0010)	American College of Radiology Imaging Network
Clinical Trial Protocol ID	(0012,0020)	6678
Clinical Trial Protocol Name	(0012,0021)	ACRIN 6678
Clinical Trial Site ID	(0012,0030)	“”
Clinical Trial Site Name	(0012,0031)	“”
Clinical Trial Coordinating Center Name	(0012,0060)	ACRIN Core Lab
Modality	(0008,0060)	CT
Protocol Name	(0018,1030)	ACRIN 6678 CT Tumor Volumetric Measurement
Scheduled Protocol Code Sequence	(0040,0008)	(dummy6678,ACR,"ACRIN6678 CT Protocol)
Indications	(yym1,m1x4)	Tumor Volumetric Measurements
Contraindications Code Sequence	(yym1,m1x7)	(newcode043,DCM121,”Pregnant”)
Content Creator’s Name	(0070,0084)	Jane Investigator
Protocol Design Comments	(yym1,m1x2)	See ACRIN 6678 Protocol documents: http://www.acrin.org/6678_protocol.aspx. In particular, see Appendix VII (CT Acquisition Parameters and Image Data Analysis) of the Protocol Document: http://www.acrin.org/Portals/0/Protocols/6678/ACRIN6678_Amend5_master-081310_AdUp_Online.pdf
Protocol Planning Notes	(yym1,m1x1)	Use of Intravenous Contrast Media, presence of motion artifacts or violation of slice width, slice interval or voxel size constraints will disqualify the CT scan series.
Approval Sequence	(yym1,m1xa)	
>Assertion Code Sequence	(30xx,50A0)	(newcode004,DCM121,”Approved for use in the clinical trial”)
>Assertion Source Identification	(0070,00QQ)	

Sequence		
>>Observer Type	(0040,A084)	PSN
>>Person Name	(0040,A123)	Dr. Marcus Welby
>>Person Identification Code Sequence	(0040,1101)	(dummy12345,NPI,”Marcus Welby, MD”)
>>Institution Name	(0008,0080)	ACR
>>Institution Code Sequence	(0008,0082)	(dummyOrg789,ACR,"American College of Radiology")
>Assertion DateTime	(30xx,50A4)	20080404102227
>Assertion Comments	(30xx,50A6)	This protocol was designed and developed by the American College of Radiology Imaging Network (ACRIN). It is intended to be used only in conjunction with institution-specific IRB approval for study entry.
>Pertinent Documents Sequence	(0038,0100)	
>>Retrieve URI	(0040,E010)	http://www.acrin.org/Portals/0/Protocols/6678/imaging/Parameters%20Chart%20for%20CT%20Volumetric%20Measurements.pdf

The following diagrams are included to facilitate thinking about how the protocol objects might be created, moved and modified in the process of addressing some of the key use cases to make sure the objects are reasonably designed for those purposes. This supplement will **not** mandate specific workflows or dataflows.

Managing Protocols Within a Site



Reviewing and comparing Defined Protocols on the Review Station are considered to be human tasks since they involve judgement (e.g., with respect to tradeoffs between diagnostic requirements, image quality and dose) and understanding (e.g., due to the different characteristics of different models, some parameters are used on some models and not others, and the same value for a given parameter can give different results on different models). While a tool might highlight parameter value differences between protocols, or provide access to mapping tables, the judgement and approval lies with the human.

CONCEPTS

Policies

The use of Defined Protocols does not remove control of the scanner, or responsibility for patient safety, from the technologist. The technologist should always review scan settings and confirm they are appropriate for the patient and procedure before accepting them and proceeding with a scan.

One could imagine implementation patterns (e.g., IHE Profiles) like:

- scanner query/retrieves protocols from PACS based on modality and filters based on protocols that list this scanner in the intended systems attributes
    - perhaps the scanner never loads for execution (i.e. never enables the confirm button) any Defined Protocol that does not list the scanner's model as intended system
    - perhaps the scanner can load other protocols for editing and then saving to PACS with themselves in the intended list
    - perhaps editing/saving (aka localizing) is only done by the chief radiologist
- prior to re-installation/upgrade, a scanner saves all its built-in protocols to PACS as Defined Protocols, afterward it can retrieve all CT Defined protocols and selectively reload those for its machine id or model.

- when editing for re-save, if all the updated settings stayed within the acceptable ranges in the original protocol, the new protocol can identify itself as a localization/specialization of that protocol.

- a scanner might use the acceptable ranges/values as a way to constrain the amount of adjustment a tech can make within given protocols before the system records the tech has “gone outside” the protocol. E.g., a chest protocol might give the tech more latitude to change the kVp/mAs than a knee protocol would.

- the Performed Protocol for a prior scan can be used as guidance for a subsequent scan.