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Digital Imaging and Communications in Medicine (DICOM)

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Supplement 192: Instance Approval Storage SOP Class

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Scope and Field of Application

- 62 This Supplement defines a storage SOP Class to record and convey approval (or disapproval) of instances. The nature, basis and scope of the approval depends on the semantics of the codes used in the
 64 assertion. Specific codes and examples are provided for assertions about CT Protocols stored as DICOM instances.
- 66 The assertions are encoded using a macro in this supplement which is also used in Supplement 178. The
 68 macro was originally part of the Supplement 121 and incorporated in the Protocol SOP Classes. A decision was made to make the macro a separate SOP Class defined in this supplement.

70

CLOSED ISSUES

Scope	
1	<p>Should the Approval Macro address digital signatures of the Protocol Instances?</p> <p><i>A. No.</i></p> <p>Assertions are attributed to the Identified person or device, but authenticating the person/device and/or digitally signing the instance in a way to prevent undetected changes go beyond the scope of DICOM services implementers appear willing to support.</p> <p>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.</p>
2	<p>Do the codes in newcid3 Protocol Assertion Codes cover typical CT Protocol approval practice?</p> <p><i>A: Yes.</i></p> <p>Several reviewers felt they were sufficient for the typical types of approval and protocol management that sites would like to use now and foresee using in the near future.</p>
3	<p>What conditions should void an approval and how should voiding be reflected?</p> <p><i>A: Approvals point to an instance, so effectively anything that creates a new instance by default voids approvals. So can approvals be cloned?</i></p> <p>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.</p> <p>IHE might mandate more specific behaviors.</p>

72

Changes to NEMA Standards Publication PS 3.2

74

Digital Imaging and Communications in Medicine (DICOM)

Part 2: Conformance

76

Add new SOP Classes in Table A.1-2

78

Table A.1-2
UID VALUES

UID Value	UID NAME	Category
...		
<u>1.2.840.10008.5.1.4.1.1.X.0.1</u>	<u>Instance Approval Storage</u>	<u>Transfer</u>
...		

80

Changes to NEMA Standards Publication PS 3.3

82

Digital Imaging and Communications in Medicine (DICOM)

Part 3: Information Object Definitions

84

Add definitions to 3.8

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

88

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

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

94

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

96 **10.XW1 ASSERTION MACRO**

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

100 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 when this macro is included, the Baseline CID for the Assertion Code Sequence (30xx,50A0) will be constrained.

102

**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.
<i>>Include 'Code Sequence Macro' Table 8.8-1</i>			<i>No Baseline CID defined</i>
Assertion UID		1	TODO
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.
<i>>Include 'Identified Person or Device Macro' Table C.17-3b</i>			<i>Baseline CID for Organizational Role is CID 7452 Organizational Roles</i>
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 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. One or more Items are permitted in this Sequence.
>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
Related Assertion Sequence		3	Other assertions which may be of interest to the receiving system
>Referenced Assertion UID		1	todo

104

106

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

108 **A.1.2.QQ Approval IE**

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

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

112 **Add section to Annex A**

A.X1 PROTOCOL APPROVAL INFORMATION OBJECT DEFINITIONS

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

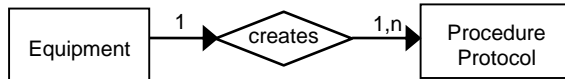
116 **A.X1.1 Approval Information Object Definition**

A.X1.1.1 Approval IOD Description

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

120 **A.X1.1.2 Approval IOD Entity-Relationship Model**

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



122

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

124 **A.X1.1.3 Approval IOD Module Table**

126

**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

128

A.X1.1.3.1 Approval IOD Content Constraints

130

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

C.17.2.4 Identified Person or Device Macro

134 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).

