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Digital Imaging and Communications in Medicine (DICOM)

8 *Supplement 192: Protocol Approval Storage SOP Class*

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VERSION: Draft for Letter Ballot

28 Developed pursuant to DICOM Work Item 2006-04-E

Table of Contents

80   **Scope and Field of Application**

This Supplement defines a storage SOP Class to record and convey approval (or disapproval) of DICOM
82 Defined Procedure Protocol instances. The nature, basis and scope of the approval depends on the
semantics of the codes used in the assertion. Specific codes and examples are provided for assertions
84 about CT Protocols.

86   **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 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.
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 prior approvals since the approval no longer points to the current instance. Also, a more recent approval may supercede a prior approval. The SCP may choose to "hide" protocol approval instances that are superceded? Interpretation of multiple available approval instances for the same protocol instance is up to the receiver* IHE might mandate more specific behaviors.

88

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	**Protocol 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.

Add subsection to 7.13 Non-Patient object models.

7.13.X Approval Information Entity

An Approval Information Entity describes an approval of an Instance.
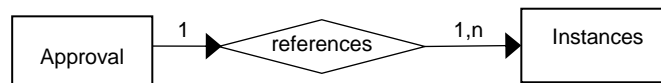
Figure 7.13.X-1. DICOM Model of the Real World – Approval

110 | **Add new section 10.XW1**

10.XW1 ASSERTION MACRO

112 This Macro is 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.

114 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
116 included, the Baseline CID for the Assertion Code Sequence (30xx,50A0) will be constrained.

Table 10.XW1-1
118 **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 UID	(30xx,50A1)	1	Unique identification of this assertion.
Asserter Identification Sequence	(0070,00QQ)	1	The person or device making the Assertion. Only a single Item shall be included in this sequence. Note: Multiple asserters wishing to make the same Assertion may be recorded as multiple Assertions, each with a single asserter.
>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 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	(30xx,50AB)	3	Other assertions which may be of interest to systems examining this assertion. Note: For example, an assertion that overrides a previous assertion or disapproves a previously approved protocol, could reference the prior approval instance making it easier to find/correlate/confirm.
>Referenced Assertion UID	(30xx,50AC)	1	Uniquely identifies a related assertion.

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120 **Add section to Annex A**

A.X1 PROTOCOL APPROVAL INFORMATION OBJECT DEFINITIONS

122 Protocol Approval Information Object Definitions (IODs) record the details of an approval of DICOM instances that contain protocols.

124 **A.X1.1   Protocol Approval Information Object Definition**

A.X1.1.1   Protocol Approval IOD Description

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

128 **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.
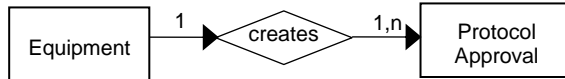
130

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

132 **A.X1.1.3   Protocol Approval IOD Module Table**

134

Table A.X1.1.3-1
Protocol 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
	Protocol Approval	C.X4.2	M

136

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

C.17.2.4   Identified Person or Device Macro

140 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).

142

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	**(30xx,50AE)**	**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*

144

Add section to Annex C

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146 **C.X4.2   Protocol Approval**

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

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

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

154 **Table C.X4-2**
PROTOCOL APPROVAL MODULE ATTRIBUTES

Attribute Name	Tag	Type	Attribute Description
Approval Subject Sequence	(30xx,50AD)	1	Instances that are the subject of the Approval Sequence. All assertions in the Approval Sequence (yym1,m1xa) apply to all instances in this sequence. One or more items shall be included in this sequence.
>Include Table 10-11. SOP Instance Reference Macro			
Approval Sequence	(yym1,m1xa)	1	Recorded approvals of the subject instances. One or more items shall be included in this sequence.
>Include 'Assertion Macro' Table 10.XW1-1			The Baseline CID for the Assertion Code Sequence is CID newcid3 "Protocol Assertion Codes". The Approver is recorded in the Asserter Identification Sequence inside the Assertion Macro.
>Institution Code Sequence	(0008,0082)	1C	Institution or organization for which use of the protocol is approved/disapproved or eligible/ineligible for reimbursement. Note: The institution identified by the code can represent a hospital network, a hospital, a clinic or a department. An instition can assign codes for it's subsidiary organizations. Required if Assertion Code Sequence (30xx,50A0) is (newcode003,DCM,"Approved for use at the institution") or (newcode003a,DCM,"Disapproved for use at the institution") or (newcode016,DCM,"Eligible for reimbursement") or (newcode016b,DCM,"Eligible for reimbursement on per patient basis") or (newcode016a,DCM,"Ineligible for reimbursement")
>Include 'Code Sequence Macro' Table 8.8-1			No Baseline CID defined

