Digital Imaging and Communications in Medicine (DICOM)

Supplement 192: Protocol Approval Storage SOP Class

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Scope and Field of Application

This Supplement defines a storage SOP Class to record and convey approval (or disapproval) of DICOM 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 about CT Protocols.
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>
<thead>
<tr>
<th>UID Value</th>
<th>UID NAME</th>
<th>Category</th>
</tr>
</thead>
<tbody>
<tr>
<td>…</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2.840.10008.5.1.4.1.1.X.0.1</td>
<td>Protocol Approval Storage</td>
<td>Transfer</td>
</tr>
<tr>
<td>…</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
Add new section 10.XW1

10.XW1  ASSERTION MACRO

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.

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.

Table 10.XW1-1
ASSERTION MACRO ATTRIBUTES

<table>
<thead>
<tr>
<th>Attribute Name</th>
<th>Tag</th>
<th>Type</th>
<th>Attribute Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assertion Code Sequence</td>
<td>(30xx,50A0)</td>
<td>1</td>
<td>The Assertion being made. Only a single Item shall be included in this sequence.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td><em>Include 'Code Sequence Macro' Table 8.8-1</em> No Baseline CID defined</td>
</tr>
<tr>
<td>Assertion UID</td>
<td>(30xx,50A1)</td>
<td>1</td>
<td>Unique identification of this assertion.</td>
</tr>
<tr>
<td>Asserter Identification Sequence</td>
<td>(0070,00QQ)</td>
<td>1</td>
<td>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. <em>Include 'Identified Person or Device Macro' Table C.17-3b</em> Baseline CID for Organizational Role is CID 7452 Organizational Roles</td>
</tr>
<tr>
<td>Assertion DateTime</td>
<td>(30xx,50A4)</td>
<td>1</td>
<td>Date and time at which the Assertion was made.</td>
</tr>
<tr>
<td>Assertion Expiry DateTime</td>
<td>(30xx,50A8)</td>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>Assertion Comments</td>
<td>(30xx,50A6)</td>
<td>3</td>
<td>Comments on the nature, extent or basis of the Assertion.</td>
</tr>
<tr>
<td>Pertinent Documents Sequence</td>
<td>(0038,0100)</td>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------</td>
<td>---</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>&gt;Referenced SOP Class UID</td>
<td>(0008,1150)</td>
<td>3</td>
<td>Unique identifier for the class of the referenced document.</td>
</tr>
<tr>
<td>&gt;Referenced SOP Instance UID</td>
<td>(0008,1155)</td>
<td>3</td>
<td>Unique identifier for the referenced document as used in DICOM instance references (see C.12.1.1.6)</td>
</tr>
<tr>
<td>&gt;HL7 Instance Identifier</td>
<td>(0040,E001)</td>
<td>3</td>
<td>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).</td>
</tr>
<tr>
<td>&gt;Retrieve URI</td>
<td>(0040,E010)</td>
<td>3</td>
<td>Retrieval access path to the referenced document. Includes fully specified scheme, authority, path, and query in accordance with RFC 2396</td>
</tr>
<tr>
<td>Related Assertion Sequence</td>
<td>(30xx,50AB)</td>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>&gt;Referenced Assertion UID</td>
<td>(30xx,50AC)</td>
<td>1</td>
<td>Uniquely identifies a related assertion.</td>
</tr>
</tbody>
</table>

Add new IOD to Table A.1-3 with Modules described below in Table A.X1.1.3-1

Add section to Annex A
A.X1 PROTOCOL APPROVAL INFORMATION OBJECT DEFINITIONS

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

A.X1.1 Protocol Approval Information Object Definition

A.X1.1.1 Protocol Approval IOD Description

The Protocol 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 PROTOCOL APPROVAL IOD E-R MODEL

A.X1.1.3 Protocol Approval IOD Module Table

<table>
<thead>
<tr>
<th>IE</th>
<th>Module</th>
<th>Reference</th>
<th>Usage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Equipment</td>
<td>General Equipment</td>
<td>C.7.5.1</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Enhanced General Equipment</td>
<td>C.7.5.2</td>
<td>M</td>
</tr>
<tr>
<td>Approval</td>
<td>SOP Common</td>
<td>C.12.1</td>
<td>M</td>
</tr>
<tr>
<td></td>
<td>Protocol Approval</td>
<td>C.X4.2</td>
<td>M</td>
</tr>
</tbody>
</table>