**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			<i>No Baseline Context ID defined</i>
<u>Organizational Role Code Sequence</u>		<u>3</u>	<u>The organizational capacity in which the person observer is participating</u>
>Include 'Code Sequence Macro' Table 8.8-1			<u>No Baseline Context ID defined</u>
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.
<u>Device Serial Number</u>	<u>(0018,1000)</u>	<u>3</u>	<u>Manufacturer's serial number of the identified device.</u> Note: While the serial number will be unique within the scope of the Manufacturer and Model, it might not be universally unique.
<u>Software Versions</u>	<u>(0018,1020)</u>	<u>3</u>	<u>Manufacturer's designation of software version of the identified device.</u> <u>See Section C.7.5.1.1.3.</u>
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			<i>No Baseline Context ID defined</i>

138

Add section to Annex C

140 **C.X4.2 Protocol Approval**

142 The Protocol Approval Module records approvals of the content of one or more SOP Instances containing protocols by a person or device.

144 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.

146 Neither the Approval Module 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.

148 **Table C.X4-2
APPROVAL MODULE ATTRIBUTES**

Attribute Name	Tag	Type	Attribute Description
Approval Subject Sequence	TODO		Instances that are the subject of the Approval Sequence. All assertions in the Approval Sequence (yym1,m1xa) apply to all instances in the Approval Subject Sequence (xxx)
<i>>Include Table 10-11. SOP Instance Reference Macro</i>			
Approval Sequence	(yym1,m1xa)	2	Recorded approvals of the subject instances. Zero or more items shall be included in this sequence.
<i>>Include 'Assertion Macro' Table 10.XW1-1</i>			The Baseline CID for the Assertion Code Sequence is newcid3. The Approver is recorded in the Assertion Source Identification Sequence inside the Assertion Macro.

150 A number of the Assertion codes in CID newcid3 are associated with information in Attributes of a Protocol object or Attributes referenced in Constraints in a Protocol object. The Attributes associated with each
152 Assertion code are shown in Table C.X4-3.

154 **Table C.X4-3
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)
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)

156 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
158 the event the needed approval is missing, it is conceivable that it may be useful to display the other
approvals to the system operator.

162

Changes to NEMA Standards Publication PS 3.4

Digital Imaging and Communications in Medicine (DICOM)

164

Part 4: Service Class Specifications

166

Add SOP Classes to Table B.5-1

B.5 STANDARD SOP CLASSES

168

Table B.5-1
Standard SOP Classes

SOP Class	SOP Class UID	IOD Specification (defined in PS 3.3)
...		
<u>Approval Storage</u>	<u>1.2.840.10008.5.1.4.1.1.X.0.1</u>	
...		

170

Add SOP Classes to Table I.4-1

172

I.4 MEDIA STORAGE SOP CLASSES

174

Table I.4-1
Media Storage Standard SOP Classes

SOP Class	SOP Class UID	IOD Specification
...		
<u>Approval Storage</u>	<u>1.2.840.10008.5.1.4.1.1.X.0.1</u>	<u>IOD defined in PS 3.3</u>
...		

176

Changes to NEMA Standards Publication PS 3.6

Digital Imaging and Communications in Medicine (DICOM)

178

Part 6: Data Dictionary

180 **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

182

Table A-1
UID Values

UID Value	UID Name	UID Type	Part
...			
<u>1.2.840.10008.5.1.4.1.1.X.0.1</u>	<u>Approval Storage</u>	<u>SOP Class</u>	<u>PS 3.4</u>
...			