>Clinical Trial Protocol ID	(0012,0020)	1C	Identifier of the clinical trial protocol for which use of the protocol is approved or disapproved. Note: For experimental use this attribute is used to identify the experiment. Required if Assertion Code Sequence (30xx,50A0) is (newcode004,DCM,Approved for use in the clinical trial") or (newcode004a,DCM,"Disapproved for use in the clinical trial") or (newcode015,DCM,"Approved for experimental use") or (newcode015a,DCM,"Disapproved for experimental use ")

Note: The institution for which use of the protocol is approved (recorded in the Approval Sequence item) may or may not differ from the institution that is currently responsible for managing the protocol instance (recorded in the Custodial Organization Sequence (0040,A07C) of the Defined Protocol instance). Similarly, the clinical trial for which use of the protocol is approved (recorded in the Approval Sequence item) may or may not differ from the clinical trial, if any, for which the protocol instance was originally designed (recorded in the Clinical Trial Context of the Defined Protocol instance).

A number of the Assertion codes in CID newcid3 "Protocol Assertion Codes" affirm details related to Attributes in a Protocol object. The Protocol Attributes associated with each Assertion code are shown in Table C.X4-3.

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)
newcode001a	Inappropriate for the indications	Indications Code Sequence (yym1,m1x6)
newcode002	Consistent with labelling of the device	Model Specification Sequence (yym2,m2x3)
newcode002a	Inconsistent with labelling of the device	Model Specification Sequence (yym2,m2x3)
newcode008	Appropriate for the device	Model Specification Sequence (yym2,m2x3)
newcode008a	Inappropriate for the device	Model Specification Sequence (yym2,m2x3)
newcode009	Inside operational limits of the device	Model Specification Sequence (yym2,m2x3)
newcode009a	Outside operational limits of the device	Model Specification Sequence (yym2,m2x3)
newcode010	Optimized for the device instance	Model Specification Sequence (yym2,m2x3) Device Serial Number (0018,1000)
newcode010a	Not optimized for the device instance	Model Specification Sequence (yym2,m2x3) Device Serial Number (0018,1000)

Note: An instance may contain multiple approvals. Receiving systems will determine which approvals apply
168   and what may be useful to display to the system operator.

170

172

Changes to NEMA Standards Publication PS 3.4

174 # Digital Imaging and Communications in Medicine (DICOM)

Part 4: Service Class Specifications

176

Add SOP Classes to Table GG.3-1

178 **GG.3**   **SOP CLASSES**

Table GG.3-1
180 **Standard SOP Classes**

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

---

182 ***Add application behaviors to GG.6***

GG.6.X   **PROTOCOL APPROVAL SOP CLASS**

184 Approvals are based on assertions. Receipt or generation of an assertion will interact with organizational
authentication and authorization policies. For example, an approval may be received by mistake as part of
186 the transfer of a patient record.

Add Query/Retrieve Service Classes (BB is a placeholder)

BB Protocol Approval Query/Retrieve Service Classes

BB.1 OVERVIEW

190 BB.1.1 Scope

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

194 BB.1.2 Conventions

Key Attributes serve two purposes; they may be used as Matching Key Attributes or as Return Key Attributes.
196 Matching Key Attributes may be used for matching (criteria to be used in the C-FIND request to determine whether an
entity matches the query). Return Key Attributes may be used to specify desired return Attributes (what elements in
198 addition to the Matching Key Attributes have to be returned in the C-FIND response).

Note

200 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.

202 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.