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

C.17.2.4 Identified Person or Device Macro

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

<table>
<thead>
<tr>
<th>Attribute Name</th>
<th>Tag</th>
<th>Type</th>
<th>Attribute Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observer Type</td>
<td>(0040,A084)</td>
<td>1</td>
<td>Enumerated Values:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>PSN – Person</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>DEV – Device</td>
</tr>
<tr>
<td>Field</td>
<td>Code</td>
<td>Class</td>
<td>Description</td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>----------------</td>
<td>-------</td>
<td>----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Person Name</td>
<td>(0040,A123)</td>
<td>1C</td>
<td>Name of the person observer for this document instance. Required if Observer Type value is PSN.</td>
</tr>
<tr>
<td>Person Identification Code Sequence</td>
<td>(0040,1101)</td>
<td>2C</td>
<td>Coded identifier of person observer. Zero or one Item shall be included in this sequence. Required if Observer Type value is PSN.</td>
</tr>
<tr>
<td>Organizational Role Code Sequence</td>
<td>(30xx,50AE)</td>
<td>3</td>
<td>The organizational capacity in which the person observer is participating</td>
</tr>
<tr>
<td>Station Name</td>
<td>(0008,1010)</td>
<td>2C</td>
<td>Name of the device observer for this document instance. Required if Observer Type value is DEV.</td>
</tr>
<tr>
<td>Device UID</td>
<td>(0018,1002)</td>
<td>1C</td>
<td>Unique identifier of device observer. Required if Observer Type value is DEV.</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>(0008,0070)</td>
<td>1C</td>
<td>Manufacturer of the device observer. Required if Observer Type value is DEV.</td>
</tr>
<tr>
<td>Manufacturer’s Model Name</td>
<td>(0008,1090)</td>
<td>1C</td>
<td>Model Name of the device observer. Required if Observer Type value is DEV.</td>
</tr>
<tr>
<td>Station AE Title</td>
<td>(0008,0055)</td>
<td>3</td>
<td>Application Entity Title of the device identified.</td>
</tr>
<tr>
<td>Device Serial Number</td>
<td>(0018,1000)</td>
<td>3</td>
<td>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.</td>
</tr>
<tr>
<td>Software Versions</td>
<td>(0018,1020)</td>
<td>3</td>
<td>Manufacturer’s designation of software version of the identified device. See Section C.7.5.1.1.3.</td>
</tr>
<tr>
<td>Institution Name</td>
<td>(0008,0080)</td>
<td>2</td>
<td>Institution or organization to which the identified person is responsible or accountable, or which manages the identified device.</td>
</tr>
<tr>
<td>Institution Code Sequence</td>
<td>(0008,0082)</td>
<td>2</td>
<td>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.</td>
</tr>
<tr>
<td>Institutional Department Name</td>
<td>(0008,1040)</td>
<td>3</td>
<td>Department in the institution or organization to which the identified person is responsible or accountable, or that manages the identified device.</td>
</tr>
</tbody>
</table>
C.X4.2 Protocol Approval

The Protocol Approval Module records approvals of the content of one or more SOP Instances containing 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 Code in the embedded Assertion Macro.

Neither the Protocol 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.

<table>
<thead>
<tr>
<th>Attribute Name</th>
<th>Tag</th>
<th>Type</th>
<th>Attribute Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Subject Sequence</td>
<td>(30xx,50AD)</td>
<td>1</td>
<td>Instances that are the subject of the Approval Sequence. All Assertions in the Approval Sequence (yyym1, m1xa) apply to all instances in this sequence. One or more items shall be included in this sequence.</td>
</tr>
<tr>
<td>Approval Sequence</td>
<td>(yyym1, m1xa)</td>
<td>1</td>
<td>Recorded approvals of the subject instances. One or more items shall be included in this sequence.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>The Baseline CID for the Assertion Code Sequence is CID newcid3 &quot;Protocol Assertion Codes&quot;. The Approver is recorded in the Asserter Identification Sequence inside the Assertion Macro.</td>
</tr>
</tbody>
</table>
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 institution can assign codes for its 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")

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. A receiving system might display the associated attribute contents together with the Assertion code to convey the full meaning of the assertion.

Table C.X4-3
Associated Attributes for Protocol Assertion Codes

<table>
<thead>
<tr>
<th>Code Value</th>
<th>Code Meaning</th>
<th>Associated Attribute</th>
</tr>
</thead>
<tbody>
<tr>
<td>newcode001</td>
<td>Appropriate for the indications</td>
<td>Potential Reasons for Procedure Code Sequence (0018,9909)</td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Potential Reasons for Procedure Code Sequence</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>newcode001a</td>
<td>Inappropriate for the indications</td>
<td>(0018,9909)</td>
</tr>
<tr>
<td>newcode002</td>
<td>Consistent with labelling of the device</td>
<td>(0018,9912)</td>
</tr>
<tr>
<td>newcode002a</td>
<td>Inconsistent with labelling of the device</td>
<td>(0018,9912)</td>
</tr>
<tr>
<td>newcode008</td>
<td>Appropriate for the device</td>
<td>(0018,9912)</td>
</tr>
<tr>
<td>newcode008a</td>
<td>Inappropriate for the device</td>
<td>(0018,9912)</td>
</tr>
<tr>
<td>newcode009</td>
<td>Inside operational limits of the device</td>
<td>(0018,9912)</td>
</tr>
<tr>
<td>newcode009a</td>
<td>Outside operational limits of the device</td>
<td>(0018,9912)</td>
</tr>
<tr>
<td>newcode010</td>
<td>Optimized for the device instance</td>
<td>(0018,9912) Device Serial Number (0018,1000)</td>
</tr>
<tr>
<td>newcode010a</td>
<td>Not optimized for the device instance</td>
<td>(0018,9912) Device Serial Number (0018,1000)</td>
</tr>
</tbody>
</table>

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

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 GG.3-1

GG.3 SOP CLASSES

<table>
<thead>
<tr>
<th>SOP Class</th>
<th>SOP Class UID</th>
<th>IOD Specification (defined in PS 3.3)</th>
</tr>
</thead>
<tbody>
<tr>
<td>...</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1.2.840.10008.5.1.4.1.1.X.0 Protocol Approval IOD

Add application behaviors to GG.6

GG.6.X PROTOCOL APPROVAL SOP CLASS

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 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

BB.1.1 Scope
The Protocol Approval Query/Retrieve Service Classes define application-level classes-of-service that facilitate access to Protocol Approval composite objects.

BB.1.2 Conventions
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 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).

Note
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.

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.

BB.1.3 Query/Retrieve Information Model
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 organized into an Information Model. The Information Models for the different SOP Classes specified in this Annex are defined in Section BB.6.

BB.1.4 Service Definition
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 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.
The semantics of the C-FIND service are the same as those defined in the Service Definition of the Basic Worklist Management Service Class.

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.

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.

BB.2 PROTOCOL APPROVAL INFORMATION MODELS DEFINITIONS

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.

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 Worklist Management Service.

BB.3 PROTOCOL APPROVAL INFORMATION MODELS

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

- Protocol Approval object instance.

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

BB.4 DIMSE-C SERVICE GROUPS

BB.4.1 C-FIND Operation

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.

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 Approval Information Model.

BB.4.1.1 Service Class User Behavior

No SOP Class specific SCU behavior is defined.

BB.4.1.2 Service Class Provider Behavior

No SOP Class specific SCP behavior is defined.

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 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 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.
Note

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

BB.4.3 C-GET Operation

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.

Note

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

BB.5 ASSOCIATION NEGOTIATION

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

BB.6 SOP CLASS DEFINITIONS

BB.6.1 Protocol Approval Information Model

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 shall send one C-FIND response per matching Protocol Approval Instance.

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

BB.6.1.2 Protocol Approval Attributes

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 approved, many searches will be looking for approvals that list a particular protocol instance in the Approval Subject Sequence (30xx,50AD).

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

<table>
<thead>
<tr>
<th>Description / Module</th>
<th>Tag</th>
<th>Matching Key Type</th>
<th>Return Key Type</th>
<th>Remark / Matching Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOP Common</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Specific Character Set</td>
<td>(0008,0005)</td>
<td>-</td>
<td>1C</td>
<td>This Attribute is required if expanded or replacement character sets are used. See Section C.2.2.2 and Section C.4.1.1.</td>
</tr>
<tr>
<td>SOP Class UID</td>
<td>(0008,0016)</td>
<td>R</td>
<td>1</td>
<td></td>
</tr>
</tbody>
</table>
### Description / Module

<table>
<thead>
<tr>
<th>Tag</th>
<th>Matching Key Type</th>
<th>Return Key Type</th>
<th>Remark / Matching Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>SOP Instance UID (0008,0018)</td>
<td>U</td>
<td>1</td>
<td>Shall be retrieved with Single Value or Range Matching.</td>
</tr>
<tr>
<td>Instance Creation Date (0008,0012)</td>
<td>R</td>
<td>1</td>
<td>Shall be retrieved with Single Value or Range Matching.</td>
</tr>
<tr>
<td>Instance Creation Time (0008,0013)</td>
<td>R</td>
<td>1</td>
<td>Shall be retrieved with Single Value or Range Matching.</td>
</tr>
</tbody>
</table>