184

186

Changes to NEMA Standards Publication PS 3.16

188

Digital Imaging and Communications in Medicine (DICOM)

Part 16: Content Mapping Resource

190

CID newcid3 Protocol Assertion Codes

192

**Context ID newcid3
 Protocol Assertion Codes**

194

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	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	newcode012	Disapproved for any use
DCM121	newcode017	Disapproved for pregnant females

196

Modify CID 7452 as shown

CID 7452 Organizational Roles

198

**Type: Extensible
 Version: 20141110yymmdd**

200

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
<u>DCM121</u>	<u>newcode070</u>	<u>Head of Radiology</u>		
<u>DCM121</u>	<u>newcode071</u>	<u>Chair of Protocol Committee</u>		

Coding Scheme Designator	Code Value	Code Meaning	SNOMED-CT Concept ID	UMLS Concept Unique ID
<u>DCM121</u>	<u>newcode072</u>	<u>Head of Radiology Section</u>		
<u>DCM121</u>	<u>Newcode075</u>	<u>Head of Cardiology Section</u>		
<u>DCM121</u>	<u>newcode073</u>	<u>Administrator of Imaging Department</u>		
SRT	J-07100	Nurse	106292003	C0028661
SRT	J-00187	Radiologic Technologist	159016003	C0402007
<u>DCM121</u>	<u>newcode074</u>	<u>Lead Imaging Technologist</u>		
<u>SRT</u>	<u>J-06173</u>	<u>Radiation Therapist</u>	<u>3430008</u>	
SRT	J-00187	Radiographer	159016003	C0402007
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

202

Note

204

206

208

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 recommended that "medical practitioner" be used rather than "physician" when there is uncertainty over whether the person is or is not a "surgeon".

210

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.

212 3. In the US, the medical practitioner not in training responsible for the care of a hospital patient is referred to
 214 as an "attending". In the UK they are referred 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.

216

Add the following rows to Annex D

218 **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.	
Newcode015	Approved for experimental use	The protocol is approved for use in experimental procedures.	
Newcode016	Eligible for reimbursement	The protocol is eligible for reimbursement by a given payer.	
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.	
Newcode012	Disapproved for any use	The protocol is explicitly disapproved, or approval of the protocol has been withdrawn.	
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 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 Imaging Technologist	The senior ranking imaging technologist in the organization.	
Newcode075	Head of Cardiology Section	The senior ranking cardiologist in a cardiology section.	

222

Changes to NEMA Standards Publication PS 3.17

Digital Imaging and Communications in Medicine (DICOM)

224

Part 17: Explanatory Information

226

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

Annex WW Protocol Storage Examples and Concepts (Informative)

228 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
230 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.

232

WW.1 AAPM ROUTINE ADULT HEAD PROTOCOL

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

236 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.

238

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;

		<p>Detection of calcification; When magnetic resonance imaging (MRI) imaging is unavailable or contraindicated, or if the supervising physician deems CT to be most appropriate.</p> <p style="text-align: center;">Diagnostic Tasks</p> <p>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.</p>
Content Creator's Name	(0070,0084)	Joe Contributor
Protocol Design Comments	(yym1,m1x2)	<p>Tube Current Modulation (or Automatic Exposure Control) may be used, but is often turned off; According to ACR CT Accreditation Program guidelines:</p> <ul style="list-style-type: none"> - 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. <p>NOTE: All volume CTDI values are for the 16-cm diameter CTDI phantom.</p> <p>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.</p>
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 Phycists in Medicine")
>Assertion DateTime	(30xx,50A4)	20120601145327
>Assertion Expiry DateTime	(30xx,50A8)	20170601000000 <i>(based on a 5 yearly review plan)</i>
>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

240

242 **WW.2 ACRIN 6678 CT PROTOCOL FOR TUMOR VOLUMETRIC MEASUREMENTS**

244 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.

246 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.

248 **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 Sequence	(0070,00QQ)	
>>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

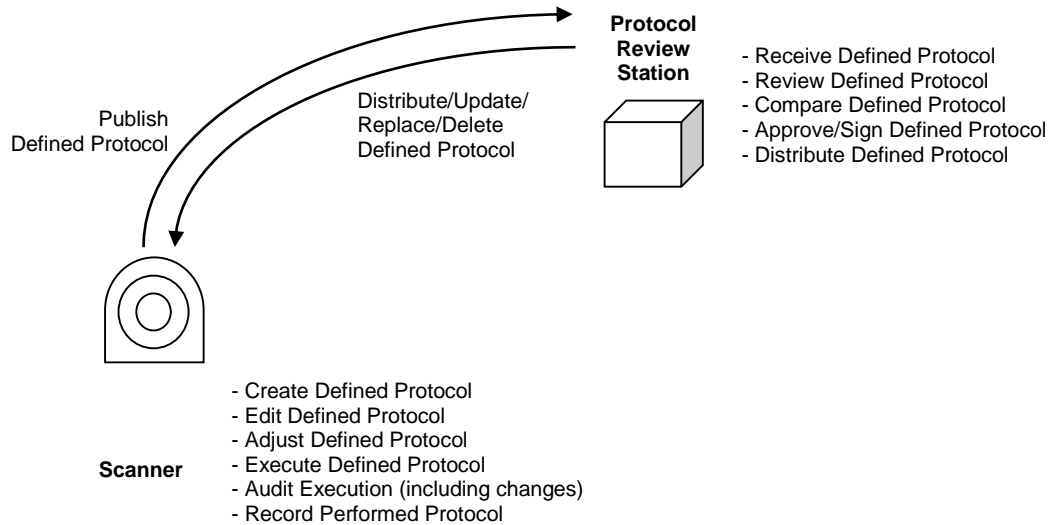
250

252

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.

256

Managing Protocols Within a Site



258

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.

260

262

264

266 **CONCEPTS**

Policies

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

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

- 272 • scanner query/retrieves protocols from PACS based on modality and filters based on protocols
that list this scanner in the intended systems attributes
- 274 ○ 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
- 276 ○ perhaps the scanner can load other protocols for editing and then saving to PACS with
themselves in the intended list
- 278 ○ perhaps editing/saving (aka localizing) is only done by the chief radiologist
- 280 • 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.
- 282 • 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.
- 284 • 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
286 protocol. E.g., a chest protocol might give the tech more latitude to change the kVp/mAs than a
knee protocol would.
- 288 • the Performed Protocol for a prior scan can be used as guidance for a subsequent scan.

290

BB Approval Query/Retrieve Service Classes

292 **BB.1 OVERVIEW**

BB.1.1 Scope

294 The Approval Query/Retrieve Service Classes define application-level classes-of-service that facilitate access to
Approval composite objects.

296

BB.1.2 Conventions

298 Key Attributes serve two purposes; they may be used as Matching Key Attributes or as Return Key Attributes. Matching
Key Attributes may be used for matching (criteria to be used in the C-FIND request to determine whether an entity

300 matches the query). Return Key Attributes may be used to specify desired return Attributes (what elements in addition
to the Matching Key Attributes have to be returned in the C-FIND response).

302 Note

304 Matching Keys are typically used in an SQL 'where' clause. Return Keys are typically used in an SQL 'select'
clause to convey the Attribute values.

306 Matching Key Attributes may be of Type "required" (R) or "optional" (O). Return Key Attributes may be of Type 1, 1C, 2,
2C, 3 as defined in PS3.5.

308 **BB.1.3 Query/Retrieve Information Model**

310 In order to serve as an SCP of the Approval Query/Retrieve Service Class, a DICOM AE possesses information about
the Attributes of a number of Approval composite SOP Instances. The information is organized into an Information
Model. The Information Models for the different SOP Classes specified in this Annex are defined in Section BB.6.

312

BB.1.4 Service Definition

314 Two peer DICOM AEs implement a SOP Class of a Approval Query/Retrieve Service Class with one serving in the SCU
role and one serving in the SCP role. SOP Classes of the Approval Query/Retrieve Service Classes are implemented
316 using the DIMSE-C C-FIND, C-MOVE and C-GET services as defined in PS3.7.

An SCP of this SOP Class shall support Level-2 conformance as defined in Section B.4.1.