204
BB.1.3 Query/Retrieve Information Model

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

210
BB.1.4 Service Definition

212 Two peer DICOM AEs implement a SOP Class of a Protocol Approval Query/Retrieve Service Class with one serving
in the SCU role and one serving in the SCP role. SOP Classes of the Protocol Approval Query/Retrieve Service
214 Classes are implemented 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.

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

218 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.

220 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.

222
BB.2 PROTOCOL APPROVAL INFORMATION MODELS DEFINITIONS

224 The Protocol 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.

226 The Protocol 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
228 Worklist Management Service.

230 **BB.3 PROTOCOL APPROVAL INFORMATION MODELS**

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

232 • Protocol Approval object instance.

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

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

BB.4.1 C-FIND Operation

238 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.

240 The SOP Class UID identifies the Protocol 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 Protocol
242 Approval Information Model.

244 **BB.4.1.1 Service Class User Behavior**

No SOP Class specific SCU behavior is defined.

246
BB.4.1.2 Service Class Provider Behavior

248 No SOP Class specific SCP behavior is defined.

250 **BB.4.2 C-MOVE Operation**

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

Query/Retrieve Level (0008,0052) is not relevant to the Protocol Approval Query/Retrieve Service Classes, and
254 therefore shall not be present in the Identifier. The only Unique Key Attribute of the Identifier shall be SOP Instance
UID (0008,0018). The SCU shall supply one UID or a list of UIDs.

256 Note

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

258
BB.4.3 C-GET Operation

260 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 Protocol Approval Query/Retrieve Service Classes.

262 Note

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

264
BB.5 ASSOCIATION NEGOTIATION

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

268 **BB.6 SOP CLASS DEFINITIONS**

BB.6.1 Protocol Approval Information Model

270 **BB.6.1.1 E/R Models**

The Protocol Approval Information Model consists of a single entity. In response to a given C-FIND request, the SCP
272 shall send one C-FIND response per matching Protocol Approval Instance.
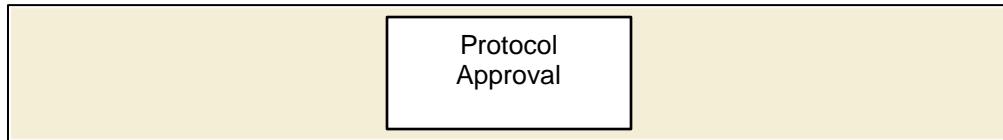
274

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

276

BB.6.1.2 Protocol Approval Attributes

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

Note: Since protocol approvals are generally relevant only in the context of the protocol instance being
280 approved, many searches will be looking for approvals that list a particular protocol instance in the
Approval Subject Sequence (30xx,50AD).

282 **Table BB.6-1. Attributes for the Protocol 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	
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.

Description / Module	Tag	Matching Key Type	Return Key Type	Remark / Matching Type
Protocol Approval				
Approval Subject Sequence	(30xx,50AD)	R	1	
>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.
Approval Sequence	(yym1,m1xa)	R	1	
>Assertion Code Sequence	(30xx,50A0)	R	1	
>>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	
>Assertion UID	(30xx,50A1)	-	1	
>Asserter Identification Sequence	(0070,00QQ)	R	1	
>>Observer Type	(0040,A084)	-	1	
>>Person Name	(0040,A123)	R	1	
>>Person Idenfication Code Sequence	(0040,1101)	R	1	
>>>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	
>>Organizational Role Code Sequence	(30xx,50AE)	R	2	
>>>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	
>>Station Name	(0008,1010)	-	3	
>>Device UID	(0018,1002)	-	3	

Description / Module	Tag	Matching Key Type	Return Key Type	Remark / Matching Type
>>Manufacturer	(0008,0070)	-	3	
>>Manufacturer's Model Name	(0008,1090)	-	3	
>>Station AE Title	(0008,0055)	-	3	
>>Institution Name	(0008,0080)	R	1	
>>Institution Code Sequence	(0008,0082)	R	1	
>>>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	
>>Institutional Department Name	(0008,1040)	U	2	
>Assertion DateTime	(30xx,50A4)	R	1	This Attribute shall be retrieved with Single Value or Range Matching.
>Assertion Expiry DateTime	(30xx,50A8)	R	2	This Attribute shall be retrieved with Single Value or Range Matching.
>Assertion Comments	(30xx,50A6)	-	2	
>Related Assertion Sequence	(30xx,50AB)	U	1	
>>Referenced Assertion UID	(30xx,50AC)	U	1	
Enhanced General Equipment				
Manufacturer	(0008,0070)	-	1	
Manufacturer's Model Name	(0008,1090)	-	2	
Software Versions	(0018,1020)	-	2	

