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Digital Imaging and Communications in Medicine (DICOM)

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Supplement 107: Substance Administration Information Services

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Scope and Field of Application

2 Recent initiatives for improving patient safetyⁱ have highlighted the need to verify the appropriateness of
 4 drugs administered to a patient at the time of administration (sometimes called “five rights checking”ⁱⁱ).
 6 Contrast agents used in imaging procedures should also be subject to such verification, but there has been
 no standard means for imaging modalities to interact with medication checking systems. Regulations
 coming into effect in the US require the bar coding of all substances administered to patients; this is intended
 to facilitate the automation of patient safety checks.

8 This Supplement introduces a new query SOP Class for imaging modalities to request verification of contrast
 agents and other drugs administered during an imaging or image-guided treatment procedure, based on the
 10 label bar code and the patient ID. The SCP responds with an authorization to proceed, or a warning, or a
 contra-indication. The SCP of this Service Class is not necessarily the medication checking system; i.e., it
 12 may be a gateway system. There are several methods by which the SCP might interact with a separate
 medication checking system, including HL7 messaging (such as the draft HL7 v3 Patient Drug
 14 Contraindications Query - PORX_RM050020UV). Such implementation design is beyond the scope of the
 DICOM standard.

16 This Supplement also introduces a new SOP Class within the Event Logging Service Class for reporting
 contrast or drug administration to a Medication Administration Record system. Again, the SCP of this
 18 Service Class is not necessarily the Medication Administration Record system, but may be a gateway
 system.

20 Bar coding of contrast agents and drugs can facilitate the provision of critical information to the imaging
 modality, such as the active ingredient, concentration, etc. However, those bar codes only identify a
 22 particular packaging from which the actual product or agent must be inferred; they do not encode the type of
 contrast agent directly. The bar code could be submitted to a service to look up the product type or active
 24 substance that is required to be encoded, e.g., in the Contrast/Bolus Module attributes. Similarly, the
 parameters of devices used in interventional procedures, e.g., catheters and stents, could be determined
 26 from a lookup of their package bar codes.

This Supplement therefore introduces a new query SOP Class to translate barcodes to product parameters.
 28 Again, there is the possible use by the SCP of interaction with a drug knowledge-base system (e.g., using
 the draft HL7 v3 Medication Detail Query - POME_RM010030).

30 This Supplement does not address adverse reaction reporting, which typically involves collection of clinical
 information that is not readily available at an imaging modality. This Supplement also does not address
 32 communication of orders and prescriptions for contrast or other drugs, which may be conveyed in the
 Modality Worklist service.

34 This Supplement proposes changes to the following Parts of the DICOM Standard:

36 PS 3.2 - Conformance
 PS 3.3 - Information Object Definitions

ⁱ See for example the US Institute of Medicine, *Priority Areas for National Action: Transforming Health Care Quality*, 2003

ⁱⁱ Right patient; Right time and frequency of administration; Right dose; Right route of administration; Right drug

	PS 3.4 -	Service Class Specifications
2	PS 3.6 -	Data Dictionary
	PS 3.16 -	Content Mapping Resource
4	PS 3.17 -	Explanatory Information

5

Part 2 Addendum

Add new SOP Classes in Table A.1-2

**Table A.1-2
UID VALUES**

UID Value	UID NAME	Category
...		
<u>1.2.840.10008.1.42</u>	<u>Substance Administration Logging</u>	<u>Workflow Management</u>
<u>1.2.840.10008.5.1.4.41</u>	<u>Product Characteristics Query</u>	<u>Query/Retrieve</u>
<u>1.2.840.10008.5.1.4.42</u>	<u>Substance Approval Query</u>	<u>Query/Retrieve</u>

10 *Add Conformance Example – see page 35*

Part 3 Addendum

Add to Part 3, Annex C, the following Modules:

15

C.XX SUBSTANCE ADMINISTRATION MODULES

C.XX.1 Product Characteristics Module

Table C.XX-1 specifies the Attributes used to convey the characteristics or parameters of a contrast agent, drug, or device.

20

**Table C.XX-1
PRODUCT CHARACTERISTICS MODULE ATTRIBUTES**

Attribute Name	Tag	Attribute Description
Product Package Identifier	(0044,0001)	Identifier of the contrast agent, drug, or device being characterized, typically from a package bar code, RFID, or other materials management ID. This ID might not be globally unique and might conflict with other IDs used within the scope of the institution.
Manufacturer	(0008,0070)	Manufacturer of product.
Product Type Code Sequence	(0044,0007)	Coded type of product. One Item shall be included in the Sequence.
<i>>Include Code Sequence Macro Table 8.8-1</i>		<i>For drugs, a coded terminology in the US is RxNorm For devices, a coded terminology in the US is the FDA CDRH Product Code Classification</i>
Product Name	(0044,0008)	Trade or generic name of product. Note: May be multi-valued.
Product Description	(0044,0009)	Further description in free form text describing the drug or device. Note: This attribute is limited by the LT Value Representation to 10240 characters. Larger text descriptions, or graphical descriptions, may be referenced in the Pertinent Documents Sequence (0038,0100).
Product Lot Identifier	(0044,000A)	Identifier of the manufacturing batch of which this product is part.
Product Expiration DateTime	(0044,000B)	The date and time after which the manufacturer no longer ensures the safety, quality, and/or proper functioning of the material.
Product Parameter Sequence	(0044,0013)	Parameters of the product. Zero or more Items may be included in the Sequence.
<i>>Include Content Item Macro Table 10.2-1</i>		<i>For drugs or contrast agents, Baseline Context Group for Concept Name Code Sequence is 4050 For devices, Baseline Context Group for Concept Name Code Sequence is 3423</i>

Pertinent Documents Sequence	(0038,0100)	Reference to a Product Label document for the product. Zero or more Items may be included in this sequence.
>Referenced SOP Class UID	(0008,1150)	Unique identifier for the class of an HL7 Structured Product Label document.
>Referenced SOP Instance UID	(0008,1155)	Unique identifier for the HL7 Structured Product Label Document as used in DICOM instance references (see C.12.1.1.6)
>HL7 Instance Identifier	(0040,E001)	Instance Identifier of the referenced HL7 Structured 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)	Retrieval access path to Product Label Document. Includes fully specified scheme, authority, path, and query in accordance with RFC 2396

C.XX.2 Substance Approval Module

25 Table C.XX-2 specifies the Attributes used to approve the administration of a contrast agent, drug, or device to a patient.

**Table C.XX-2
SUBSTANCE APPROVAL MODULE ATTRIBUTES**

Attribute Name	Tag	Attribute Description
Substance Administration Approval	(0044,0002)	Status of request for substance administration. Enumerated Values: APPROVED – Use of the substance for the patient is approved, with related notes (e.g., appropriate dose for age/weight) in Approval Status Further Description (0044,0003) WARNING – The substance may be used for the patient subject to warnings described in Approval Status Further Description (0044,0003) CONTRA_INDICATED – The substance should not be used for the patient for the reasons described in Approval Status Further Description (0044,0003)
Approval Status Further Description	(0044,0003)	Description of warning or contra-indication, or notes on approval.
Approval Status DateTime	(0044,0004)	Timestamp for the Substance Administration Approval response

C.XX.3 Substance Administration Module

30 Table C.XX-3 specifies the Attributes used to describe the act of administration of a contrast agent, drug, or device to a patient.

Table C.XX-3
SUBSTANCE ADMINISTRATION MODULE ATTRIBUTES

Attribute Name	Tag	Attribute Description
Administration Route Code Sequence	(0054,0302)	Route of administration for drug or contrast. One Item may be present in this Sequence.
<i>>Include Code Sequence Macro Table 8.8-1</i>		<i>Baseline Context Group 11.</i>

35 **C.XX.4 Substance Administration Log Module**

Table C.XX-4 specifies the Attributes used to record the act of administration of a contrast agent, drug, or device to a patient.

Table C.XX-4
SUBSTANCE ADMINISTRATION LOG MODULE ATTRIBUTES

Attribute Name	Tag	Attribute Description
Patient's Name	(0010,0010)	Patient's full name
Patient ID	(0010,0020)	Primary identification number or code for the patient.
Issuer of Patient ID	(0010,0021)	Identifier of the Assigning Authority (system, organization, agency, or department) that issued the Patient ID.
Admission ID	(0038,0010)	Identification number of the visit as assigned by the healthcare provider
Issuer of Admission ID	(0038,0011)	Name of healthcare provider that issued the Admission ID
Product Package Identifier	(0044,0001)	Identifier of the contrast agent, drug, or device administered, typically from a package bar code, RFID, or other materials management ID. This ID might not be globally unique and might conflict with other IDs used within the scope of the institution.
Product Name	(0044,0008)	Trade or generic name of product. Note: May be multi-valued.
Product Description	(0044,0009)	Text description of the contrast agent, drug, or device administered.
Substance Administration DateTime	(0044,0010)	Date and Time of Substance Administration
Substance Administration Notes	(0044,0011)	Comments provided by the operator responsible for the substance administration.
Substance Administration Device ID	(0044,0012)	Identifier for a device that controls substance administration, e.g., injector, infusion pump, etc.
Administration Route Code Sequence	(0054,0302)	Route of administration for drug or contrast. One Item may be present in this Sequence.
<i>>Include Code Sequence Macro Table 8.8-1</i>		<i>Baseline Context Group 11.</i>
Substance Administration Parameter Sequence	(0044,0019)	Parameters of the substance as administered to the patient, e.g., volume, quantity. Zero or more Items may be included in the Sequence.

<i>>Include Content Item Macro Table 10.2-1</i>		<i>For administration of drugs or contrast agents, Baseline Context Group for Concept Name Code Sequence is 3410.</i>
Operator Identification Sequence	(0008,1072)	Person administering the substance to the patient, or legally responsible for the administration, and authorized to add an entry to the Medication Administration Record. One or more Items may be present in this Sequence.
>Person Identification Code Sequence	(0040,1101)	Coded identifier of the person administering the contrast agent, drug, or device. One Item may be present in this Sequence.
<i>>>Include Code Sequence Macro Table 8.8-1</i>		<i>No baseline context ID.</i> The Coding Scheme Designator attribute may indicate a local coding scheme (e.g., with value "L") when it is implicitly that of the institution's employee identifier system. The Code Meaning attribute, though it is encoded with a VR of LO, may be encoded according to the rules of the PN VR (see Section 10.1).

Part 4 Addendum

Add to Part 4 Section 4, the following Abbreviations:

CDS Clinical Decision Support

45 **MAR** Medication Administration Record

Add to Part 4 Annex P, the following Subsection:

P.3 SUBSTANCE ADMINISTRATION LOGGING SOP CLASS DEFINITION

50 The Substance Administration Logging SOP Class allows an SCU to report to an SCP the events that are to be recorded in a patient’s Medication Administration Record (MAR) or similar log, whose definition is outside the scope of the Standard. This allows devices with DICOM protocol interfaces to report administration of diagnostic agents (including contrast) and therapeutic drugs, and implantation of devices.

55 The Substance Administration reported through this SOP Class is related to the MAR by Patient ID or Admission ID. The mechanism by which the SCU obtains this identifier is not defined by this SOP Class.

60 The log entry to the MAR is authorized by at least one of the Operators identified in the Operator Identification Sequence. The mechanism by which the SCU obtains these identifiers is not defined by this SOP Class. The SCP may refuse the log entry if none of the identified Operators is authorized to add entries to the MAR. The mechanism by which the SCP validates such authorization is not defined by this SOP Class.

- Notes:
1. The SCP of this Service Class is not necessarily the Medication Administration Record system, but may be a gateway system between this DICOM Service and an HL7 or proprietary interface of a MAR system. Such implementation design is beyond the scope of the DICOM standard.
 - 65 2. This SOP Class is not limited to only specifying medications, although the conventional name of the destination log is the Medication Administration Record. The SOP Class may also be used to record the implantation of therapeutic devices, including both drug-eluting and bare stents, prosthetic and cardiovascular devices, implantable infusion pumps, etc.
 - 70 3. The application level authorization of Operators for the purpose of logging a MAR entry is distinct from any access control mechanism at the transport layer (see User Identity Association profiles in PS3.15).

P.3.1 DIMSE Service Group

The DIMSE-N Services applicable to the Substance Administration Logging SOP Class are shown in Table P.3-1.