318 The semantics of the C-FIND service are the same as those defined in the Service Definition of the Basic Worklist
Management Service Class.

320 The semantics of the C-MOVE service are the same as those defined in the Service Definition of the Query/Retrieve
Service Class, with the exception that there is only one level of retrieval.

322 The semantics of the C-GET service are the same as those defined in the Service Definition of the Query/Retrieve
Service Class, with the exception that there is only one level of retrieval.

324

BB.2 APPROVAL INFORMATION MODELS DEFINITIONS

326 The Approval Information Models are identified by the SOP Class negotiated at Association establishment time. Each
SOP Class is composed of both an Information Model and a DIMSE-C Service Group.

328 The Approval Information Models are defined in Section BB.6, with the Entity-Relationship Model Definition and Key
Attributes Definition analogous to those defined in the Worklist Information Model Definition of the Basic Worklist
330 Management Service.

332 **BB.3 APPROVAL INFORMATION MODELS**

The Approval Information Models are based upon a one level entity:

334 • Approval object instance.

336 The Approval object instance contains Attributes associated with the Approval IE of the Composite IODs as defined in
PS3.3.

338 **BB.4 DIMSE-C SERVICE GROUPS**

BB.4.1 C-FIND Operation

340 See the C-FIND Operation definition for the Basic Worklist Management Service Class (K.4.1), and substitute "Approval" for "Worklist". The "Worklist" Search Method shall be used.

342 The SOP Class UID identifies the Approval Information Model against which the C-FIND is to be performed. The Key Attributes and values allowable for the query are defined in the SOP Class definitions for the Approval Information Model.

344

BB.4.1.1 Service Class User Behavior

346 No SOP Class specific SCU behavior is defined.

348 **BB.4.1.2 Service Class Provider Behavior**

No SOP Class specific SCP behavior is defined.

350

BB.4.2 C-MOVE Operation

352 See the C-MOVE Operation definition for the Query/Retrieve Service Class (C.4.2). No Extended Behavior or Relational-Retrieve is defined for the Approval Query/Retrieve Service Classes.

354 Query/Retrieve Level (0008,0052) is not relevant to the Approval Query/Retrieve Service Classes, and therefore shall not be present in the Identifier. The only Unique Key Attribute of the Identifier shall be SOP Instance UID (0008,0018).

356 The SCU shall supply one UID or a list of UIDs.

Note

358 More than one entity may be retrieved, using List of UID matching.

360 **BB.4.3 C-GET Operation**

362 See the C-GET Operation definition for the Query/Retrieve Service Class (C.4.2). No Extended Behavior or Relational-Retrieve is defined for the Approval Query/Retrieve Service Classes.

Note

364 More than one entity may be retrieved, using List of UID matching.

366 **BB.5 ASSOCIATION NEGOTIATION**

See the Association Negotiation definition for the Basic Worklist Management Service Class (K.5).

368

BB.6 SOP CLASS DEFINITIONS

370 **BB.6.1 Approval Information Model**

BB.6.1.1 E/R Models

372 The Approval Information Model consists of a single entity. In response to a given C-FIND request, the SCP shall send one C-FIND response per matching Approval Instance.

374



376

Figure BB.6-1. Approval Information Model E/R Diagram

378 **BB.6.1.2 Approval Attributes**

Table BB.6-1 defines the Attributes of the Approval Information Model:

380

Table BB.6-1. Attributes for the Approval Information Model

Description / Module	Tag	Matching Key Type	Return Key Type	Remark / Matching Type
SOP Common				
Specific Character Set	(0008,0005)	-	1C	This Attribute is required if expanded or replacement character sets are used. See Section C.2.2.2 and Section C.4.1.1.
SOP Class UID	(0008,0016)	R	1	
SOP Instance UID	(0008,0018)	U	1	
Protocol Context				
Custodial Organization Sequence	(0040,A07C)	R	2	
>Institution Name	(0008,0080)	R	2	
>Institution Code Sequence	(0008,0082)	R	2	This Attribute shall be retrieved with Sequence or Universal matching.
>>Code Value	(0008,0100)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>>Coding Scheme Designator	(0008,0102)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>>Code Meaning	(0008,0104)	-	1	
Responsible Group Code Sequence	(0008,mx04)	R	2	This Attribute shall be retrieved with Sequence or Universal matching.
>Code Value	(0008,0100)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Coding Scheme Designator	(0008,0102)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Code Meaning	(0008,0104)	-	1	

Description / Module	Tag	Matching Key Type	Return Key Type	Remark / Matching Type
Protocol Name	(0018,1030)	R	1	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
Potential Scheduled Protocol Code Sequence	(yym1,m1xc)	R	1	This Attribute shall be retrieved with Sequence or Universal matching.
>Code Value	(0008,0100)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Coding Scheme Designator	(0008,0102)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Code Meaning	(0008,0104)	-	1	
Potential Requested Procedure Code Sequence	(yym1,m1xd)	R	1	This Attribute shall be retrieved with Sequence or Universal matching.
>Code Value	(0008,0100)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Coding Scheme Designator	(0008,0102)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Code Meaning	(0008,0104)	-	1	
Potential Reasons for Procedure	(yym1,m1x4)	-	2	
Potential Reasons for Procedure Code Sequence	(yym1,m1x6)	R	2	This Attribute shall be retrieved with Sequence or Universal matching.
>Code Value	(0008,0100)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Coding Scheme Designator	(0008,0102)	R	1	This Attribute shall be retrieved with Single Value or Universal matching.
>Code Meaning	(0008,0104)	-	1	
Potential Diagnostic Tasks	(yym1,m1x3)	-	2	
Predecessor Protocol Sequence	(yym1,m1xa)	R	2	
>Referenced SOP Class UID	(0008,1150)	R	1	Shall be retrieved with List of UID Matching.
>Referenced SOP Instance UID	(0008,1155)	R	1	Shall be retrieved with List of UID Matching.
Content Creator's Name	(0070,0084)	R	1	Shall be retrieved with Single Value, Wild Card, or Universal Matching.

Description / Module	Tag	Matching Key Type	Return Key Type	Remark / Matching Type
Instance Creation Date	(0008,0012)	R	1	Shall be retrieved with Single Value or Range Matching. See Instance Creation Time for further details.
Instance Creation Time	(0008,0013)	R	1	Shall be retrieved with Single Value or Range Matching. If both Instance Creation Date and Instance Creation Time are specified for Range Matching, they are to be treated as as if they were a single DateTime Attribute e.g., the date range July 5 to July 7 and the time range 10am to 6pm specifies the time period starting on July 5, 10am until July 7, 6pm.
Clinical Trial Context				
Clinical Trial Sponsor Name	(0012,0010)	R	1	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
Clinical Trial Protocol ID	(0012,0020)	R	1	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
Equipment Specification				
Equipment Modality	(0008,mx0a)	R	1	
Model Specification Sequence	(yym2,m2x3)	R	2	
Manufacturer	(0008,0070)	R	1	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
Manufacturer's Related Model Group	(0008,mx0b)	R	2	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
Manufacturer's Model Name	(0008,1090)	R	2	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
Software Versions	(0018,1020)	R	2	Shall be retrieved with Single Value, Wild Card, or Universal Matching.
>Device Serial Number	(0018,1000)	-	2	

382

BB.6.1.3 Conformance Requirements

384 An implementation may conform to one or more of the Approval Query/Retrieve SOP Classes as an SCU or SCP. The Conformance Statement shall be in the format defined in PS3.2.