### Protocol Approval

<table>
<thead>
<tr>
<th>Tag</th>
<th>Matching Key Type</th>
<th>Return Key Type</th>
<th>Remark / Matching Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Approval Subject Sequence (30xx,50AD)</td>
<td>R</td>
<td>1</td>
<td>Shall be retrieved with List of UID Matching.</td>
</tr>
<tr>
<td>&gt;Referenced SOP Class UID (0008,1150)</td>
<td>R</td>
<td>1</td>
<td>Shall be retrieved with List of UID Matching.</td>
</tr>
<tr>
<td>&gt;Referenced SOP Instance UID (0008,1155)</td>
<td>R</td>
<td>1</td>
<td>Shall be retrieved with List of UID Matching.</td>
</tr>
<tr>
<td>Approval Sequence (yyym1,m1xa)</td>
<td>R</td>
<td>1</td>
<td>This Attribute shall be retrieved with Single Value or Universal matching.</td>
</tr>
<tr>
<td>&gt;Assertion Code Sequence (30xx,50A0)</td>
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<td>This Attribute shall be retrieved with Single Value or Universal matching.</td>
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<tr>
<td>&gt;&gt;Code Value (0008,0100)</td>
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<td>1</td>
<td>This Attribute shall be retrieved with Single Value or Universal matching.</td>
</tr>
<tr>
<td>&gt;&gt;Coding Scheme Designator (0008,0102)</td>
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<td>1</td>
<td>This Attribute shall be retrieved with Single Value or Universal matching.</td>
</tr>
<tr>
<td>&gt;&gt;Code Meaning (0008,0104)</td>
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<td></td>
</tr>
<tr>
<td>&gt;Assertion UID (30xx,50A1)</td>
<td>-</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>&gt;Asserter Identification Sequence (0070,00QQ)</td>
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<td></td>
</tr>
<tr>
<td>&gt;&gt;Observer Type (0040,A084)</td>
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<td></td>
</tr>
<tr>
<td>&gt;&gt;Person Name (0040,A123)</td>
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<td></td>
</tr>
<tr>
<td>&gt;&gt;Person Identification Code Sequence (0040,1101)</td>
<td>R</td>
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<td></td>
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<tr>
<td>&gt;&gt;&gt;Code Value (0008,0100)</td>
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<td>1</td>
<td>This Attribute shall be retrieved with Single Value or Universal matching.</td>
</tr>
<tr>
<td>Description / Module</td>
<td>Tag</td>
<td>Matching Key Type</td>
<td>Return Key Type</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>------------------</td>
<td>-------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>&gt;&gt;&gt;Coding Scheme Designator</td>
<td>(0008,0102)</td>
<td>R</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;&gt;Code Meaning</td>
<td>(0008,0104)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;Organizational Role Code Sequence</td>
<td>(30xx,50AE)</td>
<td>R</td>
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</tr>
<tr>
<td>&gt;&gt;&gt;Code Value</td>
<td>(0008,0100)</td>
<td>R</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;&gt;Coding Scheme Designator</td>
<td>(0008,0102)</td>
<td>R</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;&gt;Code Meaning</td>
<td>(0008,0104)</td>
<td>-</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;Station Name</td>
<td>(0008,1010)</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>&gt;&gt;Device UID</td>
<td>(0018,1002)</td>
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<td>3</td>
</tr>
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<td>(0008,0070)</td>
<td>-</td>
<td>3</td>
</tr>
<tr>
<td>&gt;&gt;Manufacturer's Model Name</td>
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<td>3</td>
</tr>
<tr>
<td>&gt;&gt;Station AE Title</td>
<td>(0008,0055)</td>
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<td>&gt;&gt;Institution Name</td>
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<td>R</td>
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<tr>
<td>&gt;&gt;&gt;Coding Scheme Designator</td>
<td>(0008,0102)</td>
<td>R</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;&gt;Code Meaning</td>
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<td>-</td>
<td>1</td>
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<td>&gt;Assertion DateTime</td>
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<td>1</td>
</tr>
<tr>
<td>&gt;Assertion Expiry DateTime</td>
<td>(30xx,50A8)</td>
<td>R</td>
<td>2</td>
</tr>
<tr>
<td>&gt;Assertion Comments</td>
<td>(30xx,50A6)</td>
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<td>2</td>
</tr>
<tr>
<td>&gt;Related Assertion Sequence</td>
<td>(30xx,50AB)</td>
<td>U</td>
<td>1</td>
</tr>
<tr>
<td>&gt;&gt;Referenced Assertion UID</td>
<td>(30xx,50AC)</td>
<td>U</td>
<td>1</td>
</tr>
</tbody>
</table>

Enhanced General Equipment
Manufacturer                  (0008,0070) | - | 1 |
Manufacturer's Model Name     (0008,1090) | - | 2 |
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.

BB.6.1.3 Conformance Requirements

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.

BB.6.1.3.1 SCU Conformance

BB.6.1.3.1.1 C-FIND SCU Conformance

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 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 SCU shall state in its Conformance Statement whether it requests Type 3 Return Key Attributes, and shall list these Optional Return Key Attributes.

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) when encoding queries and interpreting responses.

BB.6.1.3.1.2 C-MOVE SCU Conformance

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 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

An implementation that conforms to the Protocol Approval Information Model - GET SOP Class as an SCU 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).

BB.6.1.3.2 SCP Conformance

BB.6.1.3.2.1 C-FIND SCP Conformance

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 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 (30xx,50AD) would be useful to index since querying for approvals of a specific Protocol instance will be very common.

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

- whether it supports Type 3 Return Key Attributes, and shall list these Optional Return Key Attributes.
how it makes use of Specific Character Set (0008,0005) when interpreting queries, performing
matching and encoding responses.

- any behaviors that involve not returning matching instances (e.g. not returning an older approval
instance that has been superceded/overridden by a newer approval instance).

**BB.6.1.3.2.2 C-MOVE SCP Conformance**

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
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
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
by the C-MOVE.

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

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
behavior described for the Query/Retrieve Service Class in Section C.4.3.3.

**BB.6.1.4 SOP Classes**

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

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

<table>
<thead>
<tr>
<th>SOP Class Name</th>
<th>SOP Class UID</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Approval Information Model - FIND</td>
<td>1.2.840.10008.5.1.4.1.1.X.1.4</td>
</tr>
<tr>
<td>Protocol Approval Information Model - MOVE</td>
<td>1.2.840.10008.5.1.4.1.1.X.1.5</td>
</tr>
<tr>
<td>Protocol Approval Information Model - GET</td>
<td>1.2.840.10008.5.1.4.1.1.X.1.6</td>
</tr>
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</table>
Changes to NEMA Standards Publication PS 3.6

Digital Imaging and Communications in Medicine (DICOM)

Part 6: Data Dictionary

Add the following rows to Section 6

<table>
<thead>
<tr>
<th>Tag</th>
<th>Name</th>
<th>Keyword</th>
<th>VR</th>
<th>VM</th>
</tr>
</thead>
<tbody>
<tr>
<td>(yy,m1xa)</td>
<td>Approval Sequence</td>
<td>SQ</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>(30x,50A0)</td>
<td>Assertion Code Sequence</td>
<td>SQ</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>(30x,50A1)</td>
<td>Assertion UID</td>
<td>UI</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>(0070,00QQ)</td>
<td>Asserter Identification Sequence</td>
<td>SQ</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>(30x,50A4)</td>
<td>Assertion DateTime</td>
<td>DT</td>
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<td></td>
</tr>
<tr>
<td>(30x,50A8)</td>
<td>Assertion Expiry DateTime</td>
<td>DT</td>
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</tr>
<tr>
<td>(30x,50A6)</td>
<td>Assertion Comments</td>
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<td>(30x,50AB)</td>
<td>Related Assertion Sequence</td>
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<td>(30x,50AC)</td>
<td>Referenced Assertion UID</td>
<td>UI</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>(30x,50AD)</td>
<td>Approval Subject Sequence</td>
<td>SQ</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>(30x,50AE)</td>
<td>Organizational Role Code Sequence</td>
<td>SQ</td>
<td>1</td>
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</tr>
</tbody>
</table>

Add the following rows to Table A-1

<table>
<thead>
<tr>
<th>UID Value</th>
<th>UID Name</th>
<th>UID Type</th>
<th>Part</th>
</tr>
</thead>
<tbody>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2.840.10008.5.1.4.1.1.X.0.1</td>
<td>Protocol Approval Storage</td>
<td>SOP Class</td>
<td>PS 3.4</td>
</tr>
<tr>
<td>1.2.840.10008.5.1.4.1.1.X.1.4</td>
<td>Protocol Approval Information Model - FIND</td>
<td>SOP Class</td>
<td>PS 3.4</td>
</tr>
<tr>
<td>1.2.840.10008.5.1.4.1.1.X.1.5</td>
<td>Protocol Approval Information Model - MOVE</td>
<td>SOP Class</td>
<td>PS 3.4</td>
</tr>
<tr>
<td>1.2.840.10008.5.1.4.1.1.X.1.6</td>
<td>Protocol Approval Information Model - GET</td>
<td>SOP Class</td>
<td>PS 3.4</td>
</tr>
<tr>
<td>...</td>
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</table>
Add the following UID Value to Part 6 Annex A Table A-3:

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<th>Context Group Name</th>
</tr>
</thead>
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<tr>
<td>...</td>
<td>...</td>
<td>...</td>
</tr>
<tr>
<td>1.2.840.10008.6.1.XX3</td>
<td>newcid3</td>
<td>Protocol Assertion Codes</td>
</tr>
</tbody>
</table>

CID newcid3  Protocol Assertion Codes

<table>
<thead>
<tr>
<th>Coding Scheme Designator</th>
<th>Code Value</th>
<th>Code Meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>DCM121</td>
<td>newcode001</td>
<td>Appropriate for the indications</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode001a</td>
<td>Inappropriate for the indications</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode002</td>
<td>Consistent with labelling of the device</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode002a</td>
<td>Inconsistent with labelling of the device</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode003</td>
<td>Approved for use at the institution</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode003a</td>
<td>Disapproved for use at the institution</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode004</td>
<td>Approved for use in the clinical trial</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode004a</td>
<td>Disapproved for use in the clinical trial</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode015</td>
<td>Approved for experimental use</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode015a</td>
<td>Disapproved for experimental use</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode017a</td>
<td>Approved for use on pregnant patients</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode017</td>
<td>Disapproved for use on pregnant patients</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode012</td>
<td>Disapproved for any use</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode016</td>
<td>Eligible for reimbursement</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode016b</td>
<td>Eligible for reimbursement on per patient basis</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode016a</td>
<td>Ineligible for reimbursement</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode008</td>
<td>Appropriate for the device</td>
</tr>
<tr>
<td>DCM121</td>
<td>newcode008a</td>
<td>Inappropriate for the device</td>
</tr>
</tbody>
</table>
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 newcode013 Deprecated protocol

Modify CID 7452 as shown

CID 7452 Organizational Roles
Type: Extensible
Version: 20141110yymmdd

Table CID 7452. Organizational Roles

<table>
<thead>
<tr>
<th>Coding Scheme Designator</th>
<th>Code Value</th>
<th>Code Meaning</th>
<th>SNOMED-CT Concept ID</th>
<th>UMLS Concept Unique ID</th>
</tr>
</thead>
<tbody>
<tr>
<td>SRT</td>
<td>J-0016E</td>
<td>Medical Practitioner</td>
<td>158965000</td>
<td>C1306754</td>
</tr>
<tr>
<td>SRT</td>
<td>J-004E8</td>
<td>Physician</td>
<td>309343006</td>
<td>C0031831</td>
</tr>
<tr>
<td>DCM121 newcode070</td>
<td>Head of Radiology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCM121 newcode071</td>
<td>Chair of Protocol Committee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCM121 newcode076</td>
<td>Representative of Protocol Committee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCM121 newcode077</td>
<td>Representative of Ethics Committee</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCM121 newcode075</td>
<td>Head of Cardiology</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DCM121 newcode073</td>
<td>Administrator of Radiology Department</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SRT</td>
<td>J-07100</td>
<td>Nurse</td>
<td>106292003</td>
<td>C0028661</td>
</tr>
<tr>
<td>SRT</td>
<td>J-00187</td>
<td>Radiologic Technologist</td>
<td>159016003</td>
<td>C0402007</td>
</tr>
<tr>
<td>DCM121 newcode074</td>
<td>Lead Radiologic Technologist</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SRT</td>
<td>J-06173</td>
<td>Radiation Therapist</td>
<td>3430008</td>
<td></td>
</tr>
<tr>
<td>SRT</td>
<td>J-00187</td>
<td>Radiographer</td>
<td>159016003</td>
<td>C0402007</td>
</tr>
<tr>
<td>UMLS</td>
<td>C1144859</td>
<td>Intern</td>
<td>158971006</td>
<td>C1144859</td>
</tr>
<tr>
<td>SRT</td>
<td>J-005E6</td>
<td>Resident</td>
<td>405277009</td>
<td>C1320928</td>
</tr>
<tr>
<td>SRT</td>
<td>J-00172</td>
<td>Registrar</td>
<td>158971006</td>
<td>C0401974</td>
</tr>
<tr>
<td>DCM</td>
<td>121088</td>
<td>Fellow</td>
<td>309390008</td>
<td>C0586911</td>
</tr>
<tr>
<td>SRT</td>
<td>J-005E8</td>
<td>Attending</td>
<td>405279007</td>
<td>C1320929</td>
</tr>
<tr>
<td>SRT</td>
<td>J-0050A</td>
<td>Consultant</td>
<td>309390008</td>
<td>C0586911</td>
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<tr>
<td>Coding Scheme Designator</td>
<td>Code Value</td>
<td>Code Meaning</td>
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<td>UMLS Concept Unique ID</td>
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<td>----------------</td>
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<td>------------------------</td>
</tr>
<tr>
<td>SRT</td>
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<td>Scrub nurse</td>
<td>415506007</td>
<td>C1531952</td>
</tr>
<tr>
<td>SRT</td>
<td>J-00556</td>
<td>Surgeon</td>
<td>304292004</td>
<td>C0582175</td>
</tr>
<tr>
<td>DCM</td>
<td>121092</td>
<td>Sonologist</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UMLS</td>
<td>C1954848</td>
<td>Sonographer</td>
<td></td>
<td>C1954848</td>
</tr>
<tr>
<td>UMLS</td>
<td>C2985483</td>
<td>Radiation Physicist</td>
<td></td>
<td>C2985483</td>
</tr>
<tr>
<td>UMLS</td>
<td>C1708969</td>
<td>Medical Physicist</td>
<td></td>
<td>C1708969</td>
</tr>
</tbody>
</table>

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 recommended 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 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.

Add the following rows to Annex D

### DICOM Code Definitions (Coding Scheme Designator “DCM” Coding Scheme Version “01”)

<table>
<thead>
<tr>
<th>Code Value</th>
<th>Code Meaning</th>
<th>Definition</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>newcode001</td>
<td>Appropriate for the</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>indications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>newcode001a</td>
<td>Inappropriate for the</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td></td>
<td>indications</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Newcode</td>
<td>Description</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>------------------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Newcode002</td>
<td>Consistent with labelling of the device</td>
<td>The protocol is consistent with the regulatory product labelling of the device recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode002a</td>
<td>Inconsistent with labelling of the device</td>
<td>The protocol is inconsistent with the regulatory product labelling of the device recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode003</td>
<td>Approved for use at the institution</td>
<td>The protocol is approved for use at the institution recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode003a</td>
<td>Disapproved for use at the institution</td>
<td>The protocol is disapproved for use at the institution recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode004</td>
<td>Approved for use in the clinical trial</td>
<td>The protocol is approved for use in the clinical trial recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode004a</td>
<td>Disapproved for use in the clinical trial</td>
<td>The protocol is disapproved for use in the clinical trial recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode015</td>
<td>Approved for experimental use</td>
<td>The protocol is approved for use in experimental procedures.</td>
<td></td>
</tr>
<tr>
<td>Newcode015a</td>
<td>Disapproved for experimental use</td>
<td>The protocol is disapproved for use in experimental procedures.</td>
<td></td>
</tr>
<tr>
<td>Newcode016</td>
<td>Eligible for reimbursement</td>
<td>The protocol is understood to be eligible for reimbursement by a given payer.</td>
<td></td>
</tr>
<tr>
<td>Newcode016b</td>
<td>Eligible for reimbursement on per patient basis</td>
<td>The protocol is understood to be eligible for reimbursement on a per patient basis by a given payer.</td>
<td></td>
</tr>
<tr>
<td>Newcode016a</td>
<td>Ineligible for reimbursement</td>
<td>The protocol is understood to be ineligible for reimbursement by a given payer.</td>
<td></td>
</tr>
<tr>
<td>Newcode008</td>
<td>Appropriate for the device</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Newcode008a</td>
<td>Inappropriate for the device</td>
<td>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).</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Description</td>
<td>Details</td>
<td></td>
</tr>
<tr>
<td>----------</td>
<td>-----------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Newcode009</td>
<td>Inside operational limits of the device</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Newcode009a</td>
<td>Outside operational limits of the device</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Newcode010</td>
<td>Optimized for the device instance</td>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>Newcode010a</td>
<td>Not optimized for the device instance</td>
<td>The protocol is not optimized for the characteristics of the specific instance of the device recorded in the protocol instance.</td>
<td></td>
</tr>
<tr>
<td>Newcode012</td>
<td>Disapproved for any use</td>
<td>The protocol is explicitly disapproved, or approval of the protocol has been withdrawn.</td>
<td></td>
</tr>
<tr>
<td>Newcode013</td>
<td>Deprecated protocol</td>
<td>The protocol is no longer to be used. E.g. it has been replaced by another protocol.</td>
<td></td>
</tr>
<tr>
<td>Newcode017</td>
<td>Disapproved for use on pregnant patients</td>
<td>The protocol is explicitly disapproved for use on pregnant patients.</td>
<td></td>
</tr>
<tr>
<td>Newcode017a</td>
<td>Approved for use on pregnant patients</td>
<td>The protocol is specifically approved for use on pregnant patients.</td>
<td></td>
</tr>
<tr>
<td>Newcode070</td>
<td>Head of Radiology</td>
<td>The senior ranking radiologist in the organization</td>
<td></td>
</tr>
<tr>
<td>newcode071</td>
<td>Chair of Protocol Committee</td>
<td>The chair of a committee tasked with reviewing and approving protocols in the organization.</td>
<td></td>
</tr>
<tr>
<td>Newcode073</td>
<td>Administrator of Radiology Department</td>
<td>The administrative head of a department which provides radiology services.</td>
<td></td>
</tr>
<tr>
<td>Newcode074</td>
<td>Lead Radiologic Technologist</td>
<td>The senior ranking radiologic technologist in the organization.</td>
<td></td>
</tr>
<tr>
<td>Newcode075</td>
<td>Head of Cardiology</td>
<td>The senior ranking cardiologist in the organization.</td>
<td></td>
</tr>
<tr>
<td>Code</td>
<td>Position</td>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------</td>
<td>-----------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Newcode076</td>
<td>Representative of Protocol Committee</td>
<td>A representative of a committee tasked with reviewing and approving protocols in the organization.</td>
<td></td>
</tr>
<tr>
<td>Newcode077</td>
<td>Representative of Ethics Committee</td>
<td>A representative of a committee tasked with evaluating medical ethics. E.g. Institutional Review Board.</td>
<td></td>
</tr>
</tbody>
</table>
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 Approval Examples and Concepts (Informative)

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

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 1.2.3.456.7.8.

Note that the Institution Code Sequence (0008,0082) inside the Asserter Identification Sequences (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 Hospital is the institution for which the protocols are "Approved for use at the institution".

Table WW-1a Approval by Chief Radiologist

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Tag</th>
<th>Value</th>
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<tr>
<td>Manufacturer</td>
<td>(0008,0070)</td>
<td>Acme Corp.</td>
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<tr>
<td>Manufacturer's Model Name</td>
<td>(0008,1090)</td>
<td>Primo Protocol Management Workstation Plus</td>
</tr>
<tr>
<td>Device Serial Number</td>
<td>(0018,1000)</td>
<td>A59848573</td>
</tr>
<tr>
<td>Software Versions</td>
<td>(0018,1020)</td>
<td>V2.3</td>
</tr>
<tr>
<td>SOP Class UID</td>
<td>(0008,0016)</td>
<td>1.2.840.10008.5.1.4.1.1.X.0.1 (Protocol Approval)</td>
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<tr>
<td>SOP Instance UID</td>
<td>(0008,0018)</td>
<td>1.33.9.876.1.1.1</td>
</tr>
<tr>
<td>Approval Subject Sequence</td>
<td>(30xx,50AD)</td>
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</tr>
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**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           (yyym1,m1xa)
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<td>(30xx,50A0) (newcode003,DCM,&quot;Approved for use at the institution&quot;)</td>
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<tr>
<td><strong>Assertion UID</strong></td>
<td>(30xx,50A1) 1.2.33.9.876.5.5.5.5.21</td>
</tr>
<tr>
<td><strong>Asserter Identification Sequence</strong></td>
<td>(0070,00QQ)</td>
</tr>
<tr>
<td><strong>Observer Type</strong></td>
<td>(0040,A084) PSN</td>
</tr>
<tr>
<td><strong>Person Name</strong></td>
<td>(0040,A123) &quot;Welby^Marcus^^Dr.^MD&quot;</td>
</tr>
<tr>
<td><strong>Person Identification Code Sequence</strong></td>
<td>(0040,1101) (12345,99NPI,&quot;Welby^Marcus^^Dr.^MD&quot;)</td>
</tr>
<tr>
<td><strong>Organizational Role Code Sequence</strong></td>
<td>(30xx,50AE) (newcode070,DCM,&quot;Head of Radiology&quot;)</td>
</tr>
<tr>
<td><strong>Institution Name</strong></td>
<td>(0008,0080) Mercy Hospital, Centerville</td>
</tr>
<tr>
<td><strong>Institution Code Sequence</strong></td>
<td>(0008,0082) (000011113,99NPI,&quot;Mercy Hospital, Centerville&quot;)</td>
</tr>
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<td><strong>Assertion DateTime</strong></td>
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<td>(30xx,50A8) 20200601000000 (based on a 5 yearly review plan)</td>
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</table>

<table>
<thead>
<tr>
<th>Item #2</th>
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<tbody>
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<td>(30xx,50A0) (newcode017a,DCM,&quot;Approved for pregnant patients&quot;)</td>
</tr>
<tr>
<td><strong>Assertion UID</strong></td>
<td>(30xx,50A1) 1.2.33.9.876.5.5.5.5.22</td>
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<tr>
<td><strong>Asserter Identification Sequence</strong></td>
<td>(0070,00QQ)</td>
</tr>
<tr>
<td><strong>Observer Type</strong></td>
<td>(0040,A084) PSN</td>
</tr>
<tr>
<td><strong>Person Name</strong></td>
<td>(0040,A123) &quot;Welby^Marcus^^Dr.^MD&quot;</td>
</tr>
<tr>
<td><strong>Person Identification Code Sequence</strong></td>
<td>(0040,1101) (12345,99NPI,&quot;Welby^Marcus^^Dr.^MD&quot;)</td>
</tr>
<tr>
<td><strong>Organizational Role Code Sequence</strong></td>
<td>(30xx,50AE) (newcode070,DCM,&quot;Head of Radiology&quot;)</td>
</tr>
<tr>
<td><strong>Institution Name</strong></td>
<td>(0008,0080) Mercy Hospital, Centerville</td>
</tr>
<tr>
<td><strong>Institution Code Sequence</strong></td>
<td>(0008,0082) (000011113,99NPI,&quot;Mercy Hospital, Centerville&quot;)</td>
</tr>
<tr>
<td><strong>Assertion DateTime</strong></td>
<td>(30xx,50A4) 20150601145327</td>
</tr>
<tr>
<td><strong>Assertion Expiry DateTime</strong></td>
<td>(30xx,50A8) 20200601000000 (based on a 5 yearly review plan)</td>
</tr>
<tr>
<td><strong>Assertion Comments</strong></td>
<td>(30xx,50A6) &quot;Limited scan range and proper use of abdominal shielding result in negligible dose to the fetus.&quot;</td>
</tr>
</tbody>
</table>