284   Note: The Enhanced General Equipment Module describes the equipment that created the Protocol Approval instance, not the equipment on which a referenced Protocol will be performed.

286

BB.6.1.3 Conformance Requirements

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

290 BB.6.1.3.1 SCU Conformance

BB.6.1.3.1.1 C-FIND SCU Conformance

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

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

298 An implementation that conforms to the Protocol 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)
300 when encoding queries and interpreting responses.

BB.6.1.3.1.2 C-MOVE SCU Conformance

302 An implementation that conforms to the Protocol Approval Information Model - MOVE SOP Class as an
SCU shall support transfers against the Protocol Approval Information Model, using the C-MOVE SCU
304 baseline behavior 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

306

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

310 ### BB.6.1.3.2 SCP Conformance

BB.6.1.3.2.1 C-FIND SCP Conformance

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

> Note: The contents of the Referenced SOP Instance UID (0008,1155) in the Approval Subject Sequence
> 316 (30xx,50AD) would be useful to index since querying for approvals of a specific Protocol instance will be
> very common.

318

An implementation that conforms to the Protocol Approval Information Model - FIND SOP Class as an
320 SCP shall state in its Conformance Statement:

- whether it supports Type 3 Return Key Attributes, and shall list these Optional Return Key
322   Attributes.
- how it makes use of Specific Character Set (0008,0005) when interpreting queries, performing
324   matching and encoding responses.
- any behaviors that involve not returning matching instances (e.g. not returning an older approval
326   instance that has been superceded/overridden by a newer approval instance).

BB.6.1.3.2.2 C-MOVE SCP Conformance

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

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

BB.6.1.3.2.3 C-GET SCP Conformance

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

340 **BB.6.1.4 SOP Classes**

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

Table BB.6.1.4-1. Protocol Approval SOP Classes
344

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

346

Changes to NEMA Standards Publication PS 3.6

348

Digital Imaging and Communications in Medicine (DICOM)

Part 6: Data Dictionary

350

Add the following rows to Section 6

Tag	Name	Keyword	VR	VM
(yym1,m1xa)	Approval Sequence		SQ	1
(30xx,50A0)	Assertion Code Sequence		SQ	1
(30xx,50A1)	Assertion UID		UI	1
(0070,00QQ)	Asserter 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
(30xx,50AB)	Related Assertion Sequence		SQ	1
(30xx,50AC)	Referenced Assertion UID		UI	1
(30xx,50AD)	Approval Subject Sequence		SQ	1
(30xx,50AE)	Organizational Role Code Sequence		SQ	1

352 *Add the following rows to Table A-1*

Table A-1
UID Values

354

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

356	**Changes to NEMA Standards Publication PS 3.16**

Digital Imaging and Communications in Medicine (DICOM)

358	**Part 16: Content Mapping Resource**

360	**CID newcid3 Protocol Assertion Codes**

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

Coding Scheme Designator	Code Value	Code Meaning
DCM121	newcode001	Appropriate for the indications
DCM121	newcode001a	Inappropriate for the indications
DCM121	newcode002	Consistent with labelling of the device
DCM121	newcode002a	Inconsistent with labelling of the device
DCM121	newcode003	Approved for use at the institution
DCM121	newcode003a	Disapproved for use at the institution
DCM121	newcode004	Approved for use in the clinical trial
DCM121	newcode004a	Disapproved for use in the clinical trial
DCM121	newcode015	Approved for experimental use
DCM121	newcode015a	Disapproved for experimental use
DCM121	newcode016	Eligible for reimbursement
DCM121	newcode016b	Eligible for reimbursement on per patient basis
DCM121	newcode016a	Ineligible for reimbursement
DCM121	newcode008	Appropriate for the device
DCM121	newcode008a	Inappropriate for the device
DCM121	newcode009	Inside operational limits of the device
DCM121	newcode009a	Outside operational limits of the device
DCM121	newcode010	Optimized for the device instance
DCM121	newcode010a	Not optimized for the device instance
DCM121	newcode012	Disapproved for any use
DCM121	newcode017a	Approved for pregnant patients
DCM121	newcode017	Disapproved for pregnant patients

364

Modify CID 7452 as shown

366	**CID 7452 Organizational Roles**

Type: Extensible
368	**Version: 20141110yymmdd**

Table CID 7452. Organizational Roles

370

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	**newcode076**	**Representative of Protocol Committee**		
DCM121	**newcode077**	**Representative of Ethics Committee**		
DCM121	**newcode072**	**Head of Radiology Section**		
DCM121	**newcode075**	**Head of Cardiology Section**		
DCM121	**newcode073**	**Administrator of Imaging Department**		
SRT	J-07100	Nurse	106292003	C0028661
SRT	J-00187	Radiologic Technologist	159016003	C0402007
DCM121	**newcode074**	**Lead Imaging Technologist**		
SRT	**J-06173**	**Radiation Therapist**	**3430008**	
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

Note

372   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

374   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
376   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".

378   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.

380   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
382   essentially the same, they are separate concepts in SNOMED, which defines no explicit relationship between them.

384

Add the following rows to Annex D

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386   **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.	
newcode001a	Inappropriate for the indications	The protocol is inappropriate 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.	
Newcode002a	Inconsistent with labelling of the device	The protocol is inconsistent 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.	
Newcode003a	Disapproved for use at the institution	The protocol is disapproved for use at the institution recorded in the approval instance.	
Newcode004	Approved for use in the clinical trial	The protocol is approved for use in the clinical trial recorded in the	

		protocol instance.	
Newcode004a	Disapproved for use in the clinical trial	The protocol is disapproved 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.	
Newcode015a	Disapproved for experimental use	The protocol is disapproved for use in experimental procedures.	
Newcode016	Eligible for reimbursement	The protocol is understood to be eligible for reimbursement by a given payer.	
Newcode016b	Eligible for reimbursement on per patient basis	The protocol is understood to be eligible for reimbursement on a per patient basis by a given payer.	
Newcode016a	Ineligible for reimbursement	The protocol is understood to be ineligible 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 (which may identify an individual device by serial number or may identify a family of devices). I.e. the protocol has incorporated model-specific parameters and optimizations as necessary.	
Newcode008a	Inappropriate for the device	The protocol is inappropriate for execution on the device recorded in the protocol instance (which may identify an individual device by serial number or may identify a family of devices).	
Newcode009	Inside operational limits of the device	The protocol specifies parameters that are within the operational limits 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.	
Newcode009a	Outside operational limits of the device	The protocol specifies parameters that are not within the operational limits of the device recorded in the protocol instance. I.e. execution of the protocol may 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 model-specific parameters and optimizations as necessary.	
Newcode010a	Not optimized for the device instance	The protocol is not optimized for the characteristics of the specific instance of the device recorded in the protocol instance.	
Newcode012	Disapproved for any use	The protocol is explicitly disapproved, or approval of the protocol has been withdrawn.	
Newcode017	Disapproved for pregnant patients	The protocol is explicitly disapproved for use on pregnant patients.	
Newcode017a	Approved for pregnant patients	The protocol is specifically approved for use on pregnant 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.	
Newcode076	Representative of Protocol Committee	A representative of a committee tasked with reviewing and approving protocols in the organization.	
Newcode077	Representative of Ethics Committee	A representative of a committee tasked with evaluating medical ethics.	

388

₃₉₀ **Changes to NEMA Standards Publication PS 3.17**

Digital Imaging and Communications in Medicine (DICOM)

₃₉₂ **Part 17: Explanatory Information**

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

₃₉₄ **Annex WW   Protocol Approval Examples and Concepts (Informative)**

The following example is provided to illustrate the usage of the Protocol Approval IOD.

₃₉₆ This example shows approval of a pair of CT Protocols for routine adult head studies. It is approved by the Chief of Radiology and by the Physicist. The Instance UIDs of the two CT Protocols are 1.2.3.456.7.7 and ₃₉₈ 1.2.3.456.7.8.

Note that the Institution Code Sequence (0008,0082) inside the Asserter Identification Sequences ₄₀₀ (0070,00QQ) communicates that Mercy Hospital is the organization to which Dr. Welby is responsible. The Institution Code Sequence (0008,0082) at the end of the first Approval Item communicates that Mercy ₄₀₂ Hospital is the institution for which the protocols are "Approved for use at the institution".

Table WW-1a Approval by Chief Radiologist

₄₀₄

Attribute	Tag	Value
Manufacturer	(0008,0070)	Acme Corp.
Manufacturer's Model Name	(0008,1090)	Primo Protocol Management Workstation Plus
Device Serial Number	(0018,1000)	A59848573
Software Versions	(0018,1020)	V2.3
SOP Class UID	(0008,0016)	1.2.840.10008.5.1.4.1.1.X.0.1 *(Protocol Approval)*
SOP Instance UID	(0008,0018)	1.33.9.876.1.1.1
Approval Subject Sequence	(30xx,50AD)	
Item #1		
>Referenced SOP Class UID	(0008,1150)	1.2.840.10008.5.1.4.1.1.200.1 *(CT Defined Procedure Protocol)*
>Referenced SOP Instance UID	(0008,1155)	1.2.3.456.7.7
Item #2		
>Referenced SOP Class UID	(0008,1150)	1.2.840.10008.5.1.4.1.1.200.1 *(CT Defined Procedure Protocol)*
>Referenced SOP Instance UID	(0008,1155)	1.2.3.456.7.8

Approval Sequence	(yym1,m1xa)	
Item #1		
>Assertion Code Sequence	(30xx,50A0)	(newcode003,DCM,"Approved for use at the institution")
>Assertion UID	(30xx,50A1)	1.2.33.9.876.5.5.5.5.21
>Asserter Identification Sequence	(0070,00QQ)	
>>Observer Type	(0040,A084)	PSN
>>Person Name	(0040,A123)	"Welby, Marcus"
>>Person Identification Code Sequence	(0040,1101)	(12345,NPI,"Marcus Welby, MD")
>>Organizational Role Code Sequence	(30xx,50AE)	(newcode070,DCM,"Head of Radiology")
>>Institution Name	(0008,0080)	Mercy Hospital, Centerville
>>Institution Code Sequence	(0008,0082)	(000011113,NPI,"Mercy Hospital, Centerville")
>Assertion DateTime	(30xx,50A4)	20150601145327
>Assertion Expiry DateTime	(30xx,50A8)	20200601000000 *(based on a 5 yearly review plan)*
>Institution Code Sequence	(0008,0082)	(000011113,NPI,"Mercy Hospital, Centerville")
Item #2		
>Assertion Code Sequence	(30xx,50A0)	(newcode017a,DCM,"Approved for pregnant patients")
>Assertion UID	(30xx,50A1)	1.2.33.9.876.5.5.5.5.22
>Asserter Identification Sequence	(0070,00QQ)	
>>Observer Type	(0040,A084)	PSN
>>Person Name	(0040,A123)	"Welby, Marcus"
>>Person Identification Code Sequence	(0040,1101)	(12345,NPI,"Marcus Welby, MD")
>>Organizational Role Code Sequence	(30xx,50AE)	(newcode070,DCM,"Head of Radiology")
>>Institution Name	(0008,0080)	Mercy Hospital, Centerville
>>Institution Code Sequence	(0008,0082)	(000011113,NPI,"Mercy Hospital, Centerville")
>Assertion DateTime	(30xx,50A4)	20150601145327
>Assertion Expiry DateTime	(30xx,50A8)	20200601000000 *(based on a 5 yearly review plan)*
>Assertion Comments	(30xx,50A6)	"Limited scan range and proper use of abdominal shielding result in negligible dose to the fetus."