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Digital Imaging and Communications in Medicine (DICOM)

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Supplement 159:

Radiopharmaceutical Radiation Dose Reporting (Dose SR)

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20 DICOM Standards Committee

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70

Scope and Field

72 This supplement to the DICOM standard introduces a template for reporting of radiation dose due to
administration of radiopharmaceuticals, as in NM or PET imaging, in DICOM. The concepts of Structured
Reporting will be used in this context.

74 The supplement was developed by WG3 (Nuclear Medicine). In this supplement, radiation-related aspects
of NM have been addressed with the advice of AAPM and SNMMI.

76 The Radiopharmaceutical Radiation Dose (RRD) report is based on the SOP class of "X-ray Radiation
Dose SR". Specific templates for the recording of the dose and the acquisition parameters in a NM
78 environment have been developed.

80 The dose report records radiopharmaceutical activity amount, and administration time and other
information. NM and PET modalities can read the reports to complete administration information essential
for PET SUV calculations. Dose Registry and Dose Reporter systems will consume these reports.

82 Patient dose from background activity is not recorded in the report.

84

86

Changes to NEMA Standards Publication PS 3.2-2013

Digital Imaging and Communications in Medicine (DICOM)

88

Part 2: Conformance

Add new SOP Classes in Table A.1-2

90

Table A.1-2
UID VALUES

UID Value	UID NAME	Category
...		
<u>1.2.840.10008.5.1.4.1.1.88.68</u>	<u>Radiopharmaceutical Radiation Dose SR</u>	<u>Transfer</u>
...		

92

94

Changes to NEMA Standards Publication PS 3.3-2013

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96

Part 3: Information Object Definitions

Change Table A.1-1 to add "C" to the Synchronization module and the NM IOD

98

Change PS3.3 Section A.5-4:A.5.4 NM Image IOD Module Table

100

**Table A.5-1
NM IMAGE IOD MODULES**

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	General Series	C.7.3.1	M
	Clinical Trial Series	C.7.3.2	U
	NM/PET Patient Orientation	C.8.4.6	M
Frame of Reference	Frame of Reference	C.7.4.1	M
	Synchronization	C.7.4.2	C- Required if time synchronization was applied.
Equipment	General Equipment	C.7.5.1	M
Image	General Image	C.7.6.1	M
	Image Pixel	C.7.6.3	M
	Acquisition Context	C.7.6.14	U - See Section A.5.4.1
	Device	C.7.6.12	U
	Specimen	C.7.6.22	U
	NM Image Pixel	C.8.4.7	M
	Multi-frame	C.7.6.6	M
	NM Multi-frame	C.8.4.8	M
	NM Image	C.8.4.9	M
	NM Isotope	C.8.4.10	M
	NM Detector	C.8.4.11	M
	NM TOMO Acquisition	C.8.4.12	C - Required if Image Type (0008,0008) Value 3 is TOMO,

			GATED TOMO, RECON TOMO or RECON GATED TOMO
	NM Multi-gated Acquisition	C.8.4.13	C - Required if Image Type (0008,0008) Value 3 is GATED, GATED TOMO, or RECON GATED TOMO
	NM Phase	C.8.4.14	C - Required if Image Type (0008,0008) Value 3 is DYNAMIC
	NM Reconstruction	C.8.4.15	C - Required if Image Type (0008,0008) Value 3 is RECON TOMO or RECON GATED TOMO
	Overlay Plane	C.9.2	U
	Multi-frame Overlay	C.9.3	U
	VOI LUT	C.11.2	U
	ICC Profile	C.11.15	U
	SOP Common	C.12.1	M
	Frame Extraction	C.12.3	C - Required if the SOP Instance was created in response to a Frame-Level retrieve request

102

Change Table A.1-1 to add "C" to the Synchronization module and the PET IMAGE IOD

104

Change PS3.3 Section A.21.3-1 - PET IMAGE IOD MODULES

106

**Table A.21.3-1
 PET IMAGE IOD MODULES**

108

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	General Series	C.7.3.1	M
	Clinical Trial Series	C.7.3.2	U
	PET Series	C.8.9.1	M
	PET Isotope	C.8.9.2	M
	PET Multi-gated Acquisition	C.8.9.3	C - Required if Series Type (0054,1000) Value 1 is GATED.

	NM/PET Patient Orientation	C.8.4.6	M
Frame of Reference	Frame of Reference	C.7.4.1	M
	Synchronization	C.7.4.2	C- Required if time synchronization was applied.
Equipment	General Equipment	C.7.5.1	M
Image	General Image	C.7.6.1	M
	Image Plane	C.7.6.2	M
	Image Pixel	C.7.6.3	M
	Device	C.7.6.12	U
	Specimen	C.7.6.22	U
	PET Image	C.8.9.4	M
	Overlay Plane	C.9.2	U
	VOI LUT	C.11.2	U
	Acquisition Context	C.7.6.14	U
	SOP Common	C.12.1	M

110 **Modify Part 3 Table C.8-10:**

**Table C.8-10
NM ISOTOPE MODULE ATTRIBUTES**

112

Table	Tag	Type	Attribute Description
...
Radiopharmaceutical Information Sequence	(0054,0016)	2	Sequence of items that describe isotope information. Zero or more items shall be included in this sequence.
...
>Radiopharmaceutical Start Time	(0018,1072)	3	Time of start of injection. See C.8.4.10.1.5 for further explanation.
>Radiopharmaceutical Stop Time	(0018,1073)	3	Time of end of injection. See C.8.4.10.1.6 for further explanation.
>Radionuclide Total Dose	(0018,1074)	3	Total amount of radionuclide injected. See C.8.4.10.1.7 for further explanation.
>Radiopharmaceutical Administration Event UID	(0008,3012)	3	Unique identification of the administration of the radiopharmaceutical to the patient. Note: The UID is the same Radiopharmaceutical Administration Event UID that is in the Radiopharmaceutical

			<u>Radiation Dose Report.</u>
...

114 **Modify Part 3 Table C.8-61:**

**Table C.8-61 –
 PET ISOTOPE MODULE ATTRIBUTES**

116

Attribute Name	Tag	Type	Attribute Description
...
>Radionuclide Total Dose	(0018,1074)	3	The radiopharmaceutical dose administered to the patient measured in Becquerels (Bq) at the Radiopharmaceutical Start Time (0018,1072). Note: In other IODs, such as the NM IOD, this same attribute is specified in MegaBecquerels (MBq).
<u>>Radiopharmaceutical Administration Event UID</u>	<u>(0008,3012)</u>	3	<u>Unique identification of the administration of the radiopharmaceutical to the patient.</u> Note: <u>The UID is the same Radiopharmaceutical Administration Event UID that is in the Radiopharmaceutical Radiation Dose Report.</u>
...

118 **Modify Part 3 Table C.8.22.4:**

**Table C.8.22-9
 ENHANCED PET ISOTOPE MODULE ATTRIBUTES**

120

Attribute Name	Tag	Type	Attribute Description
...
>Radionuclide Total Dose	(0018,1074)	2	The radiopharmaceutical dose administered to the patient measured in MegaBecquerels (MBq) at the Radiopharmaceutical Start Datetime

			(0018,1078).
>Radiopharmaceutical Administration Event UID	(0008,3012)	3	Unique identifier for the Radiopharmaceutical Administration Event. Note: The UID is the same Radiopharmaceutical Administration Event UID that is in the Radiopharmaceutical Radiation Dose Report.
...

122

124 **Add PS3.3 Section A.35.14:**

A.35.14 Radiopharmaceutical Radiation Dose SR Information Object Definition

126 **A.35.14.1 Radiopharmaceutical Radiation Dose SR Information Object Description**

128 The Radiopharmaceutical Radiation Dose SR IOD is used to convey the exposure characteristics and dose from the administration of radiopharmaceuticals.

130 **A.35.14.2 Radiopharmaceutical Radiation Dose SR IOD Entity-Relationship Model**

132 The E-R Model in Section A.1.2 of this Part applies to the Radiopharmaceutical Radiation Dose SR IOD. Table A.35.14-1 specifies the Modules of the Radiopharmaceutical Radiation Dose SR IOD.

A.35.14.3 Radiopharmaceutical Radiation Dose SR IOD Module Table

134

**Table A.35.14-1
RADIOPHARMACEUTICAL RADIATION DOSE SR IOD MODULES**

IE	Module	Reference	Usage
Patient	Patient	C.7.1.1	M
	Clinical Trial Subject	C.7.1.3	U
Study	General Study	C.7.2.1	M
	Patient Study	C.7.2.2	U
	Clinical Trial Study	C.7.2.3	U
Series	SR Document Series	C.17.1	M
	Clinical Trial Series	C.7.3.2	U
Frame of Reference	Synchronization	C.7.4.2	C - shall be present if system time is synchronized to an external reference. May be present otherwise.
Equipment	General Equipment	C.7.5.1	M

	Enhanced General Equipment	C.7.5.2	M
Document	SR Document General	C.17.2	M
	SR Document Content	C.17.3	M
	SOP Common	C.12.1	M

136

A.35.14.3.1.1 Template

138 The document may be constructed from Baseline TID 10021 "Radiopharmaceutical Radiation Dose Report" (defined in PS3.16) invoked at the root node.

A.35.14.3.1.2 Value Type

140 Value Type (0040,A040) in the Content Sequence (0040,A730) of the SR Document Content Module is
142 constrained to the following Enumerated Values (see Table C.17-7 for Value Type definitions):

- 144 TEXT
- 144 CODE
- 144 NUM
- 146 DATETIME
- 146 UIDREF
- 148 PNAME
- 148 CONTAINER

150

A.35.14.3.1.3 Relationship Constraints

152 Relationships between content items in the content of this IOD may be conveyed by-value. Table A.35.14-
154 2 specifies the relationship constraints of this IOD. See Table C.17.3-2 for Relationship Type definitions.

154

Table A.35.14-2

RELATIONSHIP CONTENT CONSTRAINTS FOR RADIOPHARMACEUTICAL RADIATION DOSE SR IOD

Source Value Type	Relationship Type (Enumerated Values)	Target Value Type
CONTAINER	CONTAINS	TEXT, CODE, NUM, DATETIME, UIDREF, PNAME, CONTAINER
TEXT, CODE, NUM	HAS OBS CONTEXT	TEXT, CODE, NUM, DATETIME, UIDREF, PNAME
CONTAINER	HAS ACQ CONTEXT	TEXT, CODE, NUM, DATETIME, UIDREF, PNAME, CONTAINER.
any type	HAS CONCEPT MOD	TEXT, CODE
TEXT, CODE, NUM, PNAME	HAS PROPERTIES	TEXT, CODE, NUM, DATETIME, UIDREF, PNAME, CONTAINER.
TEXT, CODE, NUM	INFERRED FROM	TEXT, CODE, NUM, DATETIME, UIDREF, CONTAINER.

158

Changes to NEMA Standards Publication PS 3.4-2013

Digital Imaging and Communications in Medicine (DICOM)

Part 4: Service Class Specifications

162

164 **Add SOP Class to Table B.3-3**

**Table B.3-3
 STANDARD AND RELATED GENERAL SOP CLASSES**

166

SOP Class Name	Related General SOP Class Name
...	
<u>Radiopharmaceutical Radiation Dose SR</u>	<u>Enhanced SR</u>
	<u>Comprehensive SR</u>

168 **Add SOP Class to Table B.5-1**

B.5 STANDARD SOP CLASSES

**Table B.5-1
 STANDARD SOP CLASSES**

170

SOP Class Name	SOP Class UID	IOD (See PS 3.3)
...		
<u>Radiopharmaceutical Radiation Dose SR</u>	<u>1.2.840.10008.5.1.4.1.1.88.68</u>	<u>Radiopharmaceutical Radiation Dose SR</u>

172

Add Structured Reporting SOP Class to Section B.5.1.5

B.5.1.5 Structured Reporting Storage SOP Classes

The requirements of Annex O apply to the following SOP Classes:

176 • ...

- **Radiopharmaceutical Radiation Dose SR**

178

180 **Add SOP Class to Table I.4-1**

I.4 MEDIA STORAGE SOP CLASSES

182

**Table I.4-1
Media Storage Standard SOP Classes**

SOP Class Name	SOP Class UID	IOD (See PS 3.3)
...		
Radiopharmaceutical Radiation Dose SR	1.2.840.10008.5.1.4.1.1.88.68	Radiopharmaceutical Radiation Dose SR

184

Add SOP Class to Section I.4.1.2

186 **I.4.1.2 Structured Reporting Storage SOP Classes**

The requirements of Annex O apply to the following SOP Classes:

188 ...

- X-Ray Radiation Dose SR

- 190 • **Radiopharmaceutical Radiation Dose SR**

192

Changes to NEMA Standards Publication PS 3.6-2013

194

Digital Imaging and Communications in Medicine (DICOM)

Part 6: Data Dictionary

196

Add the following Data Elements to Part 6 Section 6:

Tag	Name	Keyword	VR	VM
<u>(0008,3012)</u>	<u>Radiopharmaceutical Administration Event UID</u>	<u>RadiopharmaceuticalAdministrationEventUID</u>	<u>UI</u>	<u>1</u>

198

200

Add the following UID Value to Part 6 Annex A Table A-1:

202

**Annex A Registry of DICOM unique identifiers (UID)
 (Normative)**

204

**Table A-1
 UID VALUES**

UID Value	UID NAME	UID TYPE	Part
...
<u>1.2.840.10008.5.1.4.1.1.88.68</u>	<u>Radiopharmaceutical Radiation Dose SR Storage</u>	SOP Class	PS 3.4

206

208 Add the following UID Value to Part 6 Annex A Table A-3:

210 **Table A-3**
CONTEXT GROUP UID VALUES

Context UID	Context Identifier	Context Group Name
...
<u>1.2.840.10008.6.1.972</u>	<u>10040</u>	<u>Radiopharmaceutical Organ Dose Reference Authority</u>
<u>1.2.840.10008.6.1.973</u>	<u>10041</u>	<u>Source of Radioisotope Activity Information</u>
<u>1.2.840.10008.6.1.975</u>	<u>10043</u>	<u>Intravenous Extravasation Symptoms</u>
<u>1.2.840.10008.6.1.976</u>	<u>10044</u>	<u>Radiosensitive Organs</u>
<u>1.2.840.10008.6.1.977</u>	<u>10045</u>	<u>Radiopharmaceutical Patient State</u>
<u>1.2.840.10008.6.1.978</u>	<u>10046</u>	<u>GFR Measurements</u>
<u>1.2.840.10008.6.1.979</u>	<u>10047</u>	<u>GFR Measurement Methods</u>

212

214

Changes to NEMA Standards Publication PS 3.16-2013

216

Digital Imaging and Communications in Medicine (DICOM)

Part 16: Content Mapping Resource

218 **Amend DICOM PS3.16 Content Mapping Resource - Annex A as follows:**

Annex A Structured Reporting Templates (Normative)

220 **TID 3307 NM/PET Perfusion Measurement Group**

TID 3307

222 **NM/PET Perfusion Measurement Group**
Type: Extensible Order: Significant

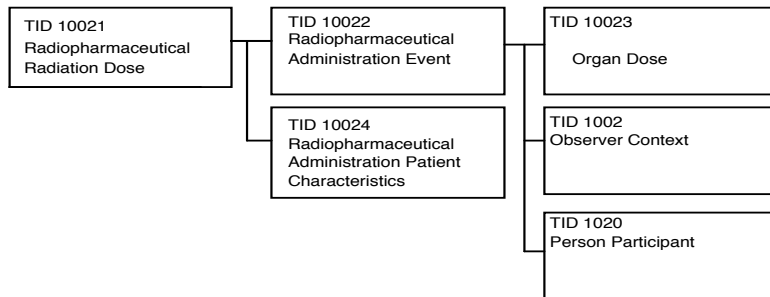
	NL	Relation with Parent	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	DT (121070, DCM, "Findings")	1	M		
2	>	HAS CONCEPT MOD	CODE	EV (121058, DCM, "Procedure reported")	1	M		DCID (3108) NM/PET Procedures
3	>	CONTAINS	CODE	EV (123001, DCM, "Radiopharmaceutical")(F-61FDB,SRT, "Radiopharmaceutical agent")	1	M		DCID (3111) Nuclear Cardiology Radiopharmaceuticals

224

Add new Section to Annex A

226 **RADIOPHARMACEUTICAL RADIATION DOSE SR IOD TEMPLATES**

228 The templates that comprise the Radiopharmaceutical Radiation Dose SR are interconnected as in Figure A-17



230 **Figure A-17. Radiopharmaceutical Radiation Dose SR IOD Template Structure**

232 **TID 10021 Radiopharmaceutical Radiation Dose**

233 This template defines a container (the root) with subsidiary content items, each of which corresponds to a
 234 single Radiopharmaceutical Administration Dose event entry. There is a defined recording observer (the
 235 system and/or person responsible for recording the assay of the radiopharmaceutical, and the person
 236 administered the radiopharmaceutical). Multiple Radiopharmaceutical Radiation Dose objects may be
 237 created for one study. Radiopharmaceutical Start DateTime in the Radiopharmaceutical Administration
 238 Event Data (TID 10022) will convey the order of administrations.

240 **TID 10021
RADIOPHARMACEUTICAL RADIATION DOSE
Type: Extensible Order: Significant**

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (113500, DCM, "Radiopharmaceutical Radiation Dose Report")	1	M		
2	>	HAS CONCEPT MOD	CODE	EV (G-C2D0, SRT, "Associated Procedure")	1	M		DCID (3108) NM/PET Procedures
3	>>	HAS CONCEPT MOD	CODE	EV (G-C0E8, SRT, "Has Intent")	1	M		DCID (3629) Procedure Intent
4	>	CONTAINS	INCLUDE	DTID (10022) Radiopharmaceutical Administration Event Data	1	M		
5	>	CONTAINS	INCLUDE	DTID (10024) Radiopharmaceutical Administration Patient Characteristics	1	U		
6	>	CONTAINS	TEXT	EV (121106, DCM, "Comment")	1	U		

242

Content Item Descriptions

Row 2	The associated procedure is the procedure performed, or if no procedure was performed the procedure that was ordered.
-------	---

244

246 **TID 10022 Radiopharmaceutical Administration Event Data**

248 The Radiopharmaceutical Administration Event conveys the dose and assay and time information of a single radiopharmaceutical event. A Radiopharmaceutical Administration event is one radioactive pharmaceutical administered to a patient.

250

TID 10022**RADIOPHARMACEUTICAL ADMINISTRATION EVENT DATA**

252

Type: Extensible Order: Significant

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (113502, DCM, "Radiopharmaceutical Administration")	1	M		
2	>	CONTAINS	CODE	EV (F-61FDB, SRT, "Radiopharmaceutical agent")	1	M		DCID (25) Radiopharmaceuticals or DCID (4021) PET Radiopharmaceutical
3	>>	HAS PROPERTIES	CODE	EV (C-10072, SRT, "Radionuclide")	1	M		DCID (18) Isotopes in Radiopharmaceuticals or DCID (4020) PET Radionuclide
4	>>	HAS PROPERTIES	NUM	EV (R-42806, SRT, "Radionuclide Half Life")	1	M		UNITS = EV (s, UCUM, "seconds")
5	>	CONTAINS	NUM	EV (123007, DCM, "Radiopharmaceutical Specific Activity")	1	U		UNITS = EV (Bq/mmol, UCUM, "Bq/mmol")
6	>	CONTAINS	UIDREF	EV (113503, DCM, "Radiopharmaceutical Administration Event UID")	1	M		
7	>	CONTAINS	CODE	EV (113505, DCM, "Intravenous Extravasation Symptoms")	1-n	U		DCID (10043) Intravenous Extravasation Symptoms

8	>	CONTAINS	NUM	EV (113506, DCM, "Estimated Extravasation Activity")	1	U		UNITS =EV (%, UCUM, "percent")
9	>	CONTAINS	DATETIME	EV (123003, DCM, "Radiopharmaceutical Start DateTime")	1	M		
10	>	CONTAINS	DATETIME	EV (123004, DCM, "Radiopharmaceutical Stop DateTime")	1	U		
11	>	CONTAINS	NUM	EV (113507, DCM, "Administered activity")	1	M		UNITS = EV (MBq, UCUM, "MBq")
12	>	CONTAINS	NUM	EV (123005, DCM, "Radiopharmaceutical Volume")	1	U		UNITS = EV (cm3, UCUM, "cm3")
13	>	CONTAINS	NUM	EV (113508, DCM, "Pre-Administration Measured Activity")	1	U		UNITS = EV (MBq, UCUM, "MBq")
14	>>	HAS OBS CONTEXT	CODE	EV (113540, DCM, "Activity Measurement Device")	1	U		DCID (10041) Source of Radioisotope Activity Information
15	>>	HAS OBS CONTEXT	INCLUDE	DTID (1002) Observer Context	1-n	U		
16	>	CONTAINS	NUM	EV (113509, DCM, "Post-Administration Measured Activity")	1	U		UNITS = EV (MBq, UCUM, "MBq")
17	>>	HAS OBS CONTEXT	CODE	EV (113540, DCM, "Activity Measurement Device")	1	U		DCID (10041) Source of Radioisotope Activity Information
18	>>	HAS OBS CONTEXT	INCLUDE	DTID (1002) Observer Context	1-n	U		

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19	>	CONTAINS	INCLUDE	DTID (10023) Organ Dose	1-n	U		
20	>	CONTAINS	CODE	EV (G-C340, SRT, "Route of administration")	1	M		BCID (11) Route of Administration
21	>>	HAS PROPERTIE S	CODE	EV (G-C581, SRT, "Site of")	1	MC	IF Row 22 equals (G-D101, SRT, "Intravenous route") or (G-D103, SRT, "Intramuscular route")	DCID (3746) Percutaneous Entry Site
22	>>>	HAS CONCEPT MOD	CODE	EV (G-C171, SRT, "Laterality")	1	MC	IF Row 23 has laterality	DCID (244) Laterality
23	>	HAS OBS CONTEXT	INCLUDE	DTID (1020) Person Participant	1-n	M		\$PersonProcedureR ole = EV (113851, DCM, "Irradiation Administering")
24	>	CONTAINS	CODE	EV (121147, DCM, "Billing Code(s)")	1-n	U		
25	>	CONTAINS	CODE	EV (113510, DCM, "Drug Product Identifier")	1-n	U		
26	>	CONTAINS	TEXT	EV (111529, DCM, "Brand Name")	1	U		
27	>	CONTAINS	TEXT	EV (113511, DCM, "Radiopharmace utical Dispense Unit Identifier")	1	U		
28	>>	CONTAINS	TEXT	EV (113512, DCM, "Radiopharmace utical Lot Identifier")	1-n	U		
29	>>	CONTAINS	TEXT	EV (113513, DCM, "Reagent Vial Identifier")	1-n	U		
30	>>	CONTAINS	TEXT	EV (113514, DCM, "Radionuclide Identifier")	1-n	U		

31	>	CONTAINS	TEXT	EV (113516, DCM, "Prescription Identifier")	1	U		
32	>	CONTAINS	TEXT	EV (121106, DCM, "Comment")	1	U		

254 **Content Item Descriptions**

Row 4	The value of Half-life that was used for computing the decay of the administered radiopharmaceutical. It is not intended for use by the receiver for any further computation.
Row 5	Activity per unit mass of the radiopharmaceutical at Radiopharmaceutical Start Time
Row 6	Unique identification of a single radiopharmaceutical administration event.
Row 8	The estimated percentage of administered activity lost at the injection site. The estimation includes extravasation, paravenous administration and leakage at the injection site.
Row 9	The time the radiopharmaceutical was administered to the patient for imaging purposes.
Row 11	Total amount of radioactivity administered to the patient at Radiopharmaceutical Start Time. It is a computed field from the TID 10022 Pre-Administration Measured Activity Row 13, TID 10022 Post-Administration Measured Activity Row 17, Radionuclide Half Life Row 4 and Radiopharmaceutical Start Time Row 9. Does not include estimated extravasation activity.
Rows 13, 16	Observation DateTime (0040,A032) shall be used to record when the measurement was taken.
Row 23	Identifies the person administering the product.
Row 24	The billing codes for the preparation and administration of the radiopharmaceutical. It does not include performance and interpretation of the imaging.
Row 25	Registered drug establishment code for the product. A coding scheme example is NDC, WHO-DDE or RxNorm. Multiple entries can be used for equivalent drug product codes.
Row 27	The human readable identification of the specific radiopharmaceutical quantity (dose) administered to the patient.
Row 28	Identifies the vial, batch or lot number from which the individual radiopharmaceutical quantity (dose) was produced. Row 27 the Radiopharmaceutical Identifier records the identification for each individual dose.
Row 29	Identifies the lot or unit serial number for the reagent component for the radiopharmaceutical identified in row 27.
Row 30	Identifies the lot or unit serial number for the radionuclide component for the

	radiopharmaceutical identified in row 27.
--	---

258 **TID 10023 Organ Dose**

This template conveys the information about the dose to a single organ.

260

**TID 10023
ORGAN DOSE**

262

Type: Extensible Order: Significant

NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1		CONTAINER	EV (113517, DCM, "Organ Dose Information")	1	M		
2>	HAS CONCEPT MOD	CODE	EV (G-C0E3, SRT, "Finding Site")	1	M		DCID (10044) Radiosensitive Organs
3>	HAS CONCEPT MOD	CODE	EV (G-C171, SRT, "Laterality")	1	MC	IFF anatomy has laterality	DCID (244) Laterality
4>	CONTAINS	NUM	EV (G-D701, SRT, "Mass")	1	U		UNITS= EV (g, UCUM, "grams")
5>>	HAS CONCEPT MOD	TEXT	EV (G-C036, SRT, "Measurement Method")	1	M		
6>	CONTAINS	NUM	EV (113518, DCM, "Organ Dose")	1	M		UNITS = EV (mGy, UCUM, "mGy")
7>>	HAS PROPERTIES	CODE	EV (121406, DCM, "Reference Authority")	1	MC	XOR Row 8	BCID (10040) Radiopharmaceutical Organ Dose Reference Authority
8>>	HAS PROPERTIES	TEXT	EV (121406, DCM, "Reference Authority")	1	MC	XOR Row 7	

264 **Content Item Descriptions**

Row 3	For paired organs, use (G-A102, SRT, "Right and Left") to report the estimated absorbed dose for both organs.
Row 4	The estimated mass of organ in grams used when calculating the organ dose.
Row 5	Method used to obtain the estimate. This could include a method that does not involve performing a measurement. (E.g., Standard Organ Mass Tables)
Row 6	Organ dose (in units of mGy). Organ is specified by row 2.

266 **TID 10024 Radiopharmaceutical Administration Patient Characteristics**

268 This template describes the characteristics of the patient that are specific to the current clinical
270 presentation (visit). The characteristics noted may affect the activity received, and how dose is calculated
for the patient. Patient Characteristic concepts in this template, which may replicate attributes in the
Patient Study Module, are included here as possible targets of by-reference relationships from other
content items in the SR tree.

272

TID 10024

RADIOPHARMACEUTICAL ADMINISTRATION PATIENT CHARACTERISTICS

274

Type: Extensible Order: Significant

	NL	Rel with Parent	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (121118, DCM, "Patient Characteristics")				
2	>	CONTAINS	CODE	EV (109054, DCM, "Patient state")	1-n	U		DCID (10045) Radiopharmaceutical Patient State
3	>	CONTAINS	NUM	EV (121033, DCM, "Subject Age")	1	U		UNITS = DCID (7456) Units of Measure for Age
4	>	CONTAINS	CODE	EV (121032, DCM, "Subject Sex")	1	U		DCID (7455) Sex
5	>	CONTAINS	NUM	EV (8302-2, LN, "Patient Height")	1	U		UNITS = EV (cm, UCUM, "cm")
6	>	CONTAINS	NUM	EV (29463-7, LN, "Patient Weight")	1	U		UNITS = EV (kg, UCUM, "kg").
7	>	CONTAINS	NUM	EV (8277-6, LN, "Body Surface Area")	1	U		UNITS = EV (m2, UCUM, "m^2")
8	>>	INFERRED FROM	CODE	EV (8278-4, LN, "Body Surface Area Formula")	1	U		BCID (3663) Body Surface Area Equations
9	>	CONTAINS	NUM	EV (F-01860, SRT, "Body Mass Index")	1	U		UNITS = EV (kg/m2, UCUM, "kg/m^2")
10	>>	INFERRED FROM	CODE	EV (121420, DCM, "Equation")	1	U		DT (122265, DCM, "BMI = Wt/Ht^2")
11	>	CONTAINS	NUM	EV (14749-6, LN, "Glucose")	1	U		UNITS = EV("mmol/l", UCUM, "mmol/l")
12	>	CONTAINS	NUM	EV(113550, DCM, "Fasting Duration")	1	U		UNITS = DT(h, UCUM, "hours")
13	>	CONTAINS	NUM	EV(113551, DCM, "Hydration Volume")	1	U		UNITS = DT(ml, UCUM, "ml")

14	>	CONTAINS	TEXT	EV(113552, DCM, "Recent Physical Activity")	1	U		
15	>	CONTAINS	NUM	EV (2160-0, LN, "Serum Creatinine")	1	U		UNITS = DT(mg/dl, UCUM, "mg/dl")
16	>	CONTAINS	NUM	EV (F-70210, SRT, "Glomerular Filtration Rate")	1-n	U		UNITS = DT(ml/min{1.73_m2}, UCUM, "ml/min/1.73m2")
17	>>	HAS CONCEPT MOD	CODE	EV (G-C036, SRT, "Measurement Method")	1	U		DCID (10047) GFR Measurement Methods
18	>>	HAS CONCEPT MOD	CODE	EV (121050, DCM, "Equivalent meaning of concept name")	1	M		DCID (10046) GFR Measurements

276 **Content Item Descriptions**

Row 3	Defaults to value of Patient's Age (0010,1010) in Patient Study Module
Row 5	Patient height may differ from Patient's Size (0010, 1020). Row 4 is the height value used for any height based protocols. Observation DateTime (0040,A032) may be used to record when the measurement was taken.
Row 6	Patient weight may differ from Patient's Weight (0010, 1030). Row 5 is the weight value used for any weight based protocols. Observation DateTime (0040,A032) shall be used to record when the measurement was taken.
Row 11	Patient's Blood Glucose level. Observation DateTime (0040,A032) shall be used to record when the measurement was taken.
Row 15	Serum Creatinine level. Observation DateTime (0040,A032) shall be used to record when the measurement was taken.
Row 16	Glomerular Filtration Rate Observation DateTime (0040,A032) shall be used to record when the measurement was taken. The formatting of the UCUM units is aligned with LOINC. See http://unitsofmeasure.org/trac/ticket/98

280 **Update the following Context Groups with additional codes in Part 16 Annex B:**

Annex B DCMR Context Groups (Normative)

282 **CID 3108 NM/PET Procedures**
 Context ID 3108

284 **NM/PET Procedures**
 Type: Extensible Version: ~~20080927~~-20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
SRT	P5-D30F8	Nuclear medicine cardiovascular study
SRT	P5-0A006	PET heart study
<u>SRT</u>	<u>P5-D6000</u>	<u>Radioisotope study of endocrine system</u>
<u>SRT</u>	<u>P5-D6500</u>	<u>Radioisotope study of hematopoietic system</u>
<u>SRT</u>	<u>P5-D5000</u>	<u>Radioisotope study of gastrointestinal system</u>
<u>SRT</u>	<u>P5-D0063</u>	<u>Radionuclide study for localization of inflammatory disease</u>
<u>SRT</u>	<u>P5-D10F8</u>	<u>Nuclear medicine diagnostic procedure on musculoskeletal system</u>
<u>SRT</u>	<u>P5-D90F8</u>	<u>Nuclear medicine diagnostic procedure on nervous system</u>
<u>SRT</u>	<u>P5-D0040</u>	<u>Radionuclide localization of tumor</u>
<u>SRT</u>	<u>P5-D2000</u>	<u>Radioisotope study of respiratory system</u>
<u>SRT</u>	<u>P5-D7000</u>	<u>Radioisotope study of genitourinary system</u>
<u>SRT</u>	<u>P5-0A001</u>	<u>PET brain study</u>
<u>SRT</u>	<u>P5-0A00D</u>	<u>PET breast study</u>
<u>SRT</u>	<u>P5-0A00A</u>	<u>PET study for localization of tumor</u>

286

288 **CID 9301 Modality PPS Discontinuation Reasons**
 Context ID 9301

290 **Modality PPS Discontinuation Reasons**
 Type: Extensible Version: ~~20090616~~-20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
...
SRT	D0-B0330	Injection Site Extravasation
SRT	DF-10780	Radiopharmaceutical Adverse Reaction

292

294 **Add the following new Context Groups to Part 16 Annex B:**

296 **CID 10040 Radiopharmaceutical Organ Dose Reference Authority**

Context ID 10040

298 **Radiopharmaceutical Organ Dose Reference Authority**

Type: Extensible Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	113520	MIRD Pamphlet 1
DCM	113521	ICRP Publication 53
DCM	113526	MIRDOSE
DCM	113527	OLINDA-EXM
DCM	113528	Package Insert
DCM	113529	Institutionally Approved Estimates
DCM	113530	Investigational New Drug
DCM	113522	ICRP Publication 80
DCM	113523	ICRP Publication 106

300

302 **CID 10041 Source of Radioisotope Activity Information**

Context ID 10041

304 **Source of Radioisotope Activity Information**

Type: Extensible Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	113541	Dose Calibrator
DCM	113542	Infusion System
DCM	113543	Radioisotope Generator

306

308 **CID 10043 Intravenous Extravasation Symptoms**

310

Context ID 10043
Intravenous Extravasation Symptoms
Type: Extensible Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
SRT	D0-B0324	Injection site abscess
SRT	D0-B0380	Injection site anesthesia
SRT	D0-B03A4	Injection site atrophy
SRT	D0-B0394	Injection site bruising
SRT	D0-B0342	Injection site burning
SRT	D0-B0364	Injection site cyst
SRT	D0-B0354	Injection site dermatitis
SRT	D0-B0300	Injection site disorder
SRT	D0-B0352	Injection site edema
SRT	D0-B03A2	Injection site fibrosis
SRT	M-44150	Injection site granuloma
SRT	D0-B0334	Injection site hemorrhage
SRT	D0-B0311	Injection site hypersensitivity
SRT	D0-B03A0	Injection site induration
SRT	D0-B0320	Injection site infection
SRT	D0-B0350	Injection site inflammation
SRT	D0-B0312	Injection site irritation
SRT	D0-B0339	Injection site malabsorption
SRT	D0-B0360	Injection site mass
SRT	D0-B0370	Injection site necrosis
SRT	D0-B0346	Injection site nerve damage
SRT	D0-B0340	Injection site pain
SRT	D0-B0382	Injection site paresthesia
SRT	D0-B0314	Injection site pigmentation change
SRT	D0-B0310	Injection site reaction
SRT	M-78066	Injection site scar
SRT	D0-B0326	Injection site sterile abscess
SRT	D0-B0338	Injection site thrombosis
SRT	D0-B0390	Injection site ulcer

SRT	D0-B0356	Injection site urticaria
DCM	113568	Extravasation visible in image

312

314

CID 10044 Radiosensitive Organs

316

Context ID 10044

Radiosensitive Organs

318

Type: Extensible Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
SRT	T-B3000	Adrenal gland
SRT	T-74000	Bladder
SRT	T-A0100	Brain
SRT	T-04000	Breast
SRT	T-C1000	Bone Marrow
SRT	T-D0859	Bone Surface
SRT	T-59300	Colon
SRT	T-56000	Esophagus
SRT	T-AA700	Eye lenses
SRT	T-63000	Gall bladder
SRT	T-32000	Heart
SRT	T-71000	Kidney
SRT	T-62002	Liver
SRT	T-28000	Lung
SRT	T-C4000	Lymph node
SRT	T-13001	Muscle
SRT	T-51300	Oral mucosa
SRT	T-87000	Ovary
SRT	T-65000	Pancreas
SRT	T-9200B	Prostate
SRT	T-61007	Salivary Glands
SRT	T-00009	Skin
SRT	T-58000	Small intestine
SRT	T-C3000	Spleen
SRT	T-57000	Stomach
SRT	T-94000	Testis

SRT	T-C8000	Thymus
SRT	T-B6000	Thyroid
SRT	T-83000	Uterus

320

322 **CID 10045 Radiopharmaceutical Patient State**

Context ID 10045

324

Radiopharmaceutical Patient State
Type: Extensible Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
INCLUDE CID 3102 Rest-Stress		
SRT	F-70102	Abnormal Renal Function
DCM	113560	Acute unilateral renal blockage
DCM	113561	Low Thyroid Uptake
DCM	113562	High Thyroid Uptake
DCM	113563	Severely Jaundiced

326

328 **CID 10046 GFR Measurements**

Context ID 10046

330

GFR Measurements
Type: Extensible Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
LN	33914-3	Glomerular Filtration Rate (MDRD)
LN	48642-3	Glomerular filtration Rate non-black (MDRD)
LN	48643-1	Glomerular Filtration Rate black (MDRD)
LN	50044-7	Glomerular Filtration Rate female (MDRD)
LN	50210-4	Glomerular Filtration Rate Cystatin-based formula
LN	50384-7	Glomerular Filtration Rate Creatinine-based formula (Schwartz)
LN	35591-7	Cockcroft-Gault Formula estimation of GFR
LN	62238-1	CKD-EPI Formula estimation of GFR

332

334 **CID 10047** **GFR Measurement Methods**

Context ID 10047

336

GFR Measurement Methods

Type: Extensible

Version: 20140419

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
DCM	113570	Cockcroft-Gault Formula estimation of GFR
DCM	113571	CKD-EPI Formula estimation of GFR
DCM	113572	Glomerular Filtration Rate (MDRD)
DCM	113573	Glomerular filtration Rate non-black (MDRD)
DCM	113574	Glomerular Filtration Rate black (MDRD)
DCM	113575	Glomerular Filtration Rate female (MDRD)
DCM	113576	Glomerular Filtration Rate Cystatin-based formula
DCM	113577	Glomerular Filtration Rate Creatinine-based formula (Schwartz)

338

340

Amend DICOM PS3.16 Content Mapping Resource - Annex C as follows:

342

Annex C Acquisition and Protocol Context Templates (Normative)

TID 15101 NM/PET Protocol Context

344

TID 15101

NM/PET Protocol Context

346

Type: Extensible Order: Significant

	NL	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
1		CODE	EV (123001, DCM, "Radiopharmaceutical") (F-61FDB, SRT, "Radiopharmaceutical agent")	1	M		BCID 25 "Radiopharmaceuticals" BCID 4021 "PET Radiopharmaceuticals"
2	>	CODE	EV (C-B1000, SRT, "Diagnostic Radioisotope") (C-10072, SRT, "Radionuclide")	1	U		BCID 18 (NM) or 4020 (PET)
3	>	UIDREF	EV (113503, DCM, "Radiopharmaceutical Administration Event UID")	1	U		
4	>	DATETIM E	EV (123003, DCM, "Radiopharmaceutical Start Time")	1	U		
5	>	DATETIM E	EV (123004, DCM, "Radiopharmaceutical Stop Time")	1	U		
6	>	NUMERIC	EV (123005, DCM, "Radiopharmaceutical Volume")	1	U		UNITS = DT(cm3, UCUM, "cm3")
7	>	NUMERIC	EV (123006, DCM, "Radionuclide Total Dose")	1	U		UNITS = DT(Bq, UCUM, "Bq")
8	>	NUMERIC	EV (123007, DCM, "Radiopharmaceutical Specific Activity")	1	U		UNITS = DT(Bq/mol, UCUM, "Bq/mol")
9	>	CODE	EV (G-C340, SRT, "Route of Administration")	1	U		BCID 11
10	>	NUMERIC	EV (123009, DCM, "Radionuclide Syringe Counts")	1	U		UNITS = DT({counts}/s, UCUM "counts/s")
11	>	NUMERIC	EV (123010, DCM, "Radionuclide Residual")	1	U		UNITS = DT({counts}/s, UCUM "counts/s")

	NL	VT	Concept Name	VM	Req Type	Condition	Value Set Constraint
			Syringe Counts")				
12		NUMERIC	EV (14749-6, LN, "Glucose")	1	U		UNITS = EV (mmol/l, UCUM,"mmol/l")
13	>	DATE	EV (109081, DCM, "Glucose Measurement Date")	1	M		
14	>	TIME	EV (109082, DCM, "Glucose Measurement Time")	1	M		

350 **Amend DICOM PS3.16 - Content Mapping Resource - Controlled Terminology Definitions to retire the following concepts:**

352 **Annex D DICOM Controlled Terminology Definitions (Normative)**

Table D-1. DICOM Controlled Terminology Definitions

Code Value	Code Meaning	Definition	Notes
...
123001	Radiopharmaceutical	Active ingredient (molecular) used for radioactive tracing.	Retired Replaced by (F-61FDB, SRT, "Radiopharmaceutical agent")
...

354

356 **Add the following Definitions to Annex D**

Code Value	Code Meaning	Definition
	...	
113500	Radiopharmaceutical Radiation Dose Report	The procedure report is a Radiopharmaceutical Radiation Dose report
113502	Radiopharmaceutical Administration	Information pertaining to the administration of a radiopharmaceutical
113517	Organ Dose Information	Information pertaining to the estimated absorbed radiation dose to an organ.
113503	Radiopharmaceutical Administration Event UID	Unique identification of a single radiopharmaceutical administration event.
113505	Intravenous Extravasation Symptoms	Initial signs or symptoms of extravasation
113506	Estimated Extravasation Activity	The estimated percentage of administered activity lost at the injection site. The estimation includes extravasation, paravenous administration and leakage at the injection site.

113507	Administered activity	The calculated activity at the Radiopharmaceutical Start Time when the radiopharmaceutical is administered to the patient. The residual activity (i.e. radiopharmaceutical not administered), if measured, is reflected in the calculated value. The estimated extravasation is not reflected in the calculated value.
113512	Radiopharmaceutical Lot Identifier	Identifies the vial, batch or lot number from which the individual dispense radiopharmaceutical quantity (dose) is produced. The Radiopharmaceutical Dispense Unit Identifier records the identification for each individual dose.
113516	Prescription Identifier	Administered Product's Prescription Number
113513	Reagent Vial Identifier	Identifies the lot or unit serial number for the reagent component for the radiopharmaceutical.
113514	Radionuclide Vial Identifier	Identifies the lot or unit serial number for the radionuclide component for the radiopharmaceutical.
113518	Organ Dose	The absorbed radiation dose to organ
113508	Pre-Administration Measured Activity	Radioactivity measurement of radiopharmaceutical before or during the administration.
113540	Activity Measurement Device	The type of device that performed the activity measurement.
113520	MIRD Pamphlet 1	Reference authority MIRD Pamphlet No.1 (rev), Society of Nuclear Medicine, 1976
113521	ICRP Publication 53	Reference authority ICRP, 1988. Radiation Dose to Patients from Radiopharmaceuticals. ICRP Publication 53. Ann. ICRP 18 (1-4).
113526	MIRDOSE	Reference authority Stabin MG, Sparks RB, Crowe E (1994) MIRDOSE: personal computer software for internal dose assessment in nuclear medicine [Computer program]
113527	OLINDA-EXM	Reference authority Stabin MG, Sparks RB, Crowe E (2005) OLINDA/EXM: The Second-Generation Personal Computer Software for Internal Dose Assessment in Nuclear Medicine [Computer program]
113541	Dose Calibrator	The device that measures the radiation activity of the radiopharmaceutical

113542	Infusion System	Radiopharmaceutical Infusion System
113543	Generator	Radioisotope Generator
113510	Drug Product Identifier	Registered drug establishment code for product, coding scheme example is NDC or RxNorm
113528	Package Insert	Reference authority The reported organ dose is based on radiopharmaceutical's package insert.
113529	Institutionally Approved Estimates	Reference authority The reported organ dose is based on Institutionally approved estimates from the Radioactive Drug Research Committee (RDRC) of the institution itself.
113530	Investigational New Drug	Reference authority The reported organ dose is based on an Investigation new drug.
113522	ICRP Publication 80	Reference authority ICRP, 1998. Radiation Dose to Patients from Radiopharmaceuticals (Addendum to ICRP Publication 53). ICRP Publication 80. Ann. ICRP 28 (3).
113523	ICRP Publication 106	Reference authority ICRP, 2008. Radiation Dose to Patients from Radiopharmaceuticals - Addendum 3 to ICRP Publication 53. ICRP Publication 106. Ann. ICRP 38 (1-2).
113509	Post-Administration Measured Activity	Radioactivity measurement of radiopharmaceutical after the administration.
113550	Fasting Duration	The number hours the patient has gone without food.
113551	Hydration Volume	The amount of fluids the patient has consumed before the procedure.
113552	Recent Physical Activity	A description of physical activity the patient performed before the start of the procedure, such as that which may affect imaging agent biodistribution.
113560	Acute unilateral renal blockage	Blockage in one of the tubes (ureters) that drain urine from the kidneys
113561	Low Thyroid Uptake	5% or less Thyroid Uptake of Iodine
113562	High Thyroid Uptake	25% or higher Thyroid Uptake of Iodine
113563	Severely Jaundiced	The patient exhibits symptoms severe of jaundice and/or has a Bilirubin >10 mg/dL.
113570	Cockroft-Gault Formula estimation of GFR	The measurement method of the Glomerular Filtration Rate is Cockroft-Gault Formula

113571	CKD-EPI Formula estimation of GFR	The measurement method of the Glomerular Filtration Rate is CKD-EPI Formula
113572	Glomerular Filtration Rate (MDRD)	The measurement method of the Glomerular Filtration Rate is MDRD
113573	Glomerular filtration Rate non-black (MDRD)	The measurement method of the Glomerular Filtration Rate is non-black MDRD
113574	Glomerular Filtration Rate black (MDRD)	The measurement method of the Glomerular Filtration Rate is black (MDRD)
113575	Glomerular Filtration Rate female (MDRD)	The measurement method of the Glomerular Filtration Rate is female (MDRD)
113576	Glomerular Filtration Rate Cystatin-based formula	The measurement method of the Glomerular Filtration Rate is Cystatin-based formula
113577	Glomerular Filtration Rate Creatinine-based formula (Schwartz)	The measurement method of the Glomerular Filtration Rate is Creatinine-based formula (Schwartz)
113568	Extravasation visible in image	Extravasation or paravenous administration of the product is visible in the images.
113511	Radiopharmaceutical Dispense Unit Identifier	The human readable identification of the specific radiopharmaceutical dispensed quantity or dose ("dose" as unit of medication delivery, not radiation dose measure) to be administered to the patient.

360 **Modify Section to Annex J SNOMED DICOM Microglossary Retired Codes (Normative):**

Annex J SNOMED DICOM Microglossary Retired Codes (Normative)

362

SNOMED DICOM Microglossary Retired Codes

Retired Code Value	Code Meaning	Replacement Code (SNOMED)	Notes
...
<u>C-B1000</u>	<u>Diagnostic Radioisotope</u>	<u>C-10072</u>	<u>Replacement code has meaning "Radionuclide"</u>
...

364

Changes to NEMA Standards Publication PS 3.17-2013

Digital Imaging and Communications in Medicine (DICOM)

Part 17: Explanatory Information

Add a new Annex section:

Annex XX Radiopharmaceutical Radiation Dose Structured Report (Informative)

XX.1 PURPOSE OF THIS ANNEX

This Annex describes the use of the Radiopharmaceutical Radiation Dose (RRD) object. PET, Nuclear Medicine and other non- imaging procedures necessitate that radiopharmaceuticals are administered to patients. The RRD records the amount of activity and estimates patient dose. Radiopharmaceuticals are often administered to patients several minutes before the imaging step begins. A dose management system records the amount of activity administered to the patients. Currently these systems can be configured to receive patient information from HIS/RIS systems via HL7 or DICOM messaging. Figure XX-1 demonstrates a workflow for a "typical" Nuclear Medicine or PET department.

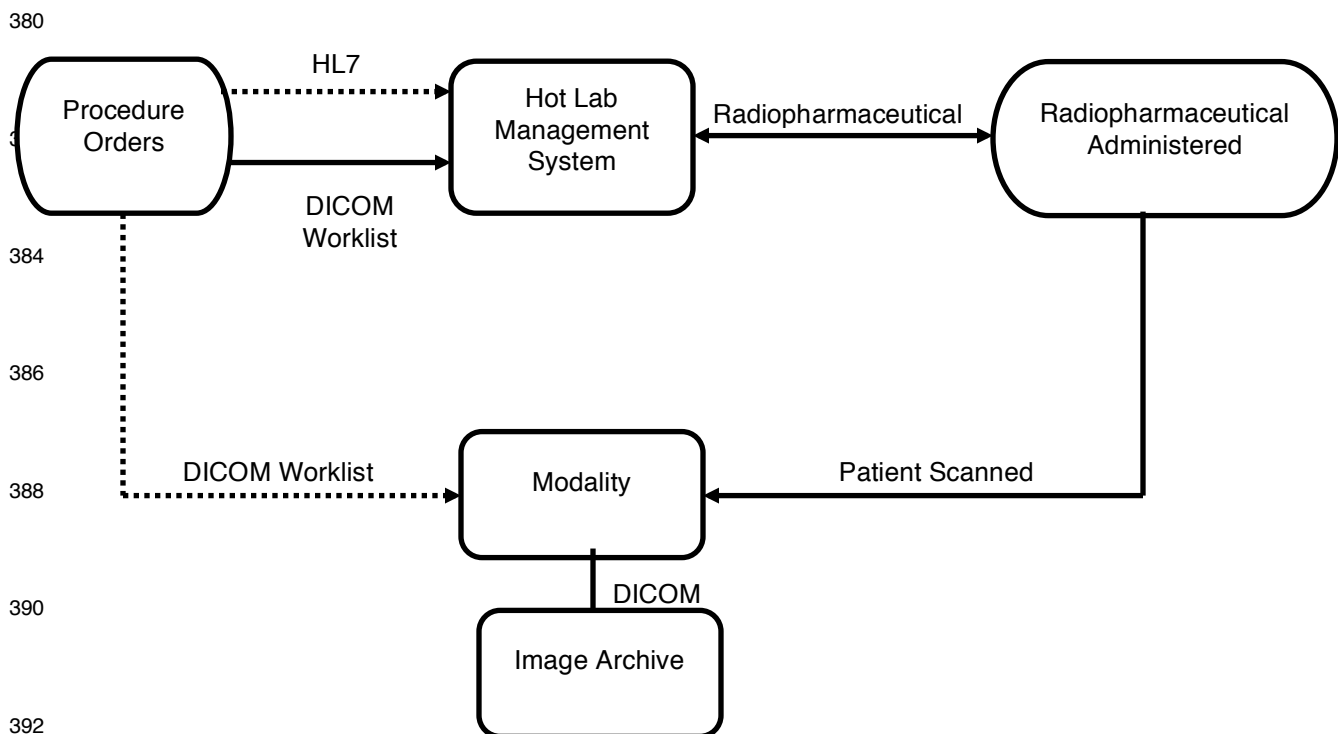


Figure XX - 1 Workflow for a "typical" Nuclear Medicine or PET department

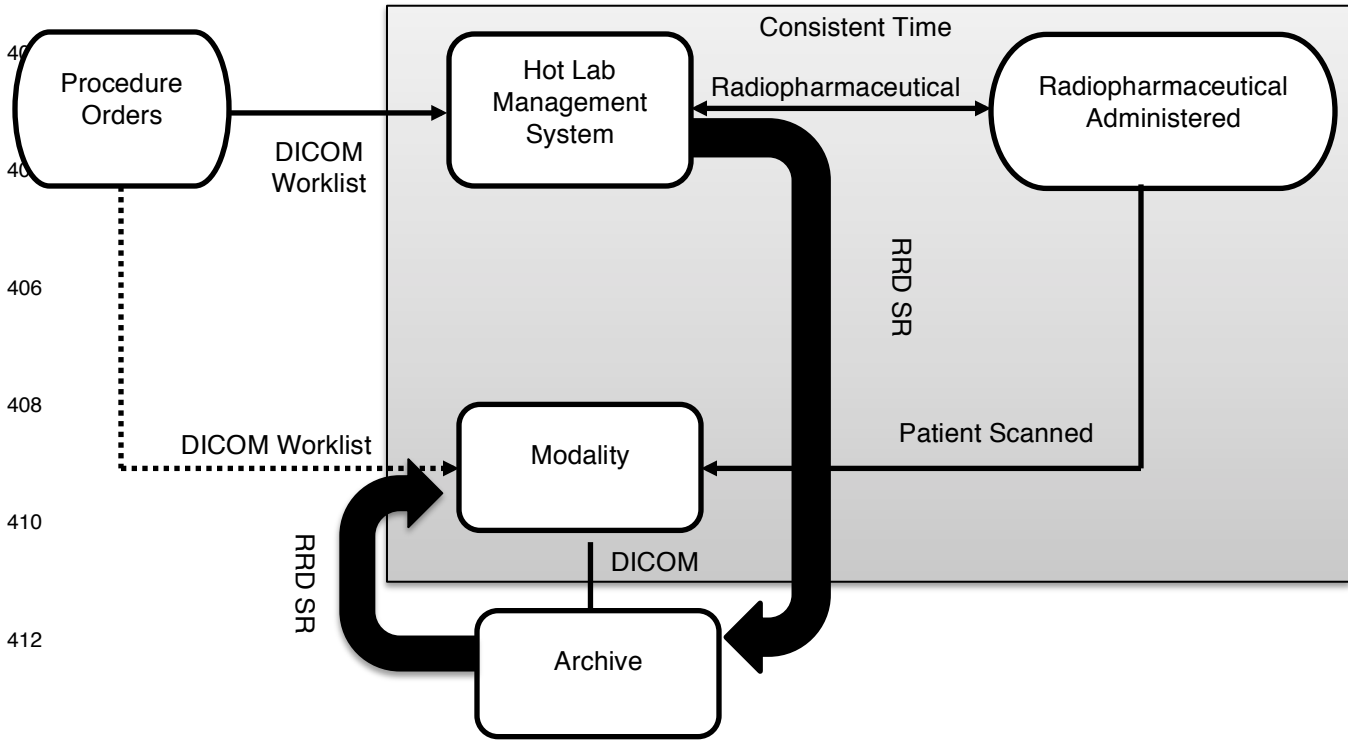
XX.2 REAL-WORLD NUCLEAR MEDICINE AND PET RADIOPHARMACEUTICAL RADIATION DOSE (RRD) SR WORKFLOW

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The Figure XX – 2 demonstrates a Hot Lab management system as the RRD creator. It records the activity amount and the administration time. It creates the RRD report and sends it to the modality. Consistent time is required to accurately communicate activity amount. The consistent time region highlights systems and steps where accurate time reporting is essential. A DICOM Store moves the report to the modality.

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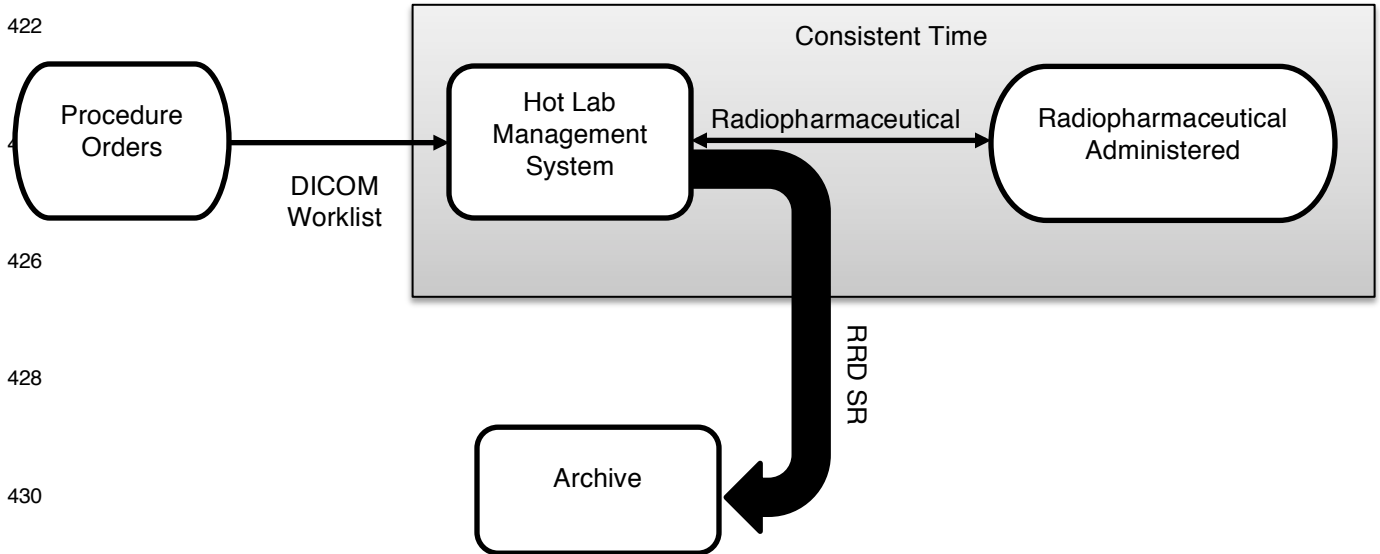
414

Figure XX - 2 Hot Lab management system as the RRD creator.

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418 The Figure XX – 3 demonstrates RRD workflow where a radiopharmaceutical is administered to a
patient for a non-imaging procedure. The report is sent to the image manager/ image archive for
storage and reporting.

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Figure XX - 3 Workflow for a non-imaging procedure

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Figure XX-4 demonstrates when an infusion system or a radioisotope generator is the RRD creator.

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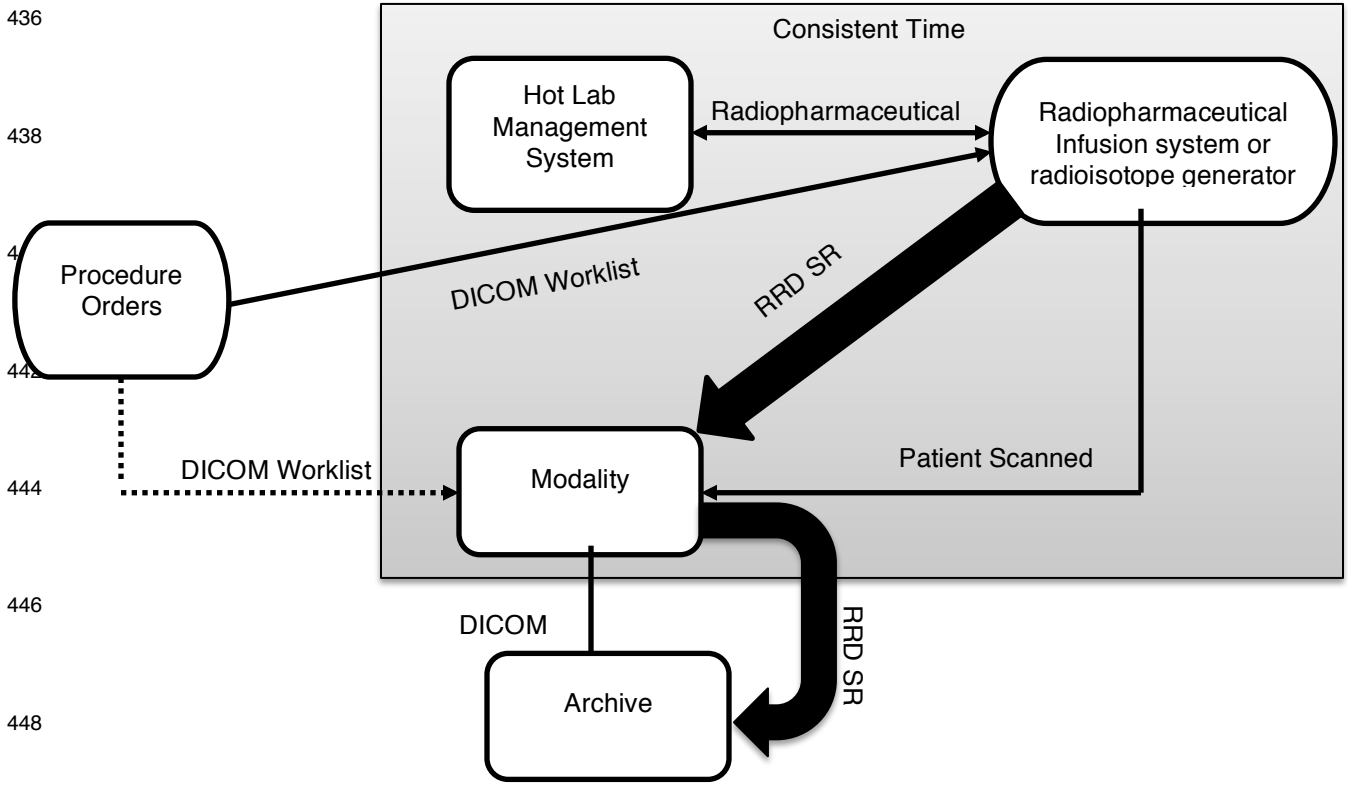
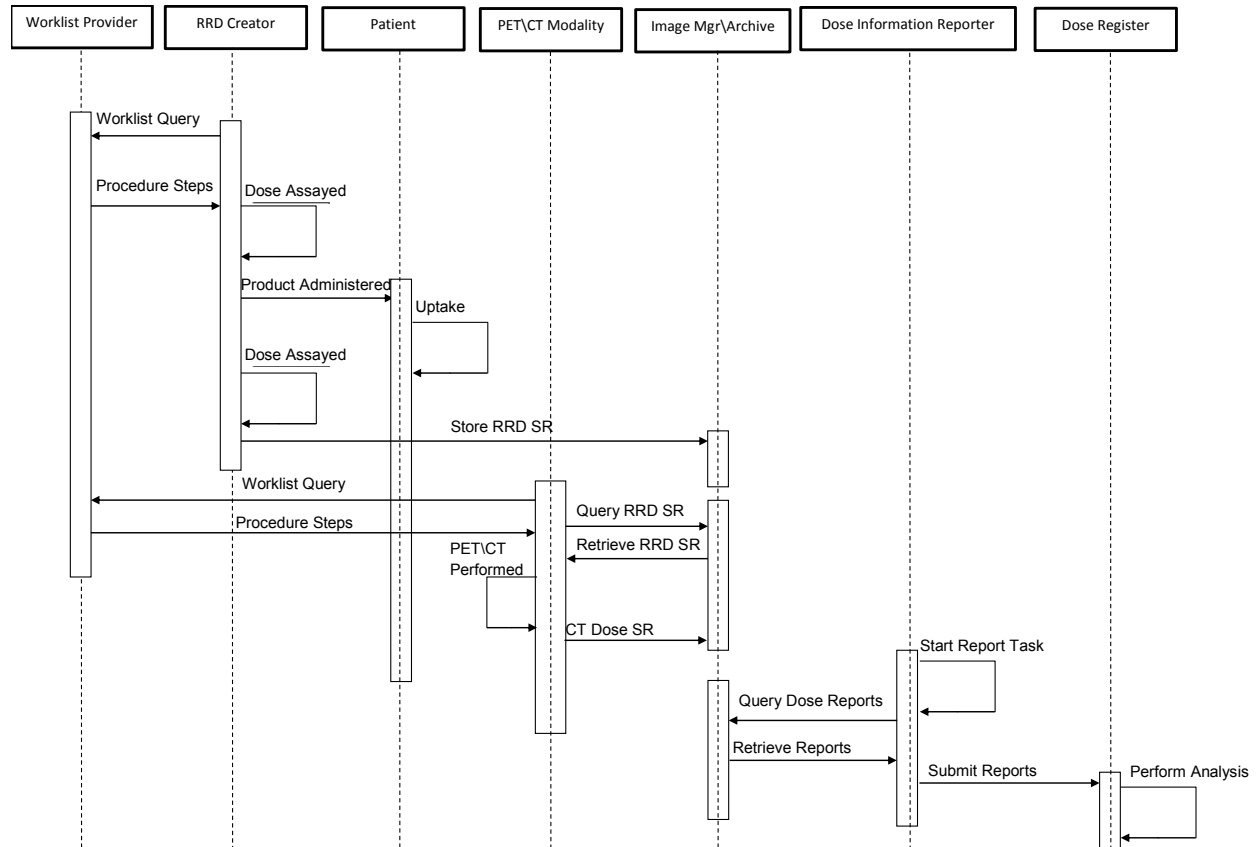


Figure XX - 4 Workflow for an infusion system or a radioisotope generator

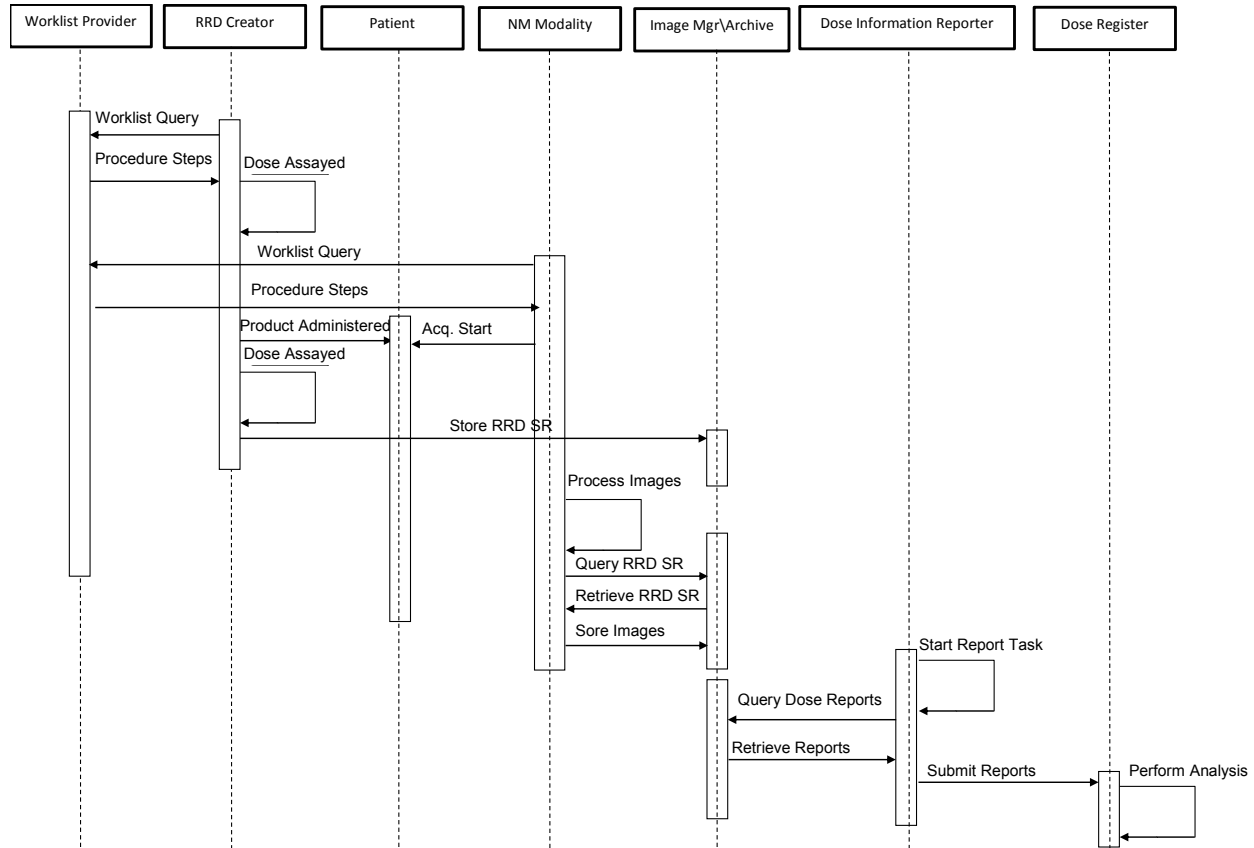
452 Figure XX – 5 is an UML sequence drawing to illustrate steps for creation and downstream use
 case for Radiopharmaceutical Radiation Dose report and CT dose report for the PET\CT system.
 454 The RRD is stored to an image archive and retrieved by the PET\CT scanner.



456

Figure XX - 5 UML sequence drawing for typical workflow

458 Figure XX-6 is an UML sequence drawing to illustrate steps for creation and downstream
 460 use for radiopharmaceutical that is administered when the modality starts acquisition. The
 drawing illustrates that the dose report is reconciled with the image at later time by an
 image processing step.



462 **Figure XX - 6 UML sequence drawing for when radiopharmaceutical and the modality are started at**
 464 **the same time**

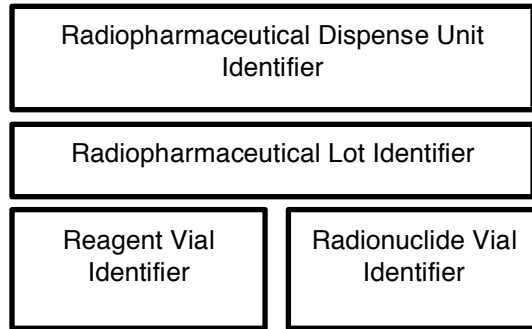
466 **XX.3 REAL-WORLD RADIOPHARMACEUTICAL AND RADIOPHARMACEUTICAL COMPONENTS IDENTIFICATION.**

The Radiopharmaceutical Radiation Dose (RRD) template provides a means to report the
 468 radiopharmaceutical identification number and the identification numbers of its components.

A typical use case is a radio-pharmacist elutes a radionuclide from a generator into a vial. The radionuclide
 470 elution is given an identification number (Radionuclide Vial Identifier). The pharmacist then draws some
 radionuclide from the vial to compound with a reagent (Reagent Vial Identifier) creating a multidose vial of
 472 a radiopharmaceutical. The multidose vial is given identification number (Radiopharmaceutical Lot
 Identifier). Individual doses are drawn from the multidose vial for administration to patients. Each of the
 474 doses is given an identification number (Radiopharmaceutical Identifier).

A second use case is a patient is prescribed 2 MBq of an oral radiopharmaceutical. The radio-pharmacist
 476 dispenses two 1 MBq capsules. Each capsule may have different lot number (Radiopharmaceutical Lot
 Identifier). The two capsules are administered at the same time as one dose (Radiopharmaceutical
 478 Identifier). The report may contain two Radiopharmaceutical Lot Identifiers one for each capsule and one
 radiopharmaceutical identifier for the dose.

480 Figure XX-7 is a diagram the displays the hierarchical relationship between the radiopharmaceutical
dispense unit identifier, radiopharmaceutical lot identifier, reagent vial identifier and the radionuclide vial
482 identifier.



484 **Figure XX-7 Radiopharmaceutical and Radiopharmaceutical Component Identification relationship**

486

488