386 **BB.6.1.3.1 SCU Conformance**

BB.6.1.3.1.1 C-FIND SCU Conformance

388 An implementation that conforms to the Approval Information Model - FIND SOP Class shall support
392 queries against the Approval Information Model using the C-FIND SCU Behavior described for the Basic
390 Worklist Management Service Class (see Section K.4.1.2 and Section BB.4.1).

An implementation that conforms to the Approval Information Model - FIND SOP Class as an SCU shall
392 state in its Conformance Statement whether it requests Type 3 Return Key Attributes, and shall list these
Optional Return Key Attributes.

394 An implementation that conforms to the Approval Information Model - FIND SOP Class as an SCU shall
state in its Conformance Statement how it makes use of Specific Character Set (0008,0005) when
396 encoding queries and interpreting responses.

BB.6.1.3.1.2 C-MOVE SCU Conformance

398 An implementation that conforms to the Approval Information Model - MOVE SOP Class as an SCU shall
support transfers against the Approval Information Model, using the C-MOVE SCU baseline behavior
400 described for the Query/Retrieve Service Class (see Section C.4.2.2.1 and Section BB.4.2).

BB.6.1.3.1.3 C-GET SCU Conformance

402 An implementation that conforms to the Approval Information Model - GET SOP Class as an SCU shall
support transfers against the Approval Information Model, using the C-GET SCU baseline behavior
404 described for the Query/Retrieve Service Class (see Section C.4.3.2).

BB.6.1.3.2 SCP Conformance

406 **BB.6.1.3.2.1 C-FIND SCP Conformance**

An implementation that conforms to the Approval Information Model - FIND SOP Class as an SCP shall
408 support queries against the Approval Information Model, using the C-FIND SCP Behavior described for the
Basic Worklist Management Service Class (see Section K.4.1.3).

410 **Note:** The contents of the Model Specification Sequence (yym2,m2x3) would be useful to database for systems
that support querying or selection of appropriate Protocols for specific systems.

412

An implementation that conforms to the Approval Information Model - FIND SOP Class as an SCP shall
414 state in its Conformance Statement whether it supports Type 3 Return Key Attributes, and shall list these
Optional Return Key Attributes.

416 An implementation that conforms to the Approval Information Model - FIND SOP Class as an SCP shall
state in its Conformance Statement how it makes use of Specific Character Set (0008,0005) when
418 interpreting queries, performing matching and encoding responses.

BB.6.1.3.2.2 C-MOVE SCP Conformance

420 An implementation that conforms to the Approval Information Model - MOVE SOP Class as an SCP shall
support transfers against the Approval Information Model, using the C-MOVE SCP baseline behavior
422 described for the Query/Retrieve Service Class (see Section C.4.2.3.1).

424 **Note:** It is expected that a device that does not match the contents of the Model Specification Sequence
(yym2,m2x3) will not execute the Protocol.

426 An implementation that conforms to the Approval Information Model - MOVE SOP Class as an SCP, which
generates transfers using the C-MOVE operation, shall state in its Conformance Statement appropriate
428 Storage Service Class, under which it shall support the C-STORE sub-operations generated by the C-
MOVE.

430 **BB.6.1.3.2.3 C-GET SCP Conformance**

432 An implementation that conforms to the Approval Information Model - GET SOP Class as an SCP shall support retrievals against the Approval Information Model using the C-GET SCP baseline behavior described for the Query/Retrieve Service Class in Section C.4.3.3.

434 **BB.6.1.4 SOP Classes**

436 The SOP Classes of the Approval Query/Retrieve Service Class identify the Information Models, and the DIMSE-C operations supported.

438 **Table BB.6.1.4-1. Approval SOP Classes**

SOP Class Name	SOP Class UID
Approval Information Model - FIND	1.2.840.10008.5.1.4.1.1.X.1.4
Approval Information Model - MOVE	1.2.840.10008.5.1.4.1.1.X.1.5
Approval Information Model - GET	1.2.840.10008.5.1.4.1.1.X.1.6

440