**Table P.3-1
DIMSE SERVICE GROUP**

DIMSE Service Element	Usage SCU/SCP
N-ACTION	M/M

The DIMSE-N Services and Protocol are specified in PS 3.7.

P.3.2 Operation

80 The DICOM AEs that claim conformance to this SOP Class as an SCU shall invoke the N-ACTION request. The DICOM AEs that claim conformance to this SOP Class as an SCP shall support the N-ACTION request.

P.3.2.1 Substance Administration Log Action Information

85 This operation allows an SCU to submit a Medication Administration Record log item or entry, providing information about a specific real-world act of Substance Administration that is the purview of the SCU. This operation shall be invoked through the DIMSE N-ACTION Service.

The Action Information attributes are defined by the Substance Administration Log Module specified in PS3.3. The DICOM AEs that claim conformance to this SOP Class as an SCU and/or an SCP shall support the Action Type and Action Information Attributes in the N-ACTION-RQ as specified in Table P.3-2.

90

**Table P.3-2
SUBSTANCE ADMINISTRATION LOGGING N-ACTION INFORMATION**

Action Type Name	Action Type ID	Attribute	Tag	Requirement Type SCU/SCP
Record Substance Administration Event	1	Specific Character Set	(0008,0005)	1C/1C (Required if an extended or replacement character set is used)
		Patient ID	(0010,0020)	1C/1C Either or both Patient ID and Admission ID shall be supplied by the SCU; the SCP shall support the attribute if supplied
		Issuer of Patient ID	(0010,0021)	3/2
		Patient's Name	(0010,0010)	2/2
		Admission ID	(0038,0010)	1C/1C Either or both Patient ID and Admission ID shall be supplied by the SCU; the SCP shall support the attribute if supplied
		Issuer of Admission ID	(0038,0011)	3/2
		Product Package Identifier	(0044,0001)	1C/1C Either or both Product Package Identifier and Product Name shall be supplied by the SCU; the SCP shall support the attribute if supplied

Product Name	(0044,0008)	1C/1C Either or both Product Package Identifier and Product Name shall be supplied by the SCU; the SCP shall support the attribute if supplied
Product Description	(0044,0009)	3/3
Substance Administration DateTime	(0044,0010)	1/1
Substance Administration Notes	(0044,0011)	3/2
Substance Administration Device ID	(0044,0012)	3/3
Administration Route Code Sequence	(0054,0302)	2/2
>Code Value	(0008,0100)	1/1
>Coding Scheme Designator	(0008,0102)	1/1
>Code Meaning	(0008,0104)	1/1
Substance Administration Parameter Sequence	(0044,0019)	3/3
> <i>All attributes of the Substance Administration Parameter Sequence</i>		3/3
Operator Identification Sequence	(0008,1072)	1/1
>Person Identification Code Sequence	(0040,1101)	1/1
>>Code Value	(0008,0100)	1/1
>>Coding Scheme Designator	(0008,0102)	1/1
>>Code Meaning	(0008,0104)	1/1

P.3.2.2 Service Class User Behavior

95 The SCU shall request logging of substance administration events for a specified Patient using the N-ACTION request primitive.

The SCU shall receive N-ACTION responses. The actions taken upon a response status of Failure, or upon non-response of the SCP, are implementation dependent.

P.3.2.3 Service Class Provider Behavior

100 The SCP shall receive, via the N-ACTION request primitive, requests for logging of substance administration events. The SCP shall incorporate those event records into a Medication Administration Record or similar log for the specified Patient.

Note: The patient's identify may be conveyed explicitly by Patient ID, or implicitly by Admission (i.e., Visit) ID. An institution may typically chose one or the other to use as the primary patient identifier at the point of care, e.g., printed on a bar coded wristband, the use of which may facilitate data entry for the log entry. However, in the "Model of the Real World for the Purpose of Modality-IS Interface" (see PS 3.3), the Visit is subsidiary to the Patient; hence the Admission ID may only be unique within the context of the patient, not within the context of the institution. The use of the Admission ID Attribute to identify the Patient is only effective if the Admission ID is unique within the context of the institution.

105

The SCP shall support inclusion into the Medication Administration Record or similar log of values of all Type 1 and Type 2 Attributes for which the SCU has provided values. The SCP may convert these attributes into a form appropriate for the destination log.

110

Note: The SCP may convert coded data to free text in the log, with loss of the specific code values, if the log does not support such coded data.

115

The SCP shall return, via the N-ACTION response primitive, the N-ACTION Response Status Code applicable to the associated action request.

P.3.2.4 Status Codes

The Service Class specific status values defined for the N-ACTION Service are specified in Table P.3-3. See PS 3.7 for additional general response status codes.

120

**Table P.3-3
RESPONSE STATUS**

Service Status	Response Status Code	Further Meaning
Success	0000	
Failure	C10E	Operator not authorized to add entry to Medication Administration Record
	C110	Patient cannot be identified from Patient ID or Admission ID
	C111	Update of Medication Administration Record failed

P.3.3 Substance Administration Logging SOP Class UID

The Substance Administration Logging SOP Class shall be uniquely identified by the Substance Administration Logging SOP Class UID, which shall have the value "1.2.840.10008.1.42".

125

P.3.4 Substance Administration Logging Instance UID

The well-known UID of the Substance Administration Logging SOP Instance shall have the value "1.2.840.10008.1.42.1".

P.3.5 Conformance Requirements

130

The DICOM AE's Conformance Statement shall be formatted as defined in PS 3.2.

P.3.5.1 SCU Conformance

The SCU shall document in its Conformance Statement the behavior and actions that cause the SCU to generate an N-ACTION-RQ primitive.

The SCU shall document how it obtains the Patient ID or Admission ID attribute (e.g., through a Modality Worklist query, bar-code scan, manual entry, etc.).

135

The SCU shall document the behavior and actions performed when a success or failure status is received.

P.3.5.2 SCP Conformance

140 The SCP shall document in its Conformance Statement how it uses the information it receives for adding data to a Medication Administration Record.

The SCP shall document the behavior and actions that cause the SCP to generate a success or failure status for a received N-ACTION-RQ.

Annex X SUBSTANCE ADMINISTRATION QUERY SERVICE CLASS (Normative)

145 **X.1 OVERVIEW**

X.1.1 Scope

The Substance Administration Query Service Class defines an application-level class-of-service that facilitates obtaining detailed information about substances or devices used in imaging, image-guided treatment, and related procedures. It also facilitates obtaining approval for the administration of a specific contrast agent or drug to a specific patient.

This Service Class is intended as part of a larger workflow that addresses patient safety in the imaging environment. This Service addresses only the communication protocol that allows a point of care device (imaging modality) to interrogate an SCP Application for information about an administered substance, or for verification of appropriateness of the substance for the patient. The SCP Application uses patient safety related data, such as allergies, current medications, appropriate dosages, patient condition indicated by lab results, etc., to respond to the queries; however, the mechanism of such use is beyond the scope of this Standard. How the point of care device uses the responses to the queries, e.g., by display to a user, or by locking of certain device functions, is also beyond the scope of this Standard.

Notes: 1. The SCP of this Service Class is not necessarily a clinical decision support (CDS) system, but may be a gateway system between this DICOM Service and an HL7 or proprietary interface of a CDS system. Such implementation design is beyond the scope of the DICOM standard.

2. The Service will result in a Query response containing zero or one items. However, to facilitate implementation, the Service uses the general query mechanism supporting multiple item responses, as used in other DICOM query service classes.

165 **X.1.2 Conventions**

Key Attributes serve two purposes; they may be used as Matching Key Attributes and 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).

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 PS 3.5.

X.1.3 Substance Administration Query Information Model

175 In order to serve as a Service Class Provider (SCP) of the Substance Administration Query Service Class, a DICOM Application Entity (AE) must be able to return information about the Attributes of a substance, device, or a substance administration act. This information is organized into well defined Substance Administration Query Information Models.

A specific SOP Class of the Substance Administration Query Service Class consists of an informative Overview, an Information Model Definition and a DIMSE-C Service Group. In this Service Class, the Information Model plays a role similar to an Information Object Definition (IOD) of other DICOM Service Classes.

X.1.4 Service Definition

185 Two peer DICOM AEs implement a SOP Class of the Substance Administration Query Service Class with one serving in the SCU role and one serving in the SCP role. SOP Classes of the Substance

Administration Query Service Class are implemented using the DIMSE-C C-FIND service as defined in PS 3.7.

Only a baseline behavior of the DIMSE-C C-FIND is used in the Service Class. Extended negotiation is not used.

190 The following description of the DIMSE-C C-FIND service provides a brief overview of the SCU/SCP semantics.

A C-FIND service conveys the following semantics:

- The SCU requests that the SCP perform a match for the Matching Keys and return values for the Return Keys that have been specified in the Identifier of the request, against the information that the SCP possesses relating to the Information Model specified in the SOP Class.

195

Note: In this Annex, the term "Identifier" refers to the Identifier service parameter of the C-FIND service as defined in PS 3.7.

- The SCP generates at most one C-FIND response for a match with an Identifier containing the values of all Matching Key Attributes and all known Return Key Attributes requested. This response shall contain a status of Pending.

200

- When the process of matching is complete, with zero or one match, a C-FIND response is sent with a status of Success and no Identifier.

- A Failure response to a C-FIND request indicates that the SCP is unable to process the request.

205

- The SCU may cancel the C-FIND service by issuing a C-CANCEL-FIND request at any time during the processing of the C-FIND service. The SCP will interrupt all matching and return a status of Canceled.

Note: The SCU needs to be prepared to receive C-FIND responses sent by the SCP until the SCP finally processed the C-CANCEL-FIND request.

210 **X.2 SUBSTANCE ADMINISTRATION QUERY INFORMATION MODEL DEFINITION**

The Substance Administration Query Information Model is identified by the SOP Class negotiated at Association establishment time. The SOP Class is composed of both an Information Model and a DIMSE-C Service Group.

215 Information Model Definitions for standard SOP Classes of the Substance Administration Query Service Class are defined in this Annex. A Substance Administration Query Information Model Definition contains:

- an Entity-Relationship Model Definition
- a Key Attributes Definition.

X.2.1 Entity-Relationship Model Definition

220 Substance Administration Query Information Models consist of a single level that includes all Matching Key Attributes and all Return Key Attributes that may be sent from the SCU to the SCP in the request, and whose values are expected to be returned from the SCP to the SCU in the response (or Query items). The Matching Key Attribute values in the request specify the Query items that are to be returned in the response. All Key Attributes (the Matching Key Attributes and the Return Key Attributes) in the request determine which Attribute values are returned in the response for that Query.

225

X.2.2 Attributes Definition

Attributes are defined for each entity in the internal Entity-Relationship Model. An Identifier in a C-FIND request shall contain values to be matched against the Attributes of the Entities in a Substance

230 Administration Query Information Model. For any Query request, the set of entities for which Attributes are returned shall be determined by the set of Matching and Return Key Attributes specified in the Identifier.

X.2.2.1 Attribute Types

All Attributes of entities in a Substance Administration Query Information Model shall be specified both as a Matching Key Attribute (either required or optional) and as a Return Key Attribute.

X.2.2.1.1 Matching Key Attributes

235 The Matching Key Attributes are Keys, which select Query items to be included in a requested Query.

X.2.2.1.1.1 Required Matching Key Attributes

A Substance Administration Query Service SCP shall support matching based on values of all Required Matching Key Attributes of the C-FIND request.

X.2.2.1.1.2 Optional Matching Key Attributes

240 In the Substance Administration Query Information Model, a set of Attributes may be defined as Optional Matching Key Attributes. Optional Matching Key Attributes contained in the Identifier of a C-FIND request may induce two different types of behavior depending on support for matching by the SCP. If the SCP

- does not support matching on the Optional Matching Key Attribute, then the Optional Matching Key Attribute shall be ignored for matching but shall be processed in the same manner as a Return Key Attribute.
- supports matching of the Optional Matching Key Attribute, then the Optional Matching Key Attribute shall be processed in the same manner as a Required Matching Key.

250 Notes: 1. The Conformance Statement of the SCP lists the Optional Matching Key Attributes that are supported for matching.
2. An SCU can not expect the SCP to support a match on an Optional Matching Key.

X.2.2.1.2 Return Key Attributes

255 The values of Return Key Attributes to be retrieved with the Query are specified with zero-length (universal matching) in the C-FIND request. SCPs shall support Return Key Attributes defined by a Substance Administration Query Information Model according to the Data Element Type (1, 1C, 2, 2C, 3) as defined in PS 3.5.

260 Every Matching Key Attribute shall also be considered as a Return Key Attribute. Therefore the C-FIND response shall contain, in addition to the values of the requested Return Key Attributes, the values of the requested Matching Key Attributes.

Notes: 1 The Conformance Statement of the SCP lists the Return Key Attributes of Type 3 that are supported.
2. An SCU may choose to supply any subset of Return Key Attributes.
3. An SCU can not expect to receive any Type 3 Return Key Attributes.
4. Return Key attributes with VR of SQ may be specified either with zero-length, or with a zero-length item in the sequence.

X.2.2.2 Attribute Matching

270 The following types of matching, which are defined by the Query/Retrieve Service Class in Annex C, may be performed on Matching Key Attributes in the Substance Administration Query Service Class. Different Matching Key Attributes may be subject for different matching types. The Substance Administration Query Information Model defines the type of matching for each Required Matching Key Attribute. The

Conformance Statement of the SCP shall define the type of matching for each Optional Matching Key Attribute. The types of matching are:

- Single Value Matching
- 275 — Sequence Matching

The following type of matching, which is defined by the Query/Retrieve Service Class in Annex C of this Part, shall be performed on Return Key Attributes in the Substance Administration Query Service Class.

- 280 — Universal Matching

See Section C.2.2.2 and subsections for specific rules governing of Matching Key Attribute encoding for and performing of different types of matching.

The Specific Character Set (0008,0005) Attribute may be present in the Identifier but is never matched, i.e., it is not considered a Matching Key Attribute. See Section C.2.2.2 for details.

285 **X.3 QUERY INFORMATION MODELS**

Each Substance Administration Query Information Model is associated with one SOP Class. The following Substance Administration Query Information Models are defined:

- Product Characteristics Query Information Model
 - Substance Approval Query Information Model
- 290

X.4 DIMSE-C SERVICE GROUP

One DIMSE-C Service is used in the construction of SOP Classes of the Substance Administration Query Service Class. The following DIMSE-C operation is used.

- 295 — C-FIND

X.4.1 C-FIND Operation

300 SCPs of SOP Classes of the Substance Administration Query Service Class are capable of processing queries using the C-FIND operation as described in PS 3.7. The C-FIND operation is the mechanism by which queries are performed. Matches against the keys present in the Identifier are returned in C-FIND responses.

X.4.1.1 C-FIND Service Parameters

X.4.1.1.1 SOP Class UID

305 The SOP Class UID identifies the Substance Administration Query Information Model against which the C-FIND is to be performed. Support for the SOP Class UID is implied by the Abstract Syntax UID of the Presentation Context used by this C-FIND operation.

X.4.1.1.2 Priority

The Priority Attribute defines the requested priority of the C-FIND operation with respect to other DIMSE operations being performed by the same SCP.

310 Processing of priority requests is not required of SCPs. Whether or not an SCP supports priority processing and the meaning of the different priority levels shall be stated in the Conformance Statement of the SCP.

X.4.1.1.3 Identifier

Both the C-FIND request and response contain an Identifier encoded as a Data Set (see PS 3.5).

X.4.1.1.3.1 Request Identifier Structure

315 An Identifier in a C-FIND request shall contain

- Key Attributes values to be matched against the values of Attributes specified in that SOP Class.
- Conditionally, the Attribute Specific Character Set (0008,0005). This Attribute shall be included if expanded or replacement character sets may be used in any of the Attributes in the Request Identifier. It shall not be included otherwise.

320

Note: This means that Specific Character Set (0008,0005) is included if the SCU supports expanded or replacement character sets in the context of this service. It will not be included if expanded or replacement character sets are not supported by the SCU.

325 The Key Attributes and values allowable for the query shall be defined in the SOP Class definition for the corresponding Substance Administration Query Information Model.

X.4.1.1.3.2 Response Identifier Structure

The C-FIND response shall not contain Attributes that were not in the request or specified in this section.

An Identifier in a C-FIND response shall contain:

- 330 — Key Attributes with values corresponding to Key Attributes contained in the Identifier of the request (Key Attributes as defined in X.2.2.1.)
- Conditionally, the Attribute Specific Character Set (0008,0005). This Attribute shall be included if expanded or replacement character sets may be used in any of the Attributes in the Response Identifier. It shall not be included otherwise. The C-FIND SCP is not required to return responses in the Specific Character Set requested by the SCU if that character set is not supported by the SCP. The SCP may return responses with a different Specific Character Set.

335

Note: This means that Specific Character Set (0008,0005) is included if the SCP supports expanded or replacement character sets in the context of this service. It will not be included if expanded or replacement character sets are not supported by the SCP.

340

- Conditionally, the Attribute HL7 Structured Document Reference Sequence (0040,A390) and its subsidiary Sequence Items as specified in the SOP Common Module (see PS3.3). This Attribute shall be included if HL7 Structured Documents are referenced within the Identifier, e.g., in the Pertinent Documents Sequence (0038,0100).

345 **X.4.1.1.4 Status**

Table X.4.-1 defines the status code values that might be returned in a C-FIND response. Fields related to status code values are defined in PS 3.7.

**Table X.4-1
C-FIND RESPONSE STATUS VALUES**

Service Status	Further Meaning	Status Codes	Related Fields
Failure	Refused: Out of Resources	A700	(0000,0902)
	Identifier Does Not Match SOP Class	A900	(0000,0901) (0000,0902)

	Unable to process	Cxxx (values C000 through CFFF as assigned by the implementation)	(0000,0901) (0000,0902)
Cancel	Matching terminated due to Cancel request	FE00	None
Success	Matching is complete - No final Identifier is supplied.	0000	None
Pending	Matches are continuing - Current Match is supplied and any Optional Keys were supported in the same manner as Required Keys.	FF00	Identifier
	Matches are continuing - Warning that one or more Optional Keys were not supported for existence for this Identifier.	FF01	Identifier

350

Note: Status Codes are returned in DIMSE response messages (See PS 3.7). The code values stated in column "Status Codes" are returned in Status Command Element (0000,0900).

X.4.1.2 C-FIND SCU Behavior

355 All C-FIND SCUs shall be capable of generating query requests that meet the requirements of the Query Search Method (see X.4.1.3.1).

Required Keys and Optional Keys associated with the Query may be contained in the Identifier.

An SCU conveys the following semantics using the C-FIND requests and responses:

- 360 — The SCU requests that the SCP perform a match of all keys specified in the Identifier of the request against the information it possesses of the Query specified in the request.
- The SCU shall interpret Pending responses to convey the Attributes of a match of an item.
- The SCU shall interpret a response with a status equal to Success, Failure, or Cancel to convey the end of Pending responses.
- 365 — The SCU shall interpret a Failure response to a C-FIND request as an indication that the SCP is unable to process the request.
- The SCU may cancel the C-FIND service by issuing a C-FIND-CANCEL request at any time during the processing of the C-FIND. The SCU shall recognize a status of Cancel to indicate that the C-FIND-CANCEL was successful.

370 X.4.1.3 C-FIND SCP Behavior

All C-FIND SCPs shall be capable of processing queries that meet the requirements of the Query Search (see X.4.1.3.1).

An SCP conveys the following semantics using the C-FIND requests and responses:

- 375 — The SCP is requested to perform a match of all the keys specified in the Identifier of the request, against the information it possesses. Attribute matching is performed using the key values specified in the Identifier of the C-FIND request as defined in Section X.2.

- The SCP generates at most one C-FIND response for a match using the "Query" Search method. Such a response shall contain an Identifier whose Attributes contain values from the match. The response shall contain a status of Pending.
 - 380 — When matching is complete and any match has been sent, the SCP generates a C-FIND response that contains a status of Success. A status of Success shall indicate that a response has been sent for any match known to the SCP.
- Notes:
1. No Identifier is contained in a response with a status of Success. For a complete definition, see PS 3.7.
 - 385 2. When there are no matches, then no responses with a status of Pending are sent, only a single response with a status of Success.
- The SCP shall generate a response with a status of Failure if it is unable to process the request. A Failure response shall contain no Identifier.
 - If the SCP receives a C-FIND-CANCEL indication before it has completed the processing of the matches it shall interrupt the matching process and return a status of Cancel.
 - 390

X.4.1.3.1 Query Search Method

The following procedure is used to generate matches.

395 The key match attributes contained in the Identifier of the C-FIND request are matched against the values of the Key Attributes for each Query entity. For each entity for which the Attributes match all of the specified match attributes, construct an Identifier. This Identifier shall contain all of the values of the Attributes for this entity that match those in the C-FIND request. Return a response for each such Identifier. If there are no matching keys, then there are no matches; return a response with a status equal to Success and with no Identifier.

400 X.5 ASSOCIATION NEGOTIATION

Association establishment is the first phase of any instance of communication between peer DICOM AEs. The Association negotiation procedure specified in PS 3.7 shall be used to negotiate the supported SOP Classes.

405 Support for the SCP/SCU role selection negotiation is optional. The SOP Class Extended Negotiation is not used by this Service Class.

X.6 SOP CLASS DEFINITIONS

X.6.1 Product Characteristics Query SOP Class

X.6.1.1 Product Characteristics Query SOP Class Overview

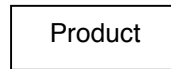
410 The Product Characteristics Query SOP class defines an application-level class of service that facilitates the communication of detailed information about drugs, contrast agents, or devices identified by a bar code or similar identifier. The detailed information is intended to be used both for automated processing and for presentation to a system operator.

The Product Characteristics Query SOP class supports the following example use cases:

- 415 — Obtain the active ingredient, concentration, or other parameters of a contrast agent for inclusion in the image SOP Instances created during use of the agent, or for setting up image acquisition parameters (e.g., ultrasound transducer frequency)
- Obtain the size parameters of a device (e.g., a catheter) for use in calibrating images that show that device
- 420 — Obtain a network reference for an online copy of the "product label" (regulated prescribing and use data) for a drug, contrast agent, or device.

X.6.1.2 Product Characteristics Query Information Model**X.6.1.2.1 E/R Model**

425 The Product Characteristics Query Information Model is represented by the Entity Relationship diagram shown in figure X.6 -1.

**Figure X.6-1 Product Characteristics E-R Diagram**

There is only one Information Entity in the model, which is the Product. The attributes of a Product can be found in the following Module in PS 3.3.

430 — Product Characteristics Module

X.6.1.2.2 Product Characteristics Query Attributes

Table X.6-1 defines the Attributes of the Product Characteristics Query Information Model:

435 **Table X.6-1**
ATTRIBUTES FOR THE PRODUCT CHARACTERISTICS QUERY INFORMATION MODEL

Description / Module	Tag	Match- ing Key Type	Return Key Type	Remark/Matching Type
Product Package Identifier	(0044,0001)	R	1	Shall be retrieved with Single Value Matching only.
Product Type Code Sequence	(0044,0007)	-	1	
>Code Value	(0008,0100)	-	1	
>Coding Scheme Designator	(0008,0102)	-	1	
>Code Meaning	(0008,0104)	-	1	
Product Name	(0044,0008)	-	1	
Product Expiration DateTime	(0044,000B)	-	2	
Product Parameter Sequence	(0044,0013)	-	2	
>Value Type	(0040,A040)	-	1	
>Concept Name Code Sequence	(0040,A043)	-	1	
>>Code Value	(0008,0100)	-	1	
>>Coding Scheme Designator	(0008,0102)	-	1	
>>Code Meaning	(0008,0104)	-	1	
>All other Attributes of Product Parameter Sequence		-	1C	Conditional on value of Value Type (0040,A040); See PS 3.3 Content Item Macro.
All other Attributes of Product		-	3	

<i>Characteristics Module</i>				
-------------------------------	--	--	--	--

The Product Package Identifier (0044,0001) might not be globally unique and might conflict with other identifiers used within the scope of the institution.

440 Note: The package identifiers are typically unique within the scope of the substance administration management systems. This is a warning that they are not UIDs.

X.6.1.3 Conformance Requirements

An implementation may conform to the Product Characteristics Query SOP Class as an SCU or an SCP. The Conformance Statement shall be in the format defined in PS 3.2.

445 X.6.1.3.1 SCU Conformance

An implementation that conforms to the Product Characteristics Query SOP Class shall support queries against the Information Model described in Section X.6.1.2 using the baseline C-FIND SCU Behavior described in Section X.4.1.2.

450 An implementation that conforms to the Product Characteristics Query SOP Class as an SCU shall state in its Conformance Statement the Return Key Attributes it requests, and how those Attributes are used in the application.

An implementation that conforms to the Product Characteristics Query 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.

455 X.6.1.3.2 SCP Conformance

An implementation that conforms to the Product Characteristics Query SOP Class shall support queries against the Product Characteristics Query Information Model described in Section X.6.1.2 using the C-FIND SCP Behavior described in Section X.4.1.3.

460 An implementation that conforms to the Product Characteristics Query SOP Class as an SCP shall state in its Conformance Statement the Return Key Attributes that it supports.

An implementation that conforms to the Product Characteristics Query SOP Class as an SCP shall state in its Conformance Statement how it makes use of Specific Character Set (0008,0005) when encoding responses.

X.6.1.4 SOP Class

465 The Product Characteristics Query SOP Class in the Substance Administration Service Class identifies the Product Characteristics Query Information Model, and the DIMSE-C operations supported. The following Standard SOP Class is identified:

SOP Class Name	SOP Class UID
Product Characteristics Query Information Model – FIND	1.2.840.10008.5.1.4.41

X.6.2 Substance Approval Query SOP Class

470 X.6.2.1 Substance Approval Query SOP Class Overview

The Substance Approval Query SOP Class defines an application-level class of service that allows a device at the point of care to obtain verification of the appropriateness of contrast agents and other drugs

administered during a procedure, based on the substance label barcode and the patient ID. The response is an authorization to proceed, or a warning, or a contra-indication for presentation to the system operator.

475 The Substance Approval Query SOP class supports the following example use cases:

- Obtain verification that administration of a specific drug or contrast agent for an image acquisition is appropriate for the patient
- Obtain verification that the implantation of a specific device under imaging guidance is appropriate for the patient

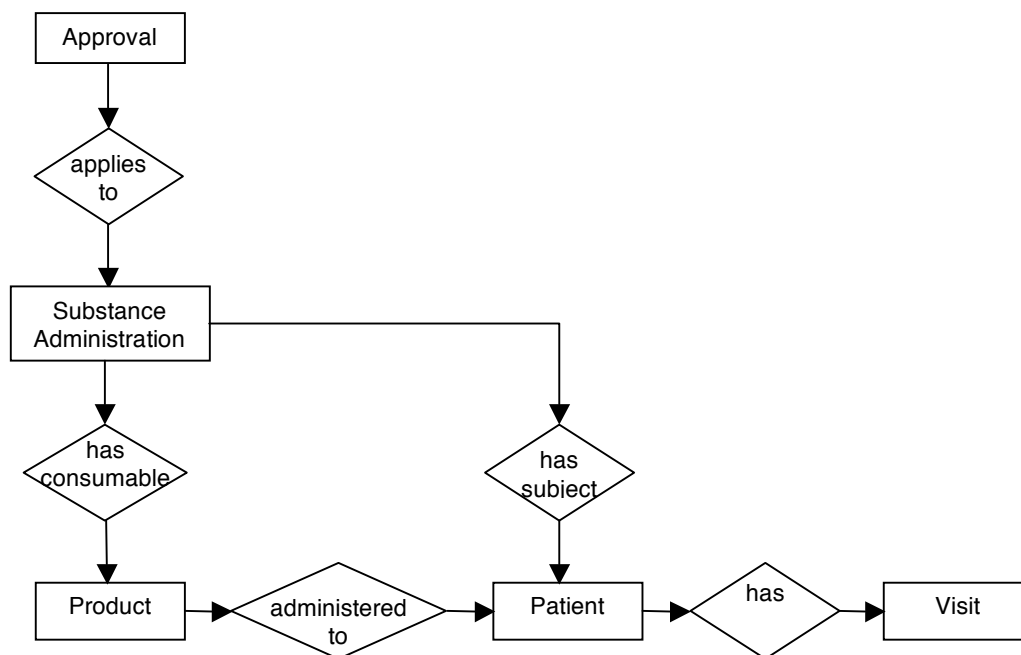
480

The Substance Approval Query SOP Class does not specify the mechanism used by the SCP to verify such appropriateness of administration (e.g., by comparison to allergy information in the patient's electronic health record). The duration of validity of an approval beyond the time of the response is not defined by the Standard.

485 X.6.2.2 Substance Approval Query Information Model

X.6.2.2.1 E/R Model

The Substance Approval Query Information Model is represented by the Entity Relationship diagram shown in figure X.6-2.



490

Figure X.6-2 Substance Approval E-R Diagram

The attributes of the Information Entities can be found in the following Modules in PS 3.3.

- Patient Identification Module
- Patient Demographics Module
- Visit Identification Module
- 495 — Substance Administration Module
- Substance Approval Module
- Product Characteristics Module

Only selected attributes of these Modules are used in the Substance Approval Query Information Model.

500 The Information Model is used in a bottom-up manner in the query; i.e., given a Product and a Patient, or alternatively a Product and a Visit, for a proposed Substance Administration act at the current time, find the Approval.

505 The Visit IE is included in the Information Model to support those institutions that identify patients (e.g., on a bar coded wristband) by Admission ID (i.e., the ID of the Visit), rather than Patient ID. This allows automation of query construction using a scan of the Admission ID. The Admission ID can be mapped to the Patient ID by the SCP for the purpose of the performing the query matching.

- Notes:
1. The Visit is identified by the Admission ID (0038,0010) Attribute, but in the “Model of the Real World for the Purpose of Modality-IS Interface” (see PS 3.3), the Visit is subsidiary to the Patient; hence the Admission ID may only be unique within the context of the patient, not within the context of the institution. The use of the Admission ID Attribute to identify the Visit (and hence the Patient) is only effective if the Admission ID is unique within the context of the institution.
 2. Certain institutions, e.g., ambulatory imaging centers that do not “admit” patients, may use the Imaging Service Request Identifier, or Accession Number, as an equivalent of the Admission ID. The SCU of this Query Service does not need to know the true origin or nature of the identifier, only that it is passed in the Query in the Admission ID (0038,0010) Attribute.
 3. There is conceptually a datetime of administration attribute of the Substance Administration act, which is implicitly assumed to be approximately the time of the query in this SOP Class.
 4. There is conceptually a dose attribute of the Product entity, which is the entire product identified by the bar code, and the request is for approval of administration of the entire product.

520 X.6.2.2.2 Substance Approval Query Attributes

Table X.6-2 defines the Attributes of the Substance Approval Query Information Model.

**Table X.6-2
ATTRIBUTES FOR THE SUBSTANCE APPROVAL QUERY INFORMATION MODEL**

Description / Module	Tag	Match- ing Key Type	Return Key Type	Remark/Matching Type
Patient				
Patient's Name	(0010,0010)	O	2	
Patient ID	(0010,0020)	R	1	Shall be retrieved with Single Value Matching only. One or both of Patient ID and Admission ID shall be present as a Matching Key in the Query
Issuer of Patient ID	(0010,0021)	O	2	
Patient's Birth Date	(0010,0030)	-	2	
Patient's Sex	(0010,0040)	-	2	
Visit				
Admission ID	(0038,0010)	R	2	Shall be retrieved with Single Value Matching only. One or both of Patient ID and Admission ID shall be present as a Matching Key in the Query

Issuer of Admission ID	(0038,0011)	O	2	
Product				
Product Package Identifier	(0044,0001)	R	1	Shall be retrieved with Single Value Matching only. Shall be present as a Matching Key in the Query.
Substance Administration				
Administration Route Code Sequence	(0054,0302)	R	1	Shall be present as a Matching Key in the Query.
>Code Value	(0008,0100)	R	1	
>Coding Scheme Designator	(0008,0102)	R	1	
>Code Meaning	(0008,0104)	-	1	
Approval				
Substance Administration Approval	(0044,0002)	-	1	
Approval Status Further Description	(0044,0003)	-	2	
Approval Status DateTime	(0044,0004)	-	1	

525 One or both of Patient ID (0010,0020) and Admission ID (0038,0010) shall be present as a Matching Key in the Query.

Product Package Identifier (0044,0001) shall be present as a Matching Key in the Query. The Product Package Identifier might not be globally unique and might conflict with other identifiers used within the scope of the institution.

530 Note: The package identifiers are typically unique within the scope of the substance administration management systems. This is a warning that they are not UIDs.

Administration Route Code Sequence (0054,0302) shall be present as a Matching Key in the Query, and a single Item shall be present in that Sequence with Code Value (0008,0100) and Coding Scheme Designator (0008,0102) as Matching Keys.

535

X.6.2.2.3 Substance Approval Query Responses

A Query response may have a status of Success or Failure (see X.4.1.1.4). A Failure Query response carries no semantics about the existence or status of approval of the Substance Administration.

540 A successful Query response will contain zero or one Pending response items. The case of zero Pending responses carries the semantics of no matching Approval Information Entity found, i.e., that the SCP cannot determine an approval, rather than that the substance administration is approved or disapproved. In this case a decision on substance administration needs to be made by the healthcare provider.

Note: Zero Pending responses may occur due do inability of the SCP to match the patient ID, product ID or route of administration.

545

In the case of one Pending response, the matching Approval Information Entity will explicitly convey the Substance Administration Approval (0044,0002) value of APPROVED, WARNING, or CONTRA_INDICATED.

X.6.2.3 Conformance Requirements

550 An implementation may conform to the Substance Approval Query SOP Class as an SCU or an SCP. The Conformance Statement shall be in the format defined in PS 3.2.

X.6.2.3.1 SCU Conformance

555 An implementation that conforms to the Substance Approval Query SOP Class shall support queries against the Information Model described in Section X.6.2.2 using the baseline C-FIND SCU Behavior described in Section X.4.1.2.

560 An implementation that conforms to the Substance Approval Query SOP Class as an SCU shall state in its Conformance Statement how the Query Attributes are used in the application, and how the application displays the returned attributes, in particular the values of Substance Administration Approval (0044,0002) and Approval Status Further Description (0044,0003). It shall state how it indicates a Query response with zero Pending items, or a Failure status.

An implementation that conforms to the Substance Approval Query 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.

X.6.2.3.2 SCP Conformance

565 An implementation that conforms to the Substance Approval Query SOP Class shall support queries against the Substance Approval Query Information Model described in Section X.6.2.2 using the C-FIND SCP Behavior described in Section X.4.1.3. It shall support all of the Attributes specified in the Information Model.

570 An implementation that conforms to the Substance Approval Query SOP Class as an SCP shall state in its Conformance Statement how it processes Required and Optional Matching Key Attributes. It shall state how it obtains the values for the Return Key Attributes.

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

575 X.6.2.4 SOP Class

The Substance Approval Query SOP Class in the Substance Administration Service Class identifies the Substance Approval Query Information Model, and the DIMSE-C operations supported. The following Standard SOP Class is identified:

SOP Class Name	SOP Class UID
Substance Approval Query Information Model - FIND	1.2.840.10008.5.1.4.42

Part 6 Addendum

580 Add the following to Section 6

Tag	Name	VR	VM
<u>(0044,0001)</u>	<u>Product Package Identifier</u>	<u>ST</u>	<u>1</u>
<u>(0044,0002)</u>	<u>Substance Administration Approval</u>	<u>CS</u>	<u>1</u>
<u>(0044,0003)</u>	<u>Approval Status Further Description</u>	<u>LT</u>	<u>1</u>
<u>(0044,0004)</u>	<u>Approval Status DateTime</u>	<u>DT</u>	<u>1</u>
<u>(0044,0007)</u>	<u>Product Type Code Sequence</u>	<u>SQ</u>	<u>1</u>
<u>(0044,0008)</u>	<u>Product Name</u>	<u>LO</u>	<u>1-n</u>
<u>(0044,0009)</u>	<u>Product Description</u>	<u>LT</u>	<u>1</u>
<u>(0044,000A)</u>	<u>Product Lot Identifier</u>	<u>LO</u>	<u>1</u>
<u>(0044,000B)</u>	<u>Product Expiration DateTime</u>	<u>DT</u>	<u>1</u>
<u>(0044,0010)</u>	<u>Substance Administration DateTime</u>	<u>DT</u>	<u>1</u>
<u>(0044,0011)</u>	<u>Substance Administration Notes</u>	<u>LO</u>	<u>1</u>
<u>(0044,0012)</u>	<u>Substance Administration Device ID</u>	<u>LO</u>	<u>1</u>
<u>(0044,0013)</u>	<u>Product Parameter Sequence</u>	<u>SQ</u>	<u>1</u>
<u>(0044,0019)</u>	<u>Substance Administration Parameter Sequence</u>	<u>SQ</u>	<u>1</u>

Add the following to Table A-1

UID Value	UID Name	UID Type	Part
...			
<u>1.2.840.10008.1.42</u>	<u>Substance Administration Logging SOP Class</u>	<u>SOP Class</u>	<u>PS 3.4</u>
<u>1.2.840.10008.1.42.1</u>	<u>Substance Administration Logging SOP Instance</u>	<u>Well-known SOP Instance</u>	<u>PS 3.4</u>
<u>1.2.840.10008.5.1.4.41</u>	<u>Product Characteristics Query SOP Class</u>	<u>SOP Class</u>	<u>PS 3.4</u>
<u>1.2.840.10008.5.1.4.42</u>	<u>Substance Approval Query SOP Class</u>	<u>SOP Class</u>	<u>PS 3.4</u>

Part 16 Addendum

Make the following changes to Part 16 Annex B

CID 3410 Numeric Parameters of Drugs/Contrast

590

Context ID 3410
Numeric Parameters of Drugs/Contrast
Type: Extensible Version: 20030327

Coding Scheme Designator	Code Value	Code Meaning
DCM	122091	Volume administered
DCM	122092	Undiluted dose administered
DCM	122093	Concentration
DCM	122094	Rate of administration
DCM	122095	Duration of administration
DCM	122096	Volume unadministered or discarded
<u>DCM</u>	<u>121382</u>	<u>Quantity administered</u>
<u>DCM</u>	<u>121383</u>	<u>Mass administered</u>

595 **CID 3423 Numeric Device Characteristics**

Context ID 3423
Numeric Device Characteristics
Type: Extensible Version: 20030327yyyymmdd

Coding Scheme Designator	Code Value	Code Meaning
SRT	G-A22A	Length
SRT	M-02550	Diameter
DCM	122097	Catheter Curve
DCM	122098	Transmit Frequency
<u>SRT</u>	<u>G-D705</u>	<u>Volume</u>
<u>DCM</u>	<u>121208</u>	<u>Inter-Marker Distance</u>

600

Add the following to Part 16 Annex B

CID 4050 Drug or Contrast Agent Characteristics

605

Context ID 4050
Drug or Contrast Agent Characteristics
Type: Extensible Version: yyyyymmdd

Coding Scheme Designator	Code Value	Code Meaning
SRT	G-C52F	Active Ingredient
DCM	121380	Active Ingredient Undiluted Concentration
DCM	121381	Contrast/Bolus Ingredient Opaque
SRT	G-D705	Volume

610 Add the following to Part 16 Annex D

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

Code Value	Code Meaning	Definition	Notes
...			
<u>121208</u>	<u>Inter-Marker Distance</u>	<u>Distance between marks on a device of calibrated size (e.g., a ruler)</u>	
<u>121380</u>	<u>Active Ingredient Undiluted Concentration</u>	<u>Concentration of the chemically or physically interesting (active) ingredient of a drug or contrast agent as delivered in product form from the manufacturer, typically in mg/ml.</u>	
<u>121381</u>	<u>Contrast/Bolus Ingredient Opaque</u>	<u>X-ray absorption of the active ingredient of a contrast agent ingredient is greater than the absorption of water (tissue).</u>	
<u>121382</u>	<u>Quantity administered</u>	<u>Number of units of substance (e.g., tablets) administered to a patient</u>	
<u>121383</u>	<u>Mass administered</u>	<u>Mass of substance administered to a patient</u>	

Part 17 Addendum

Add the following Annex to Part 17

615 **Annex X Use of Product Characteristics Attributes in Composite SOP Instances**

620 Bar coding or RFID tagging of contrast agents, drugs, and devices can facilitate the provision of critical information to the imaging modality, such as the active ingredient, concentration, etc. The Product Characteristics Query SOP Class allows a modality to submit the product bar code (or RFID tag) to an SCP to look up the product type, active substance, size/quantity, or other parameters of the product.

This product information can be included in appropriate attributes of the Contrast/Bolus, Device, or Intervention Modules of the Composite SOP Instances created by the modality. The product information then provides key acquisition context data necessary for the proper interpretation of the SOP Instances.

625 This annex provides informative information about mapping from the Product Characteristics Module attributes of the Product Characteristics Query to the attributes of Composite IODs included in several Modules.

630 Within this section, if no Product Characteristics Module source for the attribute value is provided, the modality would need to provide local data entry or user selection from a pick list to fill in appropriate values. Some values may need to be calculated based on user-performed dilution of the product at the time of administration.

X.1 CONTRAST/BOLUS MODULE

Table X-1 CONTRAST/BOLUS MODULE ATTRIBUTE MAPPING

Contrast/Bolus Module Attribute Name	Tag	Product Characteristics Module Source
Contrast/Bolus Agent	(0018,0010)	Product Name (0044,0008) Note: If Product Name is multi-valued, use the first value.
Contrast/Bolus Agent Sequence	(0018,0012)	--
>Include 'Code Sequence Macro'		Product Type Code Sequence (0044,0007) >'Code Sequence Macro'
Contrast/Bolus Route	(0018,1040)	
Contrast/Bolus Administration Route Sequence	(0018,0014)	
>Include 'Code Sequence Macro'		
>Additional Drug Sequence	(0018,002A)	
>Include 'Code Sequence Macro'		

Contrast/Bolus Volume	(0018,1041)	<i>If contrast is administered without dilution, and using full contents of dispensed product:</i> Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A) where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-D705, SRT, "Volume") and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (ml, UCUM, "ml")
Contrast/Bolus Start Time	(0018,1042)	
Contrast/Bolus Stop Time	(0018,1043)	
Contrast/Bolus Total Dose	(0018,1044)	<i>If contrast is administered using full contents of dispensed product:</i> Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-D705, SRT, "Volume") and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (ml, UCUM, "ml")
Contrast Flow Rate	(0018,1046)	
Contrast Flow Duration	(0018,1047)	
Contrast/Bolus Ingredient	(0018,1048)	Product Parameter Sequence (0044,0013) > Concept Code Sequence (0040,A168) > Code Meaning (0008,0104), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-C52F, SRT, "Active Ingredient") Note: Contrast/Bolus Ingredient is a CS VR (16 characters max, upper case), so a conversion from the LO VR is required.
Contrast/Bolus Ingredient Concentration	(0018,1049)	<i>If contrast is administered without dilution:</i> Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (121380, DCM, "Active Ingredient Undiluted Concentration") and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (mg/ml, UCUM, "mg/ml")

X.2 ENHANCED CONTRAST/BOLUS MODULE**Table X-2 ENHANCED CONTRAST/BOLUS MODULE ATTRIBUTE MAPPING**

Enhanced Contrast/Bolus Module Attribute Name	Tag	Product Characteristics Module Source
Contrast/Bolus Agent Sequence	(0018,0012)	--

>Include 'Code Sequence Macro'		Product Type Code Sequence (0044,0007) > 'Code Sequence Macro'
>Contrast/Bolus Agent Number	(0018,9337)	
>Contrast/Bolus Administration Route Sequence	(0018,0014)	
>>Include 'Code Sequence Macro'		
>Contrast/Bolus Ingredient Code Sequence	(0018,9338)	--
>>Include 'Code Sequence Macro'		Product Parameter Sequence (0044,0013) > Concept Code Sequence (0040,A168), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-C52F, SRT, "Active Ingredient")
>Contrast/Bolus Volume	(0018,1041)	<i>If contrast is administered without dilution, and using full contents of dispensed product:</i> Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-D705, SRT, "Volume") and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (ml, UCUM, "ml")
>Contrast/Bolus Ingredient Concentration	(0018,1049)	<i>If contrast is administered without dilution:</i> Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (121380, DCM, "Active Ingredient Undiluted Concentration") and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (mg/ml, UCUM, "mg/ml")
>Contrast/Bolus Ingredient Opaque	(0018,9425)	Product Parameter Sequence (0044,0013) > Concept Code Sequence (0040,A168) > Code Meaning (0008,0104), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (121381, DCM, "Contrast/Bolus Ingredient Opaque") and mapped Code Meaning is "YES" or "NO".
>Contrast Administration Profile Sequence	(0018,9340)	
>>Contrast/Bolus Volume	(0018,1041)	<i>If contrast is administered without dilution, and using full contents of dispensed product:</i> Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-D705, SRT,

		“Volume”) and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (ml, UCUM, “ml”)
>>Contrast/Bolus Start Time	(0018,1042)	
>>Contrast/Bolus Stop Time	(0018,1043)	
>>Contrast Flow Rate	(0018,1046)	
>>Contrast Flow Duration	(0018,1047)	

X.3 DEVICE MODULE

Table X-3 DEVICE MODULE ATTRIBUTE MAPPING

Device Module Attribute Name	Tag	Product Characteristics Module Source
Device Sequence	(0050,0010)	--
>Include ‘Code Sequence Macro’		Product Type Code Sequence (0044,0007) > ‘Code Sequence Macro’
>Device Length	(0050,0014)	Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-A22A, SRT, “Length”) and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (mm, UCUM, “mm”)
>Device Diameter	(0050,0016)	Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (M-02550, SRT, “Diameter”)
>Device Diameter Units	(0050,0017)	Product Parameter Sequence (0044,0013) > Measurement Units Code Sequence (0040,08EA) > Code Meaning (0008,0104), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (M-02550, SRT, “Diameter”) Note: Device Diameter Units is a CS VR (16 characters max, upper case), so a conversion from the LO VR is required.
>Device Volume	(0050,0018)	Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (G-D705, SRT, “Volume”) and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (ml, UCUM, “ml”)
>Inter-Marker Distance	(0050,0019)	Product Parameter Sequence (0044,0013) > Numeric Value (0040,A30A), where: Product Parameter Sequence > Concept Name Code Sequence (0040,A043) value is (121208, DCM, “Inter-

		Marker Distance”) and Product Parameter Sequence > Measurement Units Code Sequence (0040,08EA) is (mm, UCUM, “mm”)
>Device Description	(0050,0020)	Product Name (0044,0008) and/or Product Description (0044,0009)

640 **X.4 INTERVENTION MODULE****Table X-4 INTERVENTION MODULE ATTRIBUTE MAPPING**

Intervention Module Attribute Name	Tag	Product Characteristics Module Source
Intervention Sequence	(0018,0036)	
<i>>Include 'Code Sequence Macro'</i>		
>Intervention Status	(0018,0038)	
>Intervention Drug Sequence	(0018,0029)	--
<i>>>Include 'Code Sequence Macro'</i>		Product Type Code Sequence (0044,0007) > <i>'Code Sequence Macro'</i>
>Intervention Drug Start Time	(0018,0035)	
>Intervention Drug Stop Time	(0018,0027)	
> Administration Route Code Sequence	(0054,0302)	
<i>>>Include 'Code Sequence Macro'</i>		
>Intervention Description	(0018,003A)	

Part 2 Addendum

645 *Add Conformance Example*

**ANNEX H (informative) DICOM CONFORMANCE STATEMENT
MEDICATION-SYSTEM-GATEWAY**

Disclaimer:

650 This document is an example DICOM Conformance Statement for a fictional device called EXAMPLE-MEDICATION-SYSTEM-GATEWAY, which is a networked computer system used to provide radiology systems with access to a pharmacy system and a medication administration record system.

655 As stated in the annex title, this document is truly informative, and not normative. A conformance statement of an actual product might implement additional services and options as appropriate for its specific purpose. In addition, an actual product might implement the services described in a different manner and, for example, with different characteristics and/or sequencing of activities. In other words, this conformance statement example does not intend to standardize a particular manner that a product might implement DICOM functionality.

H.0 COVER PAGE

660 Company Name: EXAMPLE-GATEWAY-PRODUCTS.
 Product Name: EXAMPLE-MEDICATION-SYSTEM-GATEWAY
 Version: 1.0-rev. A.1
 Internal document number: 4226-xxx-yyy-zzz rev 1
 Date: YYYYMMDD

665

H.1 CONFORMANCE STATEMENT OVERVIEW

670 The EXAMPLE-MEDICATION-SYSTEM-GATEWAY is a networked computer system used to provide radiology systems with access to a pharmacy system and a medication administration record system. It allows imaging modalities systems and departmental information systems to retrieve information about drugs and contrast agents, to verify that administration of a drug or contrast agent to a particular patient is allowed, and to record the administration of a drug or contrast agent to a patient.

**Table H.1-1
 NETWORK SERVICES**

SOP Classes	User of Service (SCU)	Provider of Service (SCP)
Workflow Management		
Substance Administration Logging	No	Yes
Query/Retrieve		
Product Characteristics Query	No	Yes
Substance Approval Query	No	Yes

675

H.2 TABLE OF CONTENTS

A table of contents shall be provided to assist readers in easily finding the needed information.

H.3 INTRODUCTION

H.3.1 REVISION HISTORY

Document Version	Date	Author	Description
1.1	October 30, 2006	DICOM WG6	Version for Final Text

680

H.3.2 AUDIENCE

This document is intended for hospital staff, health system integrators, software designers or implementers. It is assumed that the reader has a working understanding of DICOM.

H.3.3 REMARKS

685 DICOM, by itself, does not guarantee interoperability. However, the Conformance Statement facilitates a first-level validation for interoperability between different applications supporting the same DICOM functionality.

This Conformance Statement is not intended to replace validation with other DICOM equipment to ensure proper exchange of information intended.

690 The scope of this Conformance Statement is to facilitate communication between the EXAMPLE-MEDICATION-SYSTEM-GATEWAY and other DICOM systems. The Conformance Statement should be read and understood in conjunction with the DICOM Standard [DICOM]. However, by itself it is not guaranteed to ensure the desired interoperability and a successful interconnectivity.

695 The EXAMPLE-MEDICATION-SYSTEM-GATEWAY relies on the associated, but independent, Pharmacy and Medication Administration Record Systems to fulfill the medical application functions implicit in the DICOM services supported. In particular, these functions are part of a critical patient safety workflow. However, those patient safety functions are not specified by DICOM, and they are not full described by this Conformance Statement. Please see the product specifications of the Pharmacy and Medication Administration Record Systems for full details on the clinical decision support and records management features of those systems.

700

The user should be aware of the following important issues:

- The comparison of different Conformance Statements is the first step towards assessing interconnectivity between EXAMPLE-MEDICATION-SYSTEM-GATEWAY and other DICOM conformant equipment.
- 705 — Test procedures should be defined to validate the desired level of connectivity.

This document is a sample DICOM Conformance Statement created for DICOM Working Group 6. It is to be used solely as an example to illustrate how to create a DICOM Conformance Statement for a server

supporting the DICOM Substance Administration Information Services. The subject of the document, EXAMPLE-MEDICATION-SYSTEM-GATEWAY, is a fictional product.

710 **H.3.4 DEFINITIONS, TERMS AND ABBREVIATIONS**

	AE	Application Entity
	DICOM	Digital Imaging and Communications in Medicine
	IE	Information Entity
	IOD	Information Object Definition
715	PDU	Protocol Data Unit
	MAR	Medication Administration Record
	SCP	Service Class Provider
	SCU	Service Class User
	SOP	Service-Object Pair
720	TCP/IP	Transmission Control Protocol/Internet Protocol
	UID	Unique Identifier
	VM	Value Multiplicity
	VR	Value Representation

H.4 NETWORKING

725 H.4.1 IMPLEMENTATION MODEL

H.4.1.1 Application Data Flow

The division of EXAMPLE-MEDICATION-SYSTEM-GATEWAY into the separate DICOM Application Entities represents their independent logical functionality.

730 By default all of the defined Application Entities have different AE Titles. However, EXAMPLE-MEDICATION-SYSTEM-GATEWAY can be configured so that the PHARMACY-SCP AE and MAR-SCP AE share the same Application Entity Title.

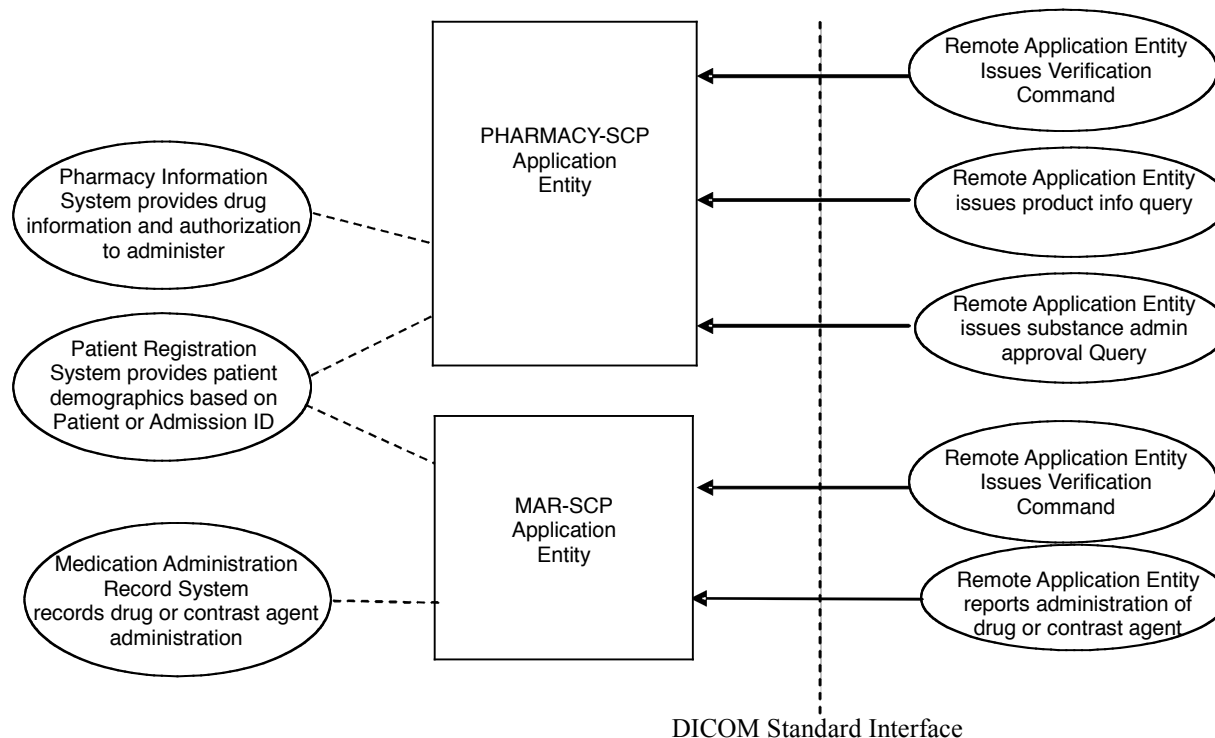


Figure H.4.1-1
EXAMPLE-MEDICATION-SYSTEM-GATEWAY DICOM DATA FLOW DIAGRAM

735

H.4.1.2 Functional Definition of AEs

H.4.1.2.1 Functional Definition of PHARMACY-SCP Application Entity

The PHARMACY-SCP AE handles incoming external queries for pharmacy (drug and contrast agent) product data, and also handles requests for approval of administration of pharmacy product. The PHARMACY-SCP AE handles queries by translating the standard DICOM queries to the non-standard interface of the Pharmacy Information System and the Patient Registration System.

740

745 The PHARMACY-SCP AE waits for another application to connect at the presentation address configured for its Application Entity Title. PHARMACY-SCP AE will accept Associations with Presentation Contexts for SOP Classes of the DICOM Substance Administration Information Service Class, and Verification Service Class. It will handle query requests on these Presentation Contexts and respond with values corresponding to the information provided by the Pharmacy Information System.

H.4.1.2.2 Functional Definition of MAR-SCP Application Entity

The MAR-SCP AE receives incoming DICOM notifications of drug or contrast agent administration, and adds them to the Medication Administration Record System database.

750 The MAR-SCP AE waits for another application to connect at the presentation address configured for its Application Entity Title. The MAR-SCP AE will accept Associations with Presentation Contexts for SOP Classes of the Substance Administration Logging and Verification SOP Classes. Any drug or contrast agent administration images notifications received on such Presentation Contexts will be added to the Medication Administration Record System database.

755 **H.4.1.3 Sequencing of Real-World Activities**

There are no sequencing constraints across the EXAMPLE-MEDICATION-SYSTEM-GATEWAY Application Entities. Each query or notification is handled independently.

H.4.2 AE SPECIFICATIONS

H.4.2.1 PHARMACY-SCP Application Entity Specification

760 **H.4.2.1.1 SOP Classes**

The PHARMACY-SCP AE provides Standard Conformance to the following DICOM SOP Classes:

**Table H.4.2-1
SOP CLASSES FOR PHARMACY-SCP AE**

SOP Class Name	SOP Class UID	SCU	SCP
Verification	1.2.840.10008.1.1	No	Yes
Product Characteristics Query	1.2.840.10008.5.1.4.41	No	Yes
Substance Approval Query	1.2.840.10008.5.1.4.42	No	Yes

765 **H.4.2.1.2 Association Policies**

H.4.2.1.2.1 General

The PHARMACY-SCP AE will never initiate Associations; it only accepts Association Requests from external DICOM AEs. The PHARMACY-SCP AE will accept Associations for Verification (C-ECHO) and Query (C-FIND) requests.

770 The DICOM standard Application Context Name for DICOM is always accepted:

**Table H.4.2-2
DICOM APPLICATION CONTEXT FOR PHARMACY-SCP AE**

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

H.4.2.1.2.2 Number of Associations

775 The PHARMACY-SCP AE can support multiple simultaneous Associations. Each time the PHARMACY-SCP AE receives an Association, a child process will be spawned to process the Verification or Query

request. The maximum number of child processes, and thus the maximum number of simultaneous Associations that can be processed, is set by configuration. The default maximum is 10 in total.

**Table H.4.2-3
NUMBER OF SIMULTANEOUS ASSOCIATIONS AS A SCP FOR PHARMACY-SCP AE**

780

Maximum number of simultaneous Associations	10 (Configurable)
---	-------------------

H.4.2.1.2.3 Asynchronous Nature

The PHARMACY-SCP AE does not support asynchronous communication (multiple outstanding transactions over a single Association). All Association requests must be completed and acknowledged before a new operation can be initiated.

785

**Table H.4.2-4
ASYNCHRONOUS NATURE AS A SCP FOR PHARMACY-SCP AE**

Maximum number of outstanding asynchronous transactions	1 (Not Configurable)
---	----------------------

H.4.2.1.2.4 Implementation Identifying Information

The implementation information for the Application Entity is:

790

**Table H.4.2-5
DICOM IMPLEMENTATION CLASS AND VERSION FOR PHARMACY-SCP AE**

Implementation Class UID	1.840.xxxxxxx.yyy.etc...
Implementation Version Name	EX_VERS_01

Note that all EXAMPLE-MEDICATION-SYSTEM-GATEWAY AE's use the same Implementation Class UID and Implementation Version Name. This Version Name is updated with each new release of the product software, as the different AE versions are never released independently.

795

H.4.2.1.3 Association Initiation Policy

The PHARMACY-SCP AE does not initiate Associations.

H.4.2.1.4 Association Acceptance Policy

H.4.2.1.4.1 Activity – Handling Query Requests

800

H.4.2.1.4.1.1 Description and Sequencing of Activity

The PHARMACY-SCP AE accepts Associations only if they have valid Presentation Contexts. If none of the requested Presentation Contexts are accepted then the Association Request itself is rejected. It can be configured to only accept Associations with certain hosts (using TCP/IP address) and/or Application Entity Titles.

805

The following sequencing applies to the PHARMACY-SCP AE for handling queries (C-FIND-Requests):

1. Peer AE opens an Association with the PHARMACY-SCP AE.
2. Peer AE sends a C-FIND-RQ Message
3. If the query is for a Substance Administration Approval, PHARMACY-SCP AE requests basic patient demographic data (e.g., name, sex) from the Patient Registration System

810

4. PHARMACY-SCP AE translates the query into a request for the Pharmacy Information System (for either Product Information or for Substance Administration Approval), which responds with the requested data (or an indication of no matching data for the query).
- 815 5. If matching information is provided, PHARMACY-SCP AE returns a C-FIND-RSP Message to the peer AE with the matching information.
6. A final C-FIND-RSP is sent indicating that the matching is complete.
7. Peer AE closes the Association. Note that the peer AE does not have to close the Association immediately. Further C-FIND Requests can be sent over the Association before it is closed.

820 The PHARMACY-SCP AE may reject Association attempts as shown in the table below. The Result, Source and Reason/Diag columns represent the values returned in the corresponding fields of an ASSOCIATE-RJ PDU (see PS 3.8, Section 9.3.4). The following abbreviations are used in the Source column:

- a. 1 – DICOM UL service-user
- b. 2 – DICOM UL service-provider (ASCE related function)
- 825 c. 3 – DICOM UL service-provider (Presentation related function)

Table H.4.2-6
ASSOCIATION REJECTION REASONS

Result	Source	Reason/Diag	Explanation
2 – rejected-transient	c	2 – local-limit-exceeded	The (configurable) maximum number of simultaneous Associations has been reached. An Association request with the same parameters may succeed at a later time.
2 – rejected-transient	c	1 – temporary-congestion	No Associations can be accepted at this time due to the real-time requirements of higher priority activities or because insufficient resources are available (e.g. memory, processes, threads). An Association request with the same parameters may succeed at a later time.
1 – rejected-permanent	a	2 – application-context-name-not-supported	The Association request contained an unsupported Application Context Name. An association request with the same parameters will not succeed at a later time.
1 – rejected-permanent	a	7 – called-AE-title-not-recognized	The Association request contained an unrecognized Called AE Title. An Association request with the same parameters will not succeed at a later time unless configuration changes are made. This rejection reason normally occurs when the Association initiator is incorrectly configured and attempts to address the Association acceptor using the wrong AE Title.
1 – rejected-permanent	a	3 – calling-AE-title-not-recognized	The Association request contained an unrecognized Calling AE Title. An Association request with the same parameters will not succeed at a later time unless configuration changes are made. This rejection reason normally occurs when the Association acceptor has not been configured to recognize the AE Title of the Association initiator.
1 – rejected-permanent	b	1 – no-reason-given	The Association request could not be parsed. An Association request with the same format will not succeed at a later time.

830 The PHARMACY-SCP AE will close the Association under the exceptional circumstances listed in Table H.4.2-7.

**Table H.4.2-7
PHARMACY-SCP AE COMMUNICATION FAILURE BEHAVIOR**

Exception	Behavior
Timeout expiry for an expected DICOM Message Request (DIMSE level timeout). I.e. The PHARMACY-SCP AE is waiting for the next C-FIND Request on an open Association but the timer expires.	The Association is aborted by issuing a DICOM A-ABORT. Error message is output to the Service Audit Trail.
Timeout expiry for an expected DICOM PDU or TCP/IP packet (Low-level timeout). I.e. The PHARMACY-SCP AE is waiting for the next message PDU but the timer expires.	The Association is aborted by issuing a DICOM A-ABORT. Error message is output to the Service Audit Trail.
Association aborted by the SCU or the network layers indicate communication loss (i.e. low-level TCP/IP socket closure)	Error message is output to the Service Audit Trail.

835 **H.4.2.1.4.1.2 Accepted Presentation Contexts**

The PHARMACY-SCP AE will accept Presentation Contexts as shown in Table H.4.2-8.

**Table H.4.2-8
ACCEPTED PRESENTATION CONTEXTS BY THE PHARMACY-SCP AE**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name	UID		
Verification	1.2.840.10008.1.1	DICOM Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
Product Characteristics Query	1.2.840.10008.5.1.4.41	DICOM Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		DICOM Explicit VR Little Endian	1.2.840.10008.1.2.1		
Substance Approval Query	1.2.840.10008.5.1.4.42	DICOM Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		DICOM Explicit VR Little Endian	1.2.840.10008.1.2.1		

840 **H.4.2.2.4.1.3 SOP Specific Conformance for Verification SOP Class**

The PHARMACY -SCP AE provides standard conformance to the Verification SOP Class as an SCP.

H.4.2.1.4.1.4 SOP Specific Conformance for Product Characteristics Query SOP Class

The PHARMACY-SCP AE supports the Return Key Attributes shown in Tables H.4.2-9 and H.4.2-10. Only those attributes requested in the query identifier are returned. Note that queries about devices are not supported.

845

Table H.4.2-9
RETURN KEY ATTRIBUTES SUPPORTED FOR PRODUCT CHARACTERISTICS QUERY

Product Package Identifier	(0044,0001)	Returned with query match value
Product Type Code Sequence	(0044,0007)	RxNorm coded type of drug
Manufacturer	(0008,0070)	
Product Name	(0044,0008)	
Product Description	(0044,0009)	
Product Lot Identifier	(0044,000A)	
Product Expiration DateTime	(0044,000B)	
Product Parameter Sequence	(0044,0013)	See Table H.4.2-10 for parameters supported
Pertinent Documents Sequence	(0038,0100)	Zero or one item returned
>Retrieve URI	(0040,E010)	

Table H.4.2-10
PRODUCT PARAMETER SEQUENCE ITEM CONCEPTS SUPPORTED

Concept Name Code Sequence (0040,A043)
(G-D705, SRT, "Volume")
(G-C52F, SRT, "Active Ingredient")

Only the ASCII (DICOM Default) character set is supported by the Pharmacy Information System; Specific Character Set (0008,0005) is not used.

H.4.2.1.4.1.5 SOP Specific Conformance for Substance Approval Query SOP Class

855 The PHARMACY-SCP AE supports the Matching Key Attributes shown in Table H.4.2-11. It can be configured to match on Patient ID, or on Admission ID, or on a combination of Patient ID and Issuer of Patient ID, or on a combination of Admission ID and Issuer of Admission ID. As required by the SOP Class, one of Patient ID or Admission ID must be present in the query, as must Product Package Identifier and Administration Route Code Sequence. Note, however, that the Pharmacy Information System does not support verification of administration route. Also note that queries about devices are not supported.

860

Table H.4.2-11
MATCHING KEY ATTRIBUTES SUPPORTED FOR SUBSTANCE APPROVAL QUERY

Patient ID	(0010,0020)
Issuer of Patient ID	(0010,0021)
Admission ID	(0038,0010)
Issuer of Admission ID	(0038,0011)
Product Package Identifier	(0044,0001)
Administration Route Code Sequence	(0054,0302)
>Code Value	(0008,0100)
>Coding Scheme Designator	(0008,0102)

865 The PHARMACY-SCP AE supports the Return Key Attributes shown in Table H.4.2-12. Only those attributes requested in the query identifier are returned.

**Table H.4.2-12
RETURN KEY ATTRIBUTES SUPPORTED FOR SUBSTANCE APPROVAL QUERY**

Patient's Name	(0010,0010)	Obtained from Patient Registration System
Patient ID	(0010,0020)	Obtained from Patient Registration System if AE configured for Admission ID matching, or Admission ID + Issuer of Admission ID matching
Issuer of Patient ID	(0010,0021)	Returned only if AE configured for Patient ID + Issuer of Patient ID matching
Patient's Birth Date	(0010,0030)	Obtained from Patient Registration System
Patient's Sex	(0010,0040)	Obtained from Patient Registration System
Admission ID	(0038,0010)	Returned only if AE configured for Admission ID matching, or Admission ID + Issuer of Admission ID matching
Issuer of Admission ID	(0038,0011)	Returned only if AE configured for Admission ID + Issuer of Admission ID matching
Product Package Identifier	(0044,0001)	Returned with query match value
Administration Route Code Sequence	(0054,0302)	Returned with query match value
Substance Administration Approval	(0044,0002)	Obtained from Pharmacy Information System
Approval Status Further Description	(0044,0003)	Obtained from Pharmacy Information System
Approval Status DateTime	(0044,0004)	

870 Specific Character Set (0008,0005) is returned with value ISO_IR 192 if the Patient Registration System provides non-ASCII Unicode characters in Patient Name.

H.4.2.1.4.1.6 Pharmacy-SCP AE C-FIND Response Behavior

The PHARMACY-SCP AE supports the C-FIND Response Status return values and behavior shown in Table H.4.2-13.

**Table H.4.2-13
PHARMACY-SCP AE C-FIND RESPONSE STATUS RETURN BEHAVIOR**

875

Service Status	Further Meaning	Error Code	Behavior
Success	Success	0000	Matching is complete. No final identifier is supplied.
Failure	Out of Resources	A700	System reached the limit in memory usage for queuing requests to the Pharmacy Information System. Error message is output to as an alert to the Service Audit Trail.
	Identifier does not match SOP Class	A900	The C-FIND query identifier contains invalid Elements or values, or is missing mandatory Elements or values for the specified SOP Class. Error message is output to the Service Audit Trail.
	Unable to process	C001	The AE is unable to establish a session with the Pharmacy Information System. Error message is output to the Service Audit Trail.
	Unable to process	C002	The AE is unable to establish a session with the Patient Registration System. Error message is output to the Service Audit Trail.
	Unable to process	C110	The AE is unable to identify the Patient. Error message is output to the Service Audit Trail.
	Unable to process	C120	The AE is unable to identify the Product. Error message is output to the Service Audit Trail.
Cancel	Matching terminated due to Cancel Request	FE00	The C-FIND SCU sent a Cancel Request. This has been acknowledged and the search for matches has been halted.
Pending	Matches are continuing and current match is supplied.	FF00	Indicates that the successful match is returned and a further response (0000) is forthcoming. This status code is returned if all Optional keys in the query identifier are actually supported.
	Matches are continuing but one or more Optional Keys were not supported.	FF01	Indicates that the successful match is returned and a further response (0000) is forthcoming. This status code is returned if there are Optional keys in the query identifier that are not supported.

H.4.2.2 MAR-SCP Application Entity Specification

H.4.2.2.1 SOP Classes

880 The MAR-SCP AE provides Standard Conformance to the following DICOM SOP Classes:

**Table H.4.2-14
SOP CLASSES FOR MAR-SCP AE**

SOP Class Name	SOP Class UID	SCU	SCP
Verification	1.2.840.10008.1.1	No	Yes
Substance Administration Logging	1.2.840.10008.1.42	No	Yes

H.4.2.2.2 Association Policies

885 **H.4.2.2.2.1 General**

The MAR-SCP AE will never initiate Associations; it only accepts Association Requests from external DICOM AEs. The MAR-SCP AE will accept Associations for Verification (C-ECHO) and Substance Administration Logging (N-ACTION) requests.

The DICOM standard Application Context Name for DICOM 3.0 is always accepted and proposed:

890

**Table H.4.2-15
DICOM APPLICATION CONTEXT FOR MAR-SCP AE**

Application Context Name	1.2.840.10008.3.1.1.1
--------------------------	-----------------------

H.4.2.2.2.2 Number of Associations

895 The MAR-SCP AE can support multiple simultaneous Associations. Each time the MAR-SCP AE receives an Association, a child process will be spawned to process the Verification or Substance Administration Logging request. The maximum number of child processes, and thus the maximum number of simultaneous Associations that can be processed, is set by configuration. The default maximum number is 10 in total.

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**Table H.4.2-16
NUMBER OF SIMULTANEOUS ASSOCIATIONS AS AN SCP FOR MAR-SCP AE**

Maximum number of simultaneous Associations requested by peer AEs	10 (Configurable)
---	-------------------

H.4.2.2.2.3 Asynchronous Nature

905 The MAR-SCP AE does not support asynchronous communication (multiple outstanding transactions over a single Association). All Association requests must be completed and acknowledged before a new operation can be initiated.

**Table H.4.2-17
ASYNCHRONOUS NATURE AS A SCP FOR MAR-SCP AE**

Maximum number of outstanding asynchronous transactions	1 (Not Configurable)
---	----------------------

H.4.2.2.2.4 Implementation Identifying Information

910 The implementation information for this Application Entity is:

**Table H.4.2-18
DICOM IMPLEMENTATION CLASS AND VERSION FOR MAR-SCP AE**

Implementation Class UID	1.840.xxxxxxx.yyy.etc...
--------------------------	--------------------------

Implementation Version Name	EX_VERS_01
-----------------------------	------------

915 Note that all EXAMPLE-MEDICATION-SYSTEM-GATEWAY AE's use the same Implementation Class UID and Implementation Version Name. This Version Name is updated with each new release of the product software, as the different AE versions are never released independently.

H.4.2.2.3 Association Initiation Policy

The MAR-SCP AE does not initiate Associations.

H.4.2.2.4 Association Acceptance Policy

920 H.4.2.2.4.1 Activity – Handling Substance Administration Logging Requests

H.4.2.2.4.1.1 Description and Sequencing of Activity

925 The MAR-SCP AE accepts Associations only if they have valid Presentation Contexts. If none of the requested Presentation Contexts are accepted then the Association Request itself is rejected. It can be configured to only accept Associations with certain hosts (using TCP/IP address) and/or Application Entity Titles.

The following sequencing applies to the MAR-SCP AE for handling Substance Administration Logging Requests (N-ACTION):

1. Peer AE opens an Association with the MAR-SCP AE.
2. Peer AE sends N-ACTION-RQ to request logging of a substance administration event.
- 930 3. If the request does not include the Patient ID, MAR-SCP AE requests the Patient ID corresponding to the Admission ID from the Patient Registration System
4. MAR-SCP AE translates the logging request into a database operation on the Medication Administration Record System database.
5. MAR-SCP AE responds with N-ACTION-RSP to indicate that it received and processed the request.
- 935 6. Peer AE closes the Association. Note that the peer AE does not have to close the Association immediately. Further N-ACTION Requests can be sent over the Association before it is closed.

The MAR-SCP AE may reject Association attempts as shown in the Table below. The Result, Source and Reason/Diag columns represent the values returned in the corresponding fields of an ASSOCIATE-RJ PDU (see PS 3.8, Section 9.3.4). The following abbreviations are used in the Source column:

- 940 a. 1 – DICOM UL service-user
- b. 2 – DICOM UL service-provider (ASCE related function)
- c. 3 – DICOM UL service-provider (Presentation related function)

945 **Table H.4.2-19**
ASSOCIATION REJECTION REASONS

Result	Source	Reason/Diag	Explanation
2 – rejected-transient	c	2 – local-limit-exceeded	The (configurable) maximum number of simultaneous Associations has been reached. An Association request with the same parameters may succeed at a later time.
2 – rejected-transient	c	1 – temporary-congestion	No Associations can be accepted at this time due to the real-time requirements of higher priority activities (e.g. during image acquisition no Associations will be accepted) or because insufficient resources are available (e.g. memory,

			processes, threads). An Association request with the same parameters may succeed at a later time.
1 – rejected-permanent	a	2 – application-context-name-not-supported	The Association request contained an unsupported Application Context Name. An association request with the same parameters will not succeed at a later time.
1 – rejected-permanent	a	7 – called-AE-title-not-recognized	The Association request contained an unrecognized Called AE Title. An Association request with the same parameters will not succeed at a later time unless configuration changes are made. This rejection reason normally occurs when the Association initiator is incorrectly configured and attempts to address the Association acceptor using the wrong AE Title.
1 – rejected-permanent	a	3 – calling-AE-title-not-recognized	The Association request contained an unrecognized Calling AE Title. An Association request with the same parameters will not succeed at a later time unless configuration changes are made. This rejection reason normally occurs when the Association acceptor has not been configured to recognize the AE Title of the Association initiator.
1 – rejected-permanent	b	1 – no-reason-given	The Association request could not be parsed. An Association request with the same format will not succeed at a later time.

The MAR-SCP AE will close the Association under the exceptional circumstances listed in Table H.4.2-20.

**Table H.4.2-20
PHARMACY-SCP AE COMMUNICATION FAILURE BEHAVIOR**

Exception	Behavior
Timeout expiry for an expected DICOM Message Request (DIMSE level timeout). I.e. The MAR-SCP AE is waiting for the next N-ACTION Request on an open Association but the timer expires.	The Association is aborted by issuing a DICOM A-ABORT. Error message is output to the Service Audit Trail.
Timeout expiry for an expected DICOM PDU or TCP/IP packet (Low-level timeout). I.e. The MAR-SCP AE is waiting for the next message PDU but the timer expires.	The Association is aborted by issuing a DICOM A-ABORT. Error message is output to the Service Audit Trail.
Association aborted by the SCU or the network layers indicate communication loss (i.e. low-level TCP/IP socket closure)	Error message is output to the Service Audit Trail.

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H.4.2.2.4.1.2 Accepted Presentation Contexts

The MAR-SCP AE will accept Presentation Contexts as shown in Table H.4.2-21.

**Table H.4.2-21
ACCEPTED PRESENTATION CONTEXTS BY MAR-SCP AE**

Presentation Context Table					
Abstract Syntax		Transfer Syntax		Role	Ext. Neg.
Name	UID	Name	UID		
Verification	1.2.840.10008.1.1	DICOM Implicit VR	1.2.840.10008.1.2	SCP	None

Presentation Context Table					
Abstract Syntax		Transfer Syntax			
		Little Endian			
Substance Administration Logging	1.2.840.10008.1.42	DICOM Implicit VR Little Endian	1.2.840.10008.1.2	SCP	None
		DICOM Explicit VR Little Endian	1.2.840.10008.1.2.1		

955

H.4.2.2.4.1.3 SOP Specific Conformance for Verification SOP Class

The MAR-SCP AE provides standard conformance to the Verification SOP Class as an SCP.

H.4.2.2.4.1.4 SOP Specific Conformance for Substance Administration Logging SOP Classes

960

As required by the SOP Class, one of Patient ID or Admission ID must be present in the Substance Administration Logging request. If the request does not include the Patient ID, the MAR-SCP AE requests the Patient ID corresponding to the Admission ID from the Patient Registration System.

The MAR-SCP AE SCP translates the attributes shown in Table H.4.2-22 into database fields of the Medication Administration Record System. All other provided attributes are converted to text strings and placed in the ClinicalNotes field of the database.

965

Table H.4.2-22
ATTRIBUTES OF LOGGING REQUEST IMPORTED TO MAR DATABASE

Patient ID	(0010,0020)
Product Package Identifier	(0044,0001)
Product Name	(0044,0008)
Substance Administration DateTime	(0044,0010)
Administration Route Code Sequence	(0054,0302)
Operator Identification Sequence	(0008,1072)

The MAR-SCP AE supports the N-ACTION Response Status return values and behavior shown in Table H.4.2-23.

970

Table H.4.2-23
MAR-SCP AE N-ACTION RESPONSE STATUS RETURN REASONS

Service Status	Further Meaning	Status Code	Reason
Success	Success	0000	The log entry was successfully received and stored in the Medication Administration Record System database.
Failure	Processing failure	0110	The AE is unable to establish a session with the Medication Administration Record System (Error ID=C003), or with the Patient Registration System (Error ID=C002). Error message is output to the Service Audit Trail.

Operator not authorized to add entry to Medication Administration Record	C10E	The AE received a user authorization rejection from the Medication Administration Record System. Error message is output to the Service Audit Trail.
Patient cannot be identified from Patient ID or Admission ID	C110	The AE is unable to identify the Patient. Error message is output to the Service Audit Trail.
Update of Medication Administration Record failed	C111	The Medication Administration Record System reported a database error. Error message is output to the Service Audit Trail.

H.4.3 NETWORK INTERFACES

H.4.3.1 Physical Network Interface

975 The EXAMPLE-MEDICATION-SYSTEM-GATEWAY supports a single network interface. One of the following physical network interfaces will be available depending on installed hardware options:

**Table H.4.3-1
SUPPORTED PHYSICAL NETWORK INTERFACES**

Ethernet 100baseT
Gigabit Ethernet

980 **H.4.3.2 Additional Protocols**

EXAMPLE-MEDICATION-SYSTEM-GATEWAY conforms to the System Management Profiles listed in Table H.4.3-2. All requested transactions for the listed profiles and actors are supported. It does not support any optional transactions.

**Table H.4.3-2
SUPPORTED SYSTEM MANAGEMENT PROFILES**

985

Profile Name	Actor	Protocols Used	Optional Transactions	Security Support
Network Address Management	DHCP Client	DHCP	N/A	
	DNS Client	DNS	N/A	

H.4.3.2.1 DHCP

990 DHCP can be used to obtain TCP/IP network configuration information. The network parameters obtainable via DHCP are shown in Table H.4.3-3. The Default Value column of the table shows the default used if the DHCP server does not provide a value. Values for network parameters set in the Service/Installation tool take precedence over values obtained from the DHCP server. Support for DHCP can be configured via the Service/Installation Tool. The Service/Installation tool can be used to configure the machine name. If DHCP is not in use, TCP/IP network configuration information can be manually configured via the Service/Installation Tool.

995

**Table H.4.3-3
SUPPORTED DHCP PARAMETERS**

DHCP Parameter	Default Value
IP Address	None
Hostname	Requested machine name
List of NTP servers	Empty list
List of DNS servers	Empty list
Routers	Empty list
Static routes	None
Domain name	None
Subnet mask	Derived from IP Address (see service manual)
Broadcast address	Derived from IP Address (see service manual)
Default router	None
Time offset	Site configurable (from Time zone)
MTU	Network Hardware Dependent
Auto-IP permission	No permission

If the DHCP server refuses to renew a lease on the assigned IP address all active DICOM Associations will be aborted.

1000 **H.4.3.2.2 DNS**

DNS can be used for address resolution. If DHCP is not in use or the DHCP server does not return any DNS server addresses, the identity of a DNS server can be configured via the Service/Installation Tool. If a DNS server is not in use, local mapping between hostname and IP address can be manually configured via the Service/Installation Tool.

1005 **H.4.4 CONFIGURATION**

H.4.4.1 AE Title/Presentation Address Mapping

H.4.4.1.1 Local AE Titles

The mapping from AE Title to TCP/IP addresses and ports is configurable and set at the time of installation by Installation Personnel.

1010

**Table H.4.4-1
DEFAULT APPLICATION ENTITY CHARACTERISTICS**

Application Entity	Role	Default AE Title	Default TCP/IP Port
PHARMACY-SCP	SCP	EX_PHAR_SCP	5000
MAR-SCP	SCP	EX_MAR_SCP	4000

The PHARMACY-SCP and MAR-SCP Application Entities can be configured to have the same AE Title.

H.4.4.1.2 Remote AE Title/Presentation Address Mapping

1015 The mapping of external AE Titles to TCP/IP addresses and ports is configurable and set at the time of installation by Installation Personnel. This mapping is necessary for resolving the IP address and port of

C-MOVE Destination Application Entities and must be correctly configured for the PHARMACY-SCP AE to correctly function as a C-MOVE SCP.

H.4.4.2 Parameters

1020

**Table H.4.4-2
CONFIGURATION PARAMETERS**

Parameter	Configurable	Default Value
General Parameters		
Maximum PDU size I can receive	Yes	128kbytes
Maximum PDU size I can send	Yes	128kbytes
Time-out waiting for response to TCP/IP connect() request. (Low-level timeout)	Yes	10 s
Time-out waiting for A-ASSOCIATE RQ PDU on open TCP/IP connection. (ARTIM timeout)	Yes	30 s
Time-out waiting for acceptance or rejection response to an Association Open Request. (Application Level timeout)	Yes	30s
Time-out waiting for acceptance of a TCP/IP message over the network. (Low-level timeout)	Yes	30 s
Time-out for waiting for data between TCP/IP packets. (Low-level timeout)	Yes	30 s
PHARMACY-SCP AE Parameters		
Maximum number of simultaneous Associations	Yes	10
AE time-out waiting on an open Association for the next message (C-FIND-RQ, Association Close Request. etc.) (DIMSE timeout)	Yes	1 minute
MAR-SCP AE Parameters		
Maximum number of simultaneous Associations	Yes	10
AE time-out waiting on an open Association for the next Request message (N-ACTION-RQ, Association Close Request. etc.) (DIMSE timeout)	Yes	1 minute

H.5 MEDIA INTERCHANGE

EXAMPLE-MEDICATION-SYSTEM-GATEWAY does not support Media Storage.

1025

H.6 SUPPORT OF EXTENDED CHARACTER SETS

All EXAMPLE-MEDICATION-SYSTEM-GATEWAY DICOM applications support the following:

ISO_IR 192 (Unicode)

H.7 SECURITY

1030

H.7.1 SECURITY PROFILES

The EXAMPLE-MEDICATION-SYSTEM-GATEWAY is configurable to support the Kerberos Identity Negotiation Association Profile.

H.7.2 ASSOCIATION LEVEL SECURITY

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The PHARMACY-SCP AE and the MAR-SCP AE can both be configured to accept Association Requests from only a limited list of Calling AE Titles. The SCP AEs can have different lists. Each SCP AE can be configured to check that the Association requestor specifies the correct Called AE Title for the SCP.

In addition the IP address of the requestor can be checked. The SCP AEs can be constrained to only accept Association Requests from a configured list of IP addresses. The SCP AE's can have different lists.

1040