Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

Radiation Exposure Monitoring for Nuclear Medicine
(REM-NM)

Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE Radiology Technical Framework V14.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on April 22, 2016 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the Radiology Technical Framework. Comments are invited and may be submitted at http://ihe.net/Radiology_Public_Comments.

This supplement describes changes to the existing technical framework documents.

"Boxed" instructions like the sample below indicate to the Volume Editor how to integrate the relevant section(s) into the relevant Technical Framework volume.

Amend Section X.X by the following:

Where the amendment adds text, make the added text **bold underline**. Where the amendment removes text, make the removed text **~~bold strikethrough~~**. When entire new sections are added, introduce with editor's instructions to "add new text" or similar, which for readability are not bolded or underlined.

General information about IHE can be found at: www.ihe.net.

Information about the IHE Radiology domain can be found at: ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE Radiology Technical Framework can be found at: http://www.ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

This supplement addresses tracking, reporting and management of radiopharmaceutical administered dose information in a manner similar to that already adopted for ionizing radiation via the REM Profile. It is intended to support use of the information for technical purposes (decay correction, reconstruction, data tagging), clinical purposes (presentation to clinicians, improved quantitation), quality assurance purposes (practice improvement) and regulatory purposes (reporting).

The profile conveys administered dose information from the laboratory or injection system to the acquisition modality, clinical repository, dose analysis system and registries, replacing manual or other means.

Open Issues and Questions

#	Issue/(Question)

Closed Issues

#	Issue/(Answer)
1.	[Agfa] If the RRD is created before the acquisition, how should the Dose Creator manage to use a consistent study instance UID that matches the study that will be eventually acquired? • Potentially it will be using the Study Instance UID from the scheduled order message, which the modality should be doing the same • But how about the unscheduled case? Or is it relevant for PET / SPECT studies? **Discussion:** Unscheduled case is not relevant. Transaction 4.4 could be sent to the Dose Creator from the RIS to inform it of the Study Instance UID. However, this would require that the hot lab systems be on-line at all times to receive those messages. **Resolved:** MWL is required so the Study Instance UID is prescribed. Unscheduled case is still open.
2.	Should the Radiopharmaceutical Activity Supplier be required to support Storage Commitment? **Resolution**: Yes to the Archive, not to the Modality. S.C. is intended to protect the primary copy, but for an RAS the primary information is recorded by other means.
3.	Should this profile include guidance on whether or not an NM or PET image should include exposure event UIDs for the X-Ray exposure events related to the CT images that were used for attenuation correction, or is the reference to the CT images sufficient? **Resolution**: No. This profile will remain silent on this issue. There is no expectation that a NM/PET image would contain the event UID(s) for the X-Ray exposure events related to the CT images.
4.	How should the Dose "Creator" get the patient/procedure context? • MWL worklist? • MPPS? **Discussion:** Using HL7 would require the Dose Creator to be live all the time to receive the HL7 messages, and queue information for when it is actually needed. Closed – worklist is the solution. Include MPPS as optional for symmetry but it is not required.

#	Issue/(Answer)
5.	Should the Acquisition Modality use values for half-life and positron fraction taken from the RAS, or use its own values if it knows them? **Discussion**: • This would raise questions of trusting sources of the physics parameters of isotopes, and may present product verification/validation issues for the modality. **Resolution**; No, modality is not required to accept values for half-life or positron fraction from the RAS. It can be an implementation decision for the modality.
6.	How should the scanner get the RRD? • Dose "Creator" could push directly to scanners. **Discussion**: Problem here is that the creator would have to shotgun the RRD to all acquisition systems that could potentially be used to scan the patient. • Scanner could query/retrieve from Image Manager based on Patient/Accession info from Worklist. • [Agfa] Would it make sense for the Dose Creator to use STOW-RS to send the RRD to DSS/OF and then the dose information will be available in MWL query? o Modality already widely supports MWL. So getting the RRD information from MWL query is a small incremental change. o Most DSS/OF will likely be interested in the dose information, similar to REM. o Using RESTful STOW-RS may lower the entry barrier given the hotlab systems traditionally do not use DICOM. **Discussion:** Modalities generally use MWL during setup of a procedure. The Dose information may not be available at that time, so the RRD information may be accessed further downstream in the acquisition/processing chain, where MWL is not used. Presumably the RRD will be generated by the Dose Creator as a DICOM object, so the Dose Creator is already required to support some DICOM anyway. **Resolved**: The Radiopharmaceutical Activity Supplier (Dose Creator) stores the dose report object to the Image Manager/Archive. The Acquisition Modality shall query/retrieve from the Image Manager/Archive based on Patient, Accession, and Study information obtained from worklist.
7.	What if scanner is not on when RAS tries to push the RRDSR? **Resolution**: Since the Modality is required to query/retrieve the RRDSR from the Image Manager/Archive, this is no longer an issue.
8.	What attributes in the RRD object should be promoted to mandatory? • Should pre-assay values (activity amount and time) be mandatory? (Probably not) • Should post-assay values be mandatory if this is performed? (Probably not) Closed
9.	Should the Radiopharmaceutical Activity Supplier be required to send the report to multiple destinations? We could lower the bar and send only to the Image Manager/Archive. In the REM Profile, the Acquisition Modality is shown in Figure 22.1-1 supporting the [Rad-62] Store Dose Information to multiple destinations (Image Manager/Archive, Dose Info Consumer and Dose Info Reporter. Resolution: Leave it required Closed
10.	Should this profile include recommendations on how to support imaging of multiple radiopharmaceuticals, such as dual-isotope cardiac studies? Should the RAS create one, or two dose reports? How would the imaging modality know if it received all of the associated exposure event info? Two reports are generated. Clarify the example of two linked worklist entries.

#	Issue/(Answer)
	Resolution: Description added in Section 4.8.4.1.2.5 Closed
11.	What attributes in the PET or NM Image IODs should be promoted to mandatory? For example, currently almost the entire NM Isotope Module and PET Isotope Module, including administration route, administration start and stop time, volume, total dose, half-life, are all optional. **Discussion:** • Radiopharmaceutical Administration Event UID (0008,3012). • Modality is now required to copy information on the radiopharmaceutical and isotope codes, etc., from the RRDSR to the created images. See Table 4.8.4.1.2.5-1. **Resolution:** Closed. Nothing else beyond those listed here.
12.	Is there is a workflow timing issue between the RAS storing the dose reports to the Image Manager and the Acquisition Modality querying for that information? There is a concern that the PACS may not make the report available for query by the modality until the study has been read. Having the PACS backfill information from the RRDSR to existing images is outside the scope of this profile. **Resolution:** Closed: Requirement added to clarify Image Manager workflow to provide the report promptly for access by the Modality.
13.	How does the RAS get a date for the weight value from worklist? Discussion: Clinical protocol would usually require measurement or verbal confirmation of patient weight at the time of administration, not relying possibly outdated information from another source through worklist. Do we need a CP in DICOM to address providing the date/time of the weight? Intent is not when the weight is measured but into which system the measurement is entered. Concern is about receiving stale information. **Resolution:** Closed: Avoid the issue by using the RAS value, and only using a worklist value as a fallback.
14.	Should there be any discussion/profiling of how data is shared/partitioned between a power injector and a dose calibrator? RRDSR already has some fields for the flow information. Sup164 is considering fields for activity. **Resolution:** Closed. This is a DICOM issue.
15.	Blood Glucose is copied from RRDSR to PET images. However, the PET IOD uses TID 3470. The problem is that row 1, “Patient State” is mandatory. What should be used here for non-cardiac studies for “Cardiac Procedural State Value”? Should they default to “Resting State”? For FDG PET studies, Glucose level is mandatory. **Resolution:** Closed. A DICOM CP will fix TID 3470.

General Introduction

Update the following Appendices to the General Introduction as indicated below. Note that these are not appendices to Volume 1.

Appendix A - Actor Summary Definitions

Add the following actors to the IHE Technical Frameworks General Introduction list of actors:

Actor	Definition
Radiopharmaceutical Activity Supplier	**A laboratory system, dose creation and/or measurement system used to generate or administer a radiopharmaceutical to a patient as part of a Nuclear Medicine procedure.**

Appendix B - Transaction Summary Definitions

Add the following transactions to the IHE Technical Frameworks General Introduction list of Transactions:

Transaction	Definition
Store Radiopharmaceutical Activity Information.	**Send details of Radiopharmaceutical Administration Events encoded in DICOM SR using DICOM Store.**

Glossary

Add the following glossary terms to the IHE Technical Frameworks General Introduction Glossary:

Glossary Term	Definition
Radiopharmaceutical Radiation Dose SR object (RRDSR)	**A DICOM Structured Report object conforming to the Radiopharmaceutical Radiation Dose SR IOD.**

Volume 1 – Profiles

Add new Profile Chapter.

40 Radiation Exposure Monitoring for Nuclear Medicine (REM-NM) Profile

The REM-NM Profile specifies communications between systems generating reports of radiopharmaceutical administration events (generally laboratory or dose creator/injector systems) and systems which receive, store, or process those reports (generally nuclear medicine modalities, local dose information management systems and/or national/regional dose registries). It defines how DICOM®[1] nuclear medicine dose SR objects are created, stored, queried, retrieved, de-identified, read, and may be processed and displayed.

40.1 REM-NM Actors, Transactions, and Content Modules

This section defines the actors, transactions, and/or content modules in this profile. General definitions of actors are given in the Technical Frameworks General Introduction Appendix A at http://www.ihe.net/Technical_Frameworks.

Figure 40.1-1 shows the actors directly involved in the REM-NM Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

[1] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards publications relating to digital communications of medical information.

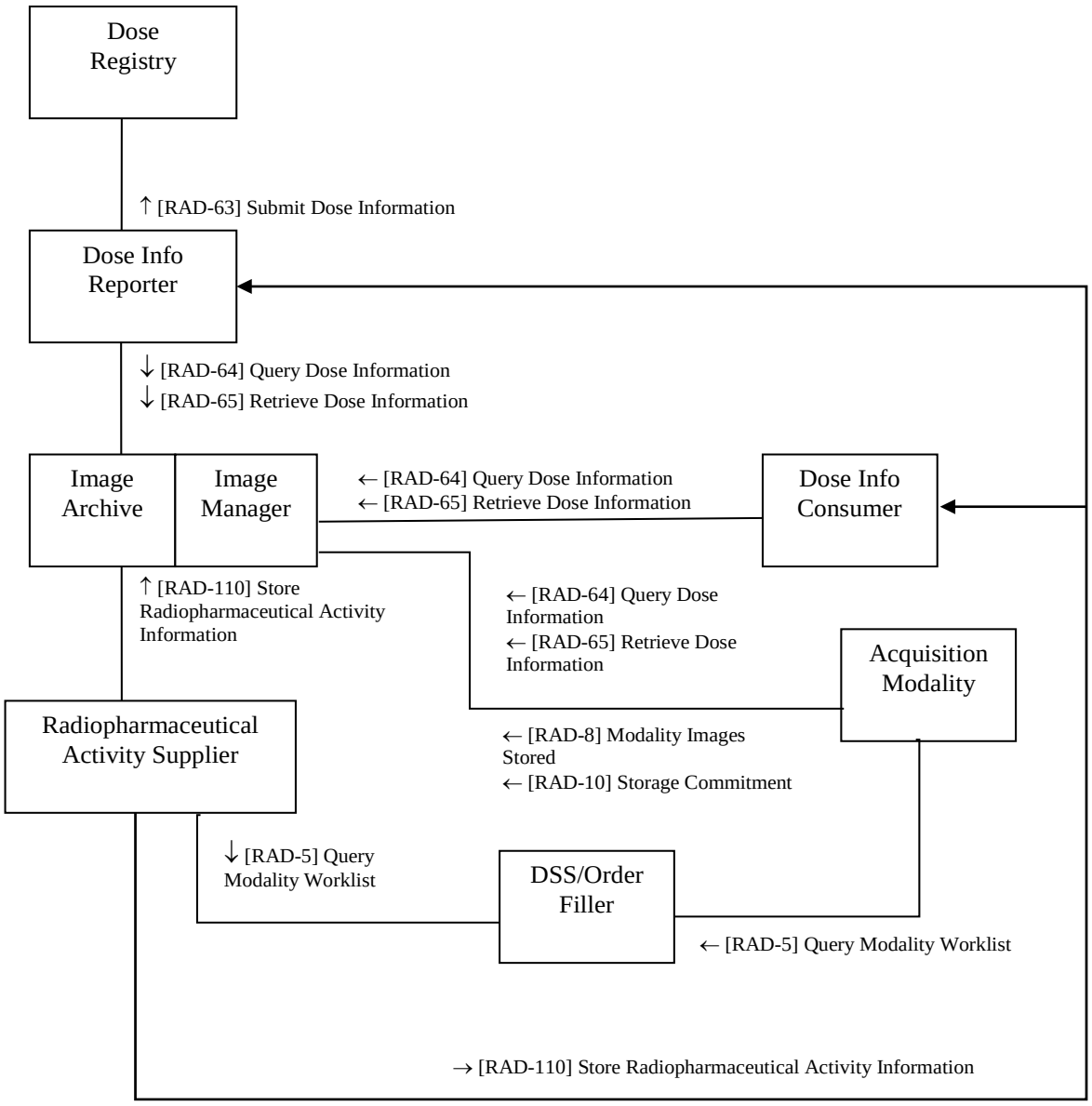


Figure 40.1-1: REM-NM Actor Diagram

215 Table 40.1-1 lists the transactions for each actor directly involved in the REM-NM Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled "R") and may support the optional transactions (labeled "O").

220 **Table 40.1-1: REM-NM Profile - Actors and Transactions**

Actors	Transactions	Optionality	Reference
Radiopharmaceutical Activity Supplier	Query Modality Worklist [RAD-5]	R	RAD TF-2: 4.5
	Store Radiopharmaceutical Activity Information [RAD-110]	R	RAD TF-3: 4.110
Acquisition Modality	Query Modality Worklist [RAD-5]	R	RAD TF-2: 4.5
	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65
Image Manager / Archive	Modality Images Stored [RAD-8]	R	RAD TF-2: 4.8
	Storage Commitment [RAD-10]	R	RAD TF-2: 4.10
	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65
	Store Radiopharmaceutical Activity Information [RAD-110]	R	RAD TF-3: 4.110
Dose Information Reporter	Submit Dose Information [RAD-63]	R	RAD TF-2: 4.63
	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65
	Store Radiopharmaceutical Activity Information [RAD-110]	R	RAD TF-3: 4.110
Dose Information Consumer	Query Dose Information [RAD-64]	R	RAD TF-2: 4.64
	Retrieve Dose Information [RAD-65]	R	RAD TF-2: 4.65
	Store Radiopharmaceutical Activity Information [RAD-110]	R	RAD TF-3: 4.110
Dose Registry	Submit Dose Information [RAD-63]	R	RAD TF-3: 4.63
DSS/Order Filler	Query Modality Worklist [RAD-5]	R	RAD TF-2: 4.5

A Radiopharmaceutical Activity Supplier may generate Dose objects on behalf of another system based on administration details obtained by manual input and/or some proprietary method, as long as it can do so completely and correctly.

Actors are encouraged to describe in their DICOM Conformance Statement additional details of how they implement specific DICOM-based transactions (e.g., the time frame in which a Radiopharmaceutical Activity Supplier is able to store a Dose object relative to the completion of the irradiation event).

40.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volumes 2 and 3) and National Extensions (Volume 4). This section documents any additional requirements on profile's actors.

40.1.1.1 Acquisition Modality

Images created for a given study by the Acquisition Modality shall have the same Study Instance UID as the associated Dose Reports (Radiopharmaceutical and X-Ray). Thus the Acquisition Modality in REM-NM is required to be grouped with both a SWF.b Acquisition Modality and an REM Acquisition Modality (if applicable). See Table 40.3-1. REM-NM Required Actor Groupings and Section 40.4.1 Concepts.

The Acquisition Modality shall record Radiopharmaceutical Administered Activity Information, if present the RRDSR, into each created image instance in the associated study. See RAD TF-2: 4.8.4.1.2.5.

40.1.1.2 Image Manager / Archive

Some Use Cases require that the Dose Report be accessible to the Acquisition Modality in a timely manner. Therefore, the Image Manager/Archive shall make the Dose Report available for retrieval during the conduct of the acquisition; i.e., it shall not sequester it until the acquisition procedure is complete.

40.2 REM-NM Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 40.2-1. Dependencies between options when applicable are specified in notes.

Table 40.2-1: REM for Nuclear Medicine - Actors and Options

Actor	Option Name	Reference
Radiopharmaceutical Activity	Patient Based Worklist (note 1)	RAD TF-2: 4.5

Actor	Option Name	Reference
Supplier	Radiopharmaceutical Activity Supplier Worklist Query (note 1)	RAD TF-2: 4.5
Acquisition Modality	Patient Based Worklist (note 1)	RAD TF-2: 4.5
	Broad Worklist Query (note 1)	RAD TF-2: 4.5
Image Manager/Archive	No options defined	--
Dose Information Reporter	No options defined	--
Dose Information Consumer	No options defined	--
Dose Registry	No options defined	--
DSS/Order Filler	No options defined	--

Note 1: The actor shall support at least one of the two options. Both may be supported.

40.3 REM-NM Required Actor Groupings

An actor from this profile (Column 1) shall implement all of the required transactions and/or content modules in this profile *in addition to* all of the transactions required for the grouped actor (Column 2).

Section 40.5 describes some optional groupings that may be of interest for security considerations and Section 40.6 describes some optional groupings in other related profiles.

Table 40.3-1: REM-NM - Required Actor Groupings

REM-NM Actor	Actor to be grouped with	Reference	Content Bindings Reference
Radiopharmaceutical Activity Supplier	ITI CT Time Client	ITI TF-1: 7.1	--
Acquisition Modality	ITI CT Time Client	ITI TF-1: 7.1	--
	REM Acquisition Modality (See Note 1)	RAD TF-1: 22.1	
	SWF.b Acquisition Modality	RAD TF-1: 34.1	--
Dose Register	None	--	--
Dose Info Reporter	None	--	--
Image Manager / Archive	None	--	--
Dose Info Consumer	None	--	--
DSS/Order Filler	SWF.b DSS/Order Filler	RAD TF-1: 34.1	--

Note 1: Required if the Acquisition Modality is a hybrid PET/CT or SPECT/CT.

40.4 REM-NM Overview

40.4.1 Concepts

There are three main concepts.

1. The Acquisition Modality is not the creator of the Dose Report (RRDSR). Instead, it is a consumer of this report.
2. There are use cases that do not involve an imaging procedure at all.
3. In some cases that do involve an imaging procedure, the Dose Report may not be available to the Acquisition Modality until some time after the imaging procedure has started.

40.4.2 Use Cases

40.4.2.1 Use Case #1: Non-Imaging Procedure

In the simplest case, there is an injection with no imaging.

40.4.2.1.1 Non-Imaging Procedure Use Case Description

A patient is scheduled for a Nuclear Medicine procedure that does not involve imaging (e.g., for measurement with a thyroid uptake probe).

The Radiopharmaceutical Activity Supplier, typically a Hot Lab management system, an infusion system, or a radioisotope generator queries the DSS/Order Filler for a Worklist entry to get the patient demographics, order and procedure details for the current patient.

The Radiopharmaceutical is prepared and administered to the patient.

Administration may be done manually or using an automated device such as an automatic injector. A variety of routes of administration are possible (e.g., oral, by inhalation, intravenous, etc.).

The Radiopharmaceutical Activity Supplier records the amount of activity that was administered to the patient, generating a new Radiopharmaceutical Administration Event UID. Some systems may derive the administered activity by measuring the dose container before (pre-administration assay) and after (residual assay) and taking the difference. Some generators measure the administered activity directly. Other details may include the volume of administered activity, extravasation, etc.

Upon completion of the radiopharmaceutical administration, the Radiopharmaceutical Activity Supplier stores the completed Radiopharmaceutical Radiation Dose Structured Report (RRDSR) to the Image Manager/Archive where it will be available as a persistent record. From there, Dose Information Consumers and Dose Information Reporters may access the report, for example to generate analysis reports or drive dashboards. (See RAD TF-1:22.3.2 for more examples of dose report analysis as described for REM).

40.4.2.1.2 Non-Imaging Procedure Process Flow

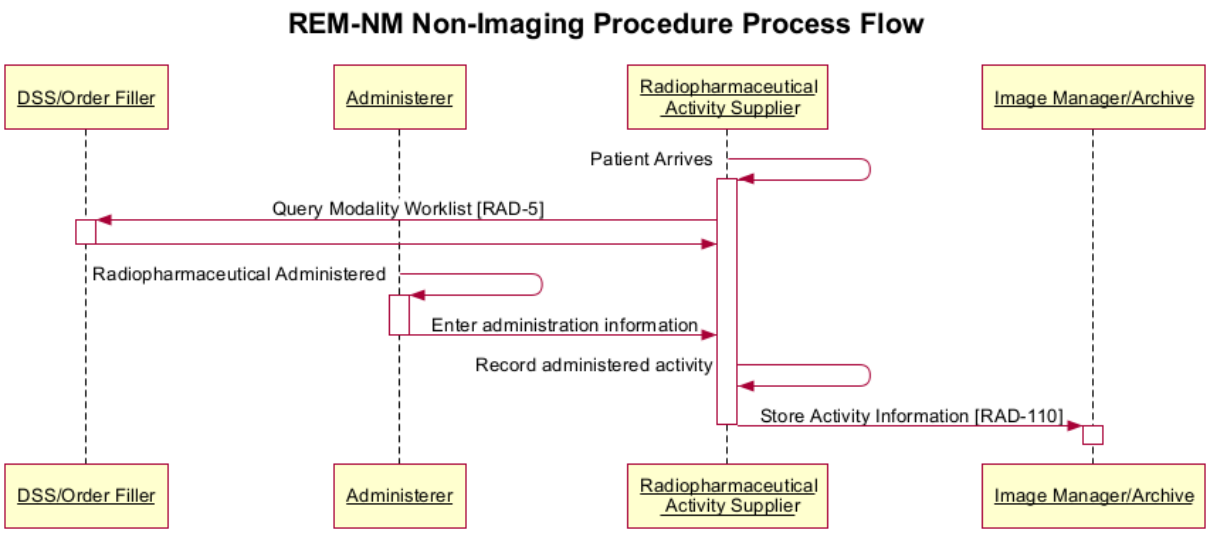


Figure 40.4.2.1.2-1: Non-Imaging Procedure Process Flow in REM-NM Profile

305 The text in Figure 40.4.2.1.2-2 was used to generate the diagram in Figure 40.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title REM-NM Non-Imaging Procedure Process Flow
Participant DSS/Order Filler as OF
Participant Administerer as Injector
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Image Manager/Archive as IM

RAS->RAS: Patient Arrives
Activate RAS

RAS->+OF: Query Modality Worklist [RAD-5]
OF->-RAS:
Injector->+Injector: Radiopharmaceutical Administered
Injector->-RAS: Enter administration information

RAS->RAS: Record administered activity
RAS->+IM: Store Activity Information [RAD-110]

Deactivate RAS
```

Figure 40.4.2.1.2-2: Diagram Pseudocode for Non-Imaging Procedure Process Flow

40.4.2.2 Use Case #2: General Imaging Procedure

In the most common imaging procedures a single radiopharmaceutical is administered on one occasion to a patient for imaging purposes.

40.4.2.2.1 General Imaging Procedure Use Case Description

A patient is scheduled for a standard Nuclear Medicine imaging procedure.

The Radiopharmaceutical Activity Supplier Actor, typically a Hot Lab management system, an infusion system, or a radioisotope generator queries the DSS/Order Filler for a Worklist entry to get the patient demographics, order and procedure details for the current patient.

The Radiopharmaceutical is prepared and administered to the patient.

Administration may be done manually or using an automated device such as an automatic injector. A variety of routes of administration are possible (e.g., oral, by inhalation, intravenous, etc.).

The Radiopharmaceutical Activity Supplier records the amount of activity that was administered to the patient, generating a new Radiopharmaceutical Administration Event UID. Some systems may derive the administered activity by measuring the dose container before (pre-administration assay) and after (residual assay) and taking the difference. Some generators measure the administered activity directly. Other details may include the volume of administered activity, extravasation, etc.

Upon completion of the radiopharmaceutical administration, the Radiopharmaceutical Activity Supplier stores the completed Radiopharmaceutical Radiation Dose Structured Report (RRDSR) to the Image Manager/Archive where it will be available as a persistent record. From there, Dose Information Consumers and Dose Information Reporters may access the report, for example to generate analysis reports or drive dashboards. (See RAD TF-1:22.3.2 for more examples of dose report analysis as described for REM.)

After an amount of time (determined by clinical protocols outside of this profile; typically 30 to 90 minutes for PET, and up to more than 24 hours for some NM cases) the patient is taken to the Acquisition Modality. As part of preparation for performing the imaging procedure, the Acquisition Modality locates the RRDSR by querying the Image Manager/Archive and retrieves the RRDSR(s) for the study. The images created by the Acquisition Modality and the RRDSR will contain the same Study Instance UID since both the Acquisition Modality and the Radiopharmaceutical Activity Supplier obtain the Study Instance UID from the Worklist. Imaging data is acquired, and the Acquisition Modality uses the administered activity information from the Dose Report to do decay correction. The Acquisition Modality also includes in the encoded images information about the radionuclide, radiopharmaceutical and administered activity obtained from the Dose Report.

The Acquisition Modality does not forward the retrieved Dose Report to the Image Manager/Archive when storing the resulting images.

A valid alternative product implementation would be for the Acquisition Modality to be grouped with a Radiopharmaceutical Activity Supplier to support scenarios in which there is no separate Radiopharmaceutical Activity Supplier.

40.4.2.2.2 General Imaging Procedure Process Flow

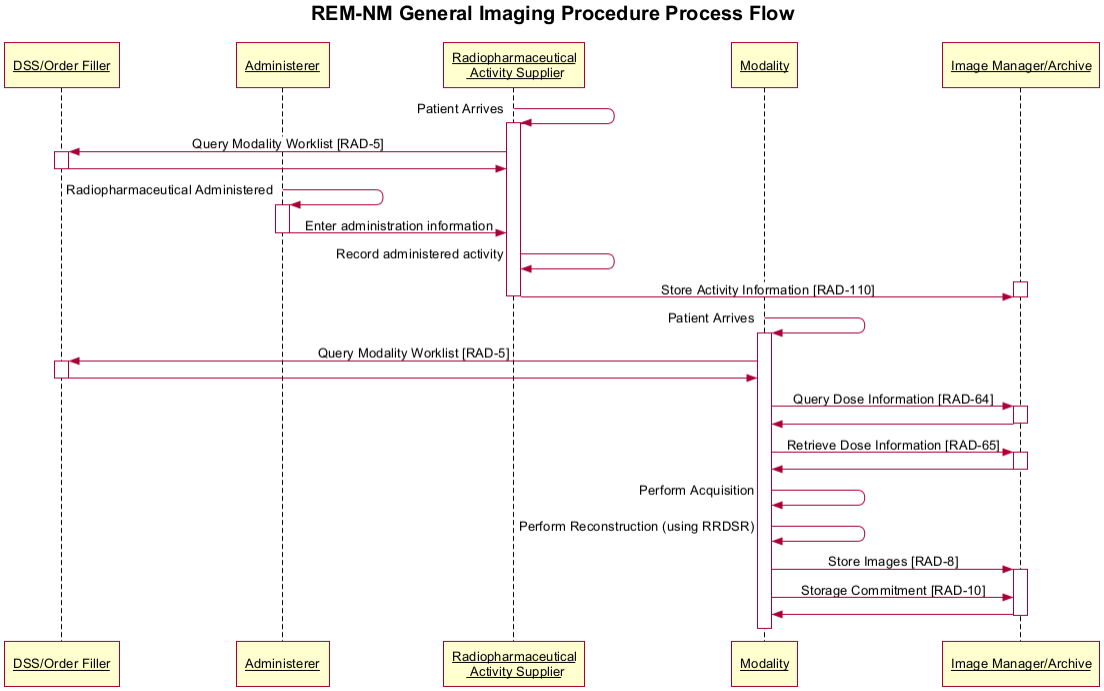


Figure 40.4.2.2-1: General Imaging Procedure Process Flow in REM-NM Profile

The text in Figure 40.4.2.2-2 was used to generate the diagram in Figure 40.4.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title REM-NM General Imaging Procedure Process Flow
Participant DSS/Order Filler as OF
Participant Administerer as Injector
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Modality
Participant Image Manager/Archive as IM

RAS->RAS: Patient Arrives
Activate RAS

RAS->+OF: Query Modality Worklist [RAD-5]
OF->-RAS:
Injector->+Injector:Radiopharmaceutical Administered
Injector->-RAS: Enter administration information

RAS->RAS: Record administered activity
RAS->+IM: Store Activity Information [RAD-110]



Deactivate IM

Deactivate RAS

Modality->Modality: Patient Arrives
Activate Modality
Modality->+OF: Query Modality Worklist [RAD-5]
OF->-Modality:
Modality->+IM: Query Dose Information [RAD-64]
IM->-Modality:
Modality->+IM: Retrieve Dose Information [RAD-65]
IM->-Modality:

Modality->Modality: Perform Acquisition
Modality->Modality: Perform Reconstruction (using RRDSR)
Modality->+IM: Store Images [RAD-8]
Modality->IM: Storage Commitment [RAD-10]
IM->-Modality:
```

Figure 40.4.2.2-2: Diagram Pseudocode for General Imaging Procedure Process Flow

40.4.2.3 Use Case #3: Simultaneous Administration and Imaging

This use case is very similar to Use Case #2, with one exception. In this use case a radiopharmaceutical is administered to a patient during the imaging process. This means the Dose Report is not available until some time after the acquisition setup has been completed. The Acquisition Modality will need to accommodate this case by allowing lookup of the Dose Report when it is actually needed, after the traditional scan setup.

40.4.2.3.1 Simultaneous Administration and Imaging Use Case Description

A patient is scheduled for a standard Nuclear Medicine imaging procedure.

The Radiopharmaceutical Activity Supplier Actor, typically a Hot Lab management system, an infusion system, or a radioisotope generator queries the DSS/Order Filler for a Worklist entry to get the patient demographics, order and procedure details for the current patient.

The Radiopharmaceutical is prepared.

At some point, the patient is also taken to the Modality. The Acquisition Modality queries the Order Filler for a Worklist Entry for the imaging procedure.

The Modality begins the data acquisition procedure, and the radiopharmaceutical is administered to the patient at approximately the same time (the order in which these events occur may depend on the exact procedure and radiopharmaceutical being used).

Administration may be done manually or using an automated device such as an automatic injector. A variety of routes of administration are possible (e.g., oral, by inhalation, intravenous, etc.).

The Radiopharmaceutical Activity Supplier records the amount of activity that was administered to the patient, generating a new Radiopharmaceutical Administration Event UID. Some systems may derive the administered activity by measuring the dose container before (pre-administration assay) and after (residual assay) and taking the difference. Some generators measure the administered activity directly. Other details may include the volume of administered activity, extravasation, etc.

Upon completion of the radiopharmaceutical administration, the Radiopharmaceutical Activity Supplier stores the completed Radiopharmaceutical Radiation Dose Structured Report (RRDSR) to the Image Manager/Archive where it will be available as a persistent record. From there, Dose Information Consumers and Dose Information Reporters may access the report, for example to generate analysis reports or drive dashboards. (See RAD TF-1:22.3.2 for more examples of dose report analysis as described for REM.)

The Acquisition Modality allows enough time for the RRDSR to be created and stored. The Acquisition Modality locates the RRDSR by querying the Image Manager/Archive and retrieves the RRDSR(s) for the study. The Acquisition Modality uses the administered activity information from the Dose Report to do decay correction. The Acquisition Modality also includes in the encoded images information about the radionuclide, radiopharmaceutical and administered activity obtained from the Dose Report. The images created by the Acquisition Modality and the RRDSR will contain the same Study Instance UID since both the Acquisition Modality and the Radiopharmaceutical Activity Supplier obtain the Study Instance UID from the Worklist.

The Acquisition Modality does not forward the Dose Report to the Image Manager/Archive when storing the resulting images.

A valid alternative product implementation would be for the Acquisition Modality to be grouped with a Radiopharmaceutical Activity Supplier to support scenarios in which there is no separate Radiopharmaceutical Activity Supplier, or if the Modality needs to report more dose information in a new Dose Report.

40.4.2.3.2 Simultaneous Administration and Imaging Process Flow

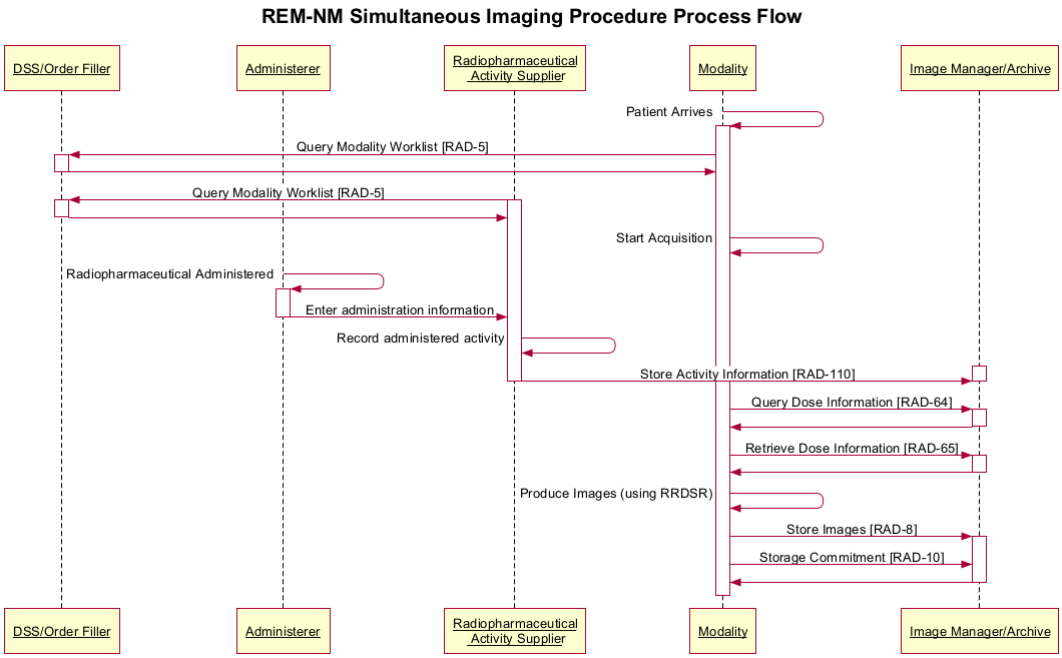


Figure 40.4.2.3.2-1: Simultaneous Administration and Imaging Process Flow in REM-NM Profile

The text in Figure 40.4.2.3.2-2 was used to generate the diagram in Figure 40.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title REM-NM Simultaneous Imaging Procedure Process Flow
Participant DSS/Order Filler as OF
Participant Administerer as Injector
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Modality
Participant Image Manager/Archive as IM

Modality->Modality: Patient Arrives
Activate Modality
Modality->+OF: Query Modality Worklist [RAD-5]
OF->-Modality:

RAS->+OF: Query Modality Worklist [RAD-5]
Activate RAS
OF->-RAS:
Modality->Modality: Start Acquisition
Injector->+Injector: Radiopharmaceutical Administered
Injector->-RAS: Enter administration information
RAS->RAS: Record administered activity
RAS->+IM: Store Activity Information [RAD-Z]
deactivate IM

Deactivate RAS

Modality->+IM: Query Dose Information [RAD-64]
IM->-Modality:
Modality->+IM: Retrieve Dose Information [RAD-65]
IM->-Modality:
Modality->Modality: Produce Images (using RRDSR)
Modality->+IM: Store Images [RAD-8]
Modality->IM: Storage Commitment [RAD-10]
IM->-Modality:
```

Figure 40.4.2.3.2-2: Diagram Pseudocode for Simultaneous Imaging Procedure Process Flow

40.4.2.4 Use Case #4: Dose Information Reporter Pull-based Workflow

Two alternative methods for distributing the dose information to the Dose Information Reporter (and on to the Registry) are presented in Use Case #4 and #5.

The Dose Information Reporter processes Dose Reports that were created by the Radiopharmaceutical Activity Supplier. In this Use Case the Dose Information Reporter retrieves the Dose Reports from the Image Manager/Archive.

40.4.2.4.1 Dose Information Reporter Pull-based Workflow Use Case Description

This Use Case begins when the Dose Report is stored on the Image Manager/Archive by the Radiopharmaceutical Activity Supplier.

The Dose Information Reporter periodically collects Dose Reports to be submitted to a Dose Registry. The Dose Reports are obtained by querying the Image Manager/Archive. Selected reports are de-identified by the Dose Information Reporter and then submitted to the Dose

Registry. The analysis performed by the Dose Registry (e.g., population analysis) is beyond the scope of this profile.

The Dose Information Reporter may also generate weekly or monthly departmental reports summarizing the departmental activity. The Dose Information Reporter periodically collects relevant Dose Reports by querying the Image Manage/Archive. Information from these Dose Reports is summarized in a departmental report document. The content of these summary reports is beyond the scope of this profile, and may be site dependent.

40.4.2.4.2 Dose Information Reporter Pull-based Process Flow

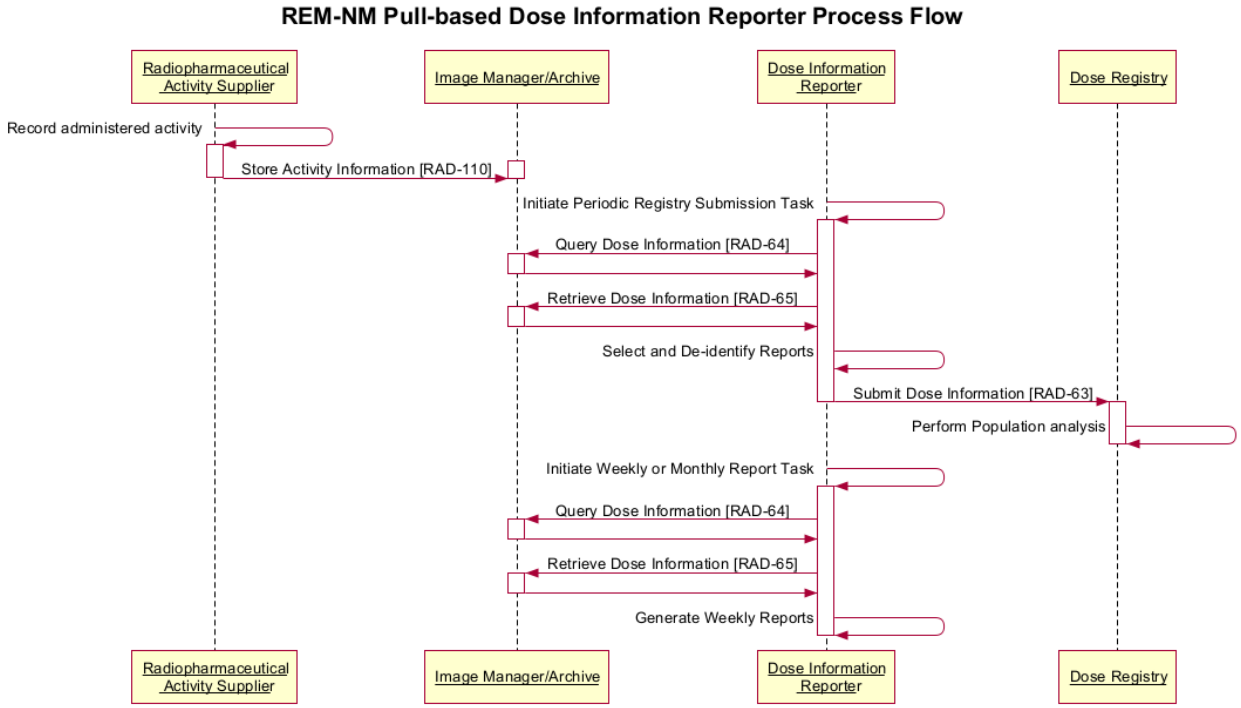


Figure 40.4.2.4.2-1: Pull-based Dose Information Reporter Process Flow in REM-NM Profile

The text in Figure 40.4.2.4.2-2 was used to generate the diagram in Figure 40.4.2.4.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title REM-NM Pull-based Dose Information Reporter Process Flow
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Image Manager/Archive as IM
Participant Dose Information\n Reporter as Reporter
Participant Dose Registry as Dose Register
RAS->RAS: Record administered activity
Activate RAS
RAS->+IM: Store Activity Information [RAD-110]

Deactivate IM
Deactivate RAS

Reporter->+Reporter : Initiate Periodic Registry Submission Task
Reporter->+IM: Query Dose Information [RAD-64]
IM->-Reporter:
Reporter->+IM: Retrieve Dose Information [RAD-65]
IM->-Reporter:
Reporter->Reporter: Select and De-identify Reports
Reporter->+Dose Register: Submit Dose Information [RAD-63]
Deactivate Reporter
Dose Register->-Dose Register: Perform Population analysis

Reporter->+Reporter : Initiate Weekly or Monthly Report Task
Reporter->+IM: Query Dose Information [RAD-64]
IM->-Reporter:
Reporter->+IM: Retrieve Dose Information [RAD-65]
IM->-Reporter:
Reporter->-Reporter : Generate Weekly Reports
```

Figure 40.4.2.4.2-2: Diagram Pseudocode for Pull-based Dose information Reporter Process Flow

40.4.2.5 Use Case #5: Dose Information Reporter Push-based Workflow

The Dose Information Reporter processes Dose Reports that were created by the Radiopharmaceutical Activity Supplier. In this Use Case, the Dose Information Reporter receives the Dose Reports pushed directly from the Radiopharmaceutical Activity Supplier.

40.4.2.5.1 Dose Information Reporter Push-based Workflow Use Case Description

This Use Case begins when the Dose Report is stored on the Dose Information Reporter by the Radiopharmaceutical Activity Supplier.

The Dose Information Reporter periodically selects Dose Reports that it has received, to be submitted to a Dose Registry. Selected reports are de-identified by the Dose Information Reporter and then submitted to the Dose Registry. The analysis performed by the Dose Registry (e.g., population analysis) is beyond the scope of this profile.

The Dose Information Reporter may also generate weekly or monthly departmental reports summarizing the departmental activity based on the Dose Reports that it has received. The Dose Information Reporter periodically selects relevant Dose Reports for processing. Information

from these Dose Reports is summarized in a departmental report document. The content of these summary reports is beyond the scope of this profile, and may be site dependent.

40.4.2.5.2 Dose Information Reporter Push-based Process Flow

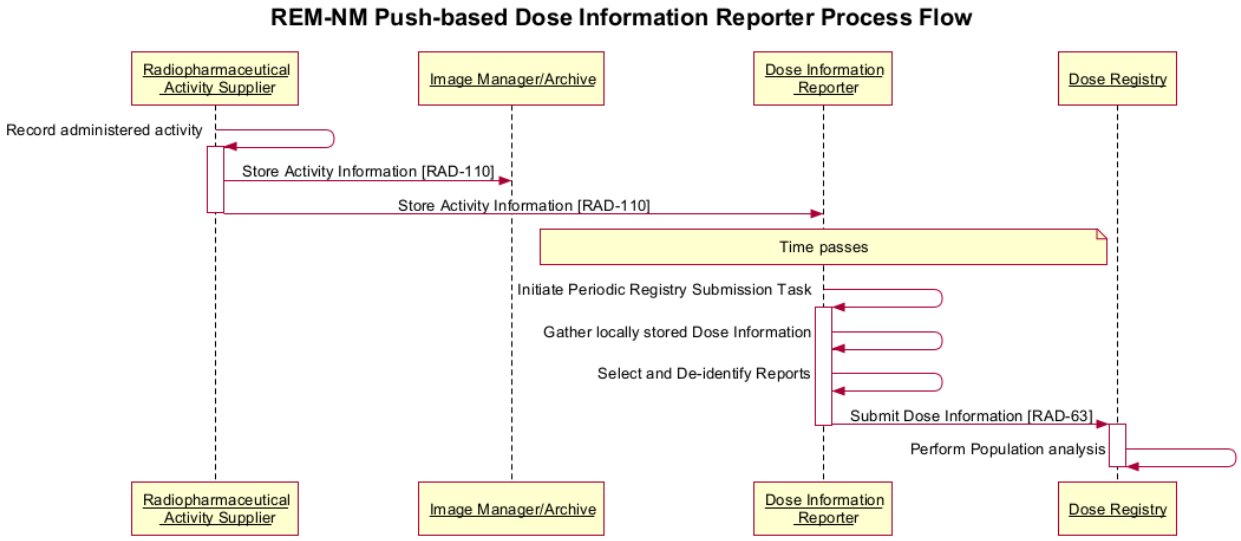


Figure 40.4.2.5.2-1: Push-based Dose Information Reporter Process Flow in REM-NM Profile

The text in Figure 40.4.2.5.2-2 was used to generate the diagram in Figure 40.4.2.5.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title REM-NM Push-based Dose Information Reporter Process Flow
Participant Radiopharmaceutical\n Activity Supplier as RAS
Participant Image Manager/Archive as IM
Participant Dose Information\n Reporter as Reporter
Participant Dose Registry as Dose Register
RAS->RAS: Record administered activity
Activate RAS
RAS->IM: Store Activity Information [RAD-110]

IM->-:
RAS->Reporter: Store Activity Information [RAD-110]
Deactivate RAS
Note over Reporter: Time passes

Reporter->+Reporter : Initiate Periodic Registry Submission Task
Reporter->Reporter: Gather locally stored Dose Information
Reporter->Reporter: Select and De-identify Reports
Reporter->+Dose Register: Submit Dose Information [RAD-63]
Deactivate Reporter
Dose Register->-Dose Register: Perform Population analysis
```

Figure 40.4.2.5.2-2: Diagram Pseudocode for Push-based Dose Information Reporter Process Flow

40.5 REM-NM Security Considerations

Dose Objects have the same security considerations as images.

Security and Privacy policies may require the de-identification of some or all of the PHI details prior to the submission or use of Dose Objects (see RAD TF-3: 4.63.4.1.2.1). De-identification behavior may need to vary by destination due to differences in PHI exposure risk and the need to retain some details, such as approximate patient age or weight, when performing Radiation Dose analysis.

40.6 REM-NM Cross Profile Considerations

Several synergies and interactions of the REM-NM Profile with other profiles are specifically called out here.

40.6.1 Radiology Profiles

40.6.1.1 Portable Data for Imaging (PDI)

The Dose objects from this profile may be included on PDI media, either along with the rest of the study data to provide a “complete package”, or on their own as a way of conveying Dose objects to a patient, another organization or a dose registry.

40.6.1.2 Teaching Files and Clinical Trials Export (TCE)

As DICOM objects, the Dose objects can be referenced in a TCE manifest and processed along with other objects from a study. This could allow submitting dose details in clinical trials where such information is relevant, or including dose details in a teaching file, perhaps one specifically addressing protocol dose and the effects on image quality.

40.6.1.3 Radiation Exposure Monitoring (REM)

Radiation Exposure Monitoring is closely related to REM-NM. Actors supporting REM-NM may consider also supporting REM (see RAD TF-1: 22).

40.6.2 ITI Profiles

40.6.2.1 Cross-Enterprise Document Sharing (XD*)

Since Dose objects are normal DICOM SR objects, the collection of XDS Profiles (XDS, XDS-I, XDR, XDM, etc.) can be used to distribute or access dose records across multiple sites.

40.6.2.2 Audit Trail and Node Authentication (ATNA)

Audit events relevant to the transactions of the REM-NM Profile are identified in RAD TF-3: Table 5.1-2 in the Radiology Audit Trail Option.

Modify the following section in TF-1:

22 Radiation Exposure Monitoring (REM) Integration Profile

This Integration Profile specifies how details of radiation exposure resulting from imaging procedures are exchanged among the imaging systems, local dose information management systems and cross-institutional systems such as dose registries. The data flow in the profile is intended to facilitate recording individual procedure dose information, collecting dose data related to specific patients, and performing population analysis.

Use of the relevant DICOM objects (CT Dose SR, Projection X-Ray Dose SR) is clarified and constrained.

The profile focuses on conveying the details of individual irradiation events. A proper radiation exposure management program at an imaging facility would involve a medical physicist and define such things as local policies, local reporting requirements, annual reviews, etc. Although this profile is intended to facilitate such activities, it does not define such policies, reports or processing, or in itself constitute a radiation exposure management program.

The profile addresses dose reporting for imaging procedures performed on CT and projection X-ray systems, including mammography. It does not ~~**currently**~~ address procedures such as nuclear medicine ~~**(PET or SPECT)**~~, radiotherapy, or implanted seeds. **Administration of radiopharmaceuticals for nuclear medicine procedures (PET, general NM including planar imaging, SPECT, as well as non-imaging procedures) is addressed in the REM-NM Profile.**

The profile is intended to support quality assurance (QA) of the technical process (was the dose appropriate for the procedure performed). It is less suited to QA of the ordering process (was the procedure ordered/scheduled appropriate for the indications (appropriateness criteria)), or QA of the operational process (were any differences between the procedure scheduled and the procedure performed justified by the situation/equipment/patient and appropriately approved).

Add the following new section to TF-1:

22.5.1.5 REM for Nuclear Medicine (REM-NM)

REM for Nuclear Medicine is closely related to REM. Actors supporting REM may consider also supporting REM-NM (see RAD TF-1: 40).

Volume 2 – Transactions

Modify Section 4.8.4.1.2 of the Modality Images Stored transaction as follows:

4.8.4.1.2.4 Recording of X-Ray Dose Information

Acquisition Modality Actors claiming the Radiation Exposure Monitoring (REM) Profile shall record the Irradiation Event UID (0008,3010) of the event(s) that resulted in the data from which the image was derived in each image created; if the image or frame is derived from more than one irradiation event, multiple values shall be present (see DICOM CP 1090). The value(s) of the Irradiation Event UID shall match those encoded in the corresponding SR Dose Information instance. If the SR Dose Information instance is not being created by the equipment that actually administered the radiation, the equipment creating the SR Dose Information shall assure that all images contain the correct Irradiation Event UIDs.

The Irradiation Event UIDs may be used to identify images corresponding to irradiation events for purposes such as identifying irradiated tissues and organs for dose mapping or for advanced effective dose estimations or for comparing the noise characteristics of the images with the dose.

The Irradiation Event UIDs (0008,3010) shall be included in both original and derived images produced by the Acquisition Modality (such as retrospective reconstructions from the same raw data with different slice thickness or reconstruction intervals, multi-planar or 3D reconstructions from the same irradiation event, as well as for processing and for presentation projection images).

For further information on Irradiation Events, see RAD TF-3: 4.62 Store Dose Information, and RAD TF-1: 22 Radiation Exposure Monitoring Profile.

4.8.4.1.2.5 Recording of Radiopharmaceutical Administered Activity Information

Acquisition Modality Actors claiming the REM for Nuclear Medicine (REM-NM) Profile shall copy the dose information, if present in the Radiopharmaceutical Radiation Dose SR object (RRDSR), into each created image instance (both original and derived) as shown in Table 4.8.4.1.2.5-2.

This requirement applies to both original and derived images produced by the Acquisition Modality (such as attenuation corrected and non-attenuation corrected images created from the same raw data, or retrospective reconstructions from the same raw data with different slice thickness or number of iterations).

The Synchronization Module shall be included in PET and NM Images.

Table 4.8.4.1.2.5-2: Mapping Radiopharmaceutical Dose Information to Images

SR Concept	Attribute	RRDSR	NM IOD	PET IOD	Enhanced PET IOD
EV (F-61FDB, SRT, "Radiopharmaceutical agent")	Radiopharmaceutical Code Sequence (0054,0304)	Source-1	Copy-1	Copy-1	Copy-1
EV (C-10072, SRT, "Radionuclide")	Radionuclide Code Sequence (0054,0300)	Source-1	Copy-1	Copy-1	Copy-1
EV (123007, DCM, "Radiopharmaceutical Specific Activity")	Radiopharmaceutical Specific Activity (0018,1077)	Source-1	n.a.	Copy-1	Copy-1
EV (113503, DCM, "Radiopharmaceutical Administration Event UID")	Radiopharmaceutical Administration Event UID (0008,3012)	Source-1	Copy-1	Copy-1	Copy-1
EV (123003, DCM, "Radiopharmaceutical Start DateTime")	Radiopharmaceutical Start Time (0018,1072)	Source-1	Copy-1	Radiopharmaceutical Start Time (0018,1072) Radiopharmaceutical Start DateTime (0018,1078)	Radiopharmaceutical Start DateTime (0018,1078)
EV (123004, DCM, "Radiopharmaceutical Stop DateTime")	Radiopharmaceutical Stop Time (0018,1073)	Source-1	Copy-1	Radiopharmaceutical Stop Time (0018,1073) Radiopharmaceutical Stop DateTime (0018,1079)	Radiopharmaceutical Stop DateTime (0018,1079)
EV (113507, DCM, "Administered activity")	Radionuclide Total Dose (0018,1074)	Source-1	Copy-1	Copy-1 {convert MBq to Bq}	Copy-1
EV (123005, DCM, "Radiopharmaceutical Volume")	Radiopharmaceutical Volume (0018,1071)	Source-1	Copy-1	Copy-1	Copy-1
EV (G-C340, SRT, "Route of administration")	Radiopharmaceutical Route (0018,1070)	Source-1	Copy-1	Radiopharmaceutical Route (0018,1070) Administration Route Code Sequence (0054,0302)	Administration Route Code Sequence (0054,0302)
EV (8302-2, LN, "Patient Height")	Patient's Size (0010,1020)	Source-1	Copy-1	Copy-1	Copy-1
EV (29463-7, LN, "Patient Weight")	Patient's Weight (0010,1030)	Source-1	Copy-1	Copy-1	Copy-1
EV (14749-6, LN, "Glucose")	Acquisition Context Sequence (0040,0555) TID 3470 NM/PET Acquisition Context	Source-1	n.a.	Copy-1	Copy-1

The Radiopharmaceutical Administration Event UID (0008,3012) may be used to identify images corresponding to radiopharmaceutical administration events for purposes such as identifying irradiated tissues and organs for dose mapping or for advanced effective dose estimations or for comparing the noise characteristics of the images with the dose.

For further information on Radiopharmaceutical Administration Events, see RAD TF-3: 4.110 Store Radiopharmaceutical Activity Information, and RAD TF-1: 40 REM for Nuclear Medicine Profile.

When two or more radiopharmaceuticals are being imaged together, the same workflow applies, except that the RAS will have created an RRDSR for each radiopharmaceutical administered to the patient. The modality will need to retrieve all pertinent RRDSR objects from the Image Manager/Archive. Each RRDSR will correspond to a unique subset of sequence Items in the Radiopharmaceutical Information Sequence encoded in the NM, PET or Enhanced PET IOD.

Add a new transaction Section 4.110.

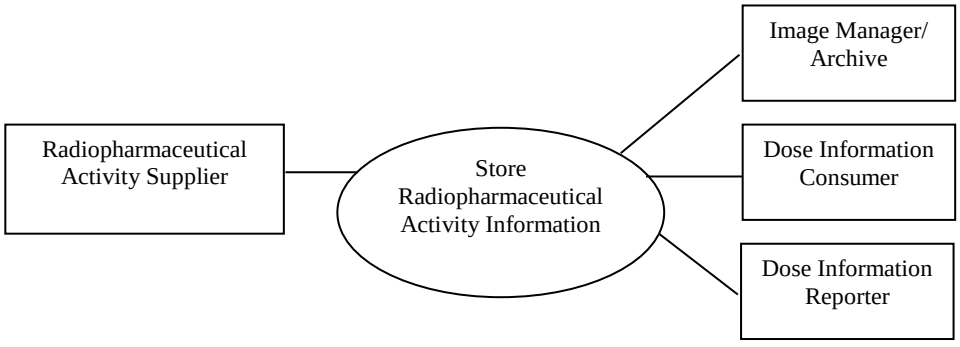
4.110 Store Radiopharmaceutical Activity Information

This section corresponds to Transaction RAD-110 of the IHE Radiology Technical Framework. Transaction RAD-110 is used by the Radiopharmaceutical Activity Supplier, Acquisition Modality, Image Manager/Archive, Dose Information Reporter and Dose Information Consumer Actors.

4.110.1 Scope

This section describes DICOM Storage requests of Structured Report objects containing DICOM Radiopharmaceutical Radiation Dose SR object (RRDSR) objects which detail radiopharmaceutical administration events. A Radiopharmaceutical Activity Supplier sends DICOM RRDSR objects to an Image Manager/Archive for storage so they can be later used for monitoring or analysis of patient radiation exposure.

4.110.2 Use Case Roles



Actor: Radiopharmaceutical Activity Supplier.

Role: Generate DICOM RRDSR objects describing irradiation events performed by the Radiopharmaceutical Activity Supplier and store them to one or more receiving actors.

Actor: Image Manager/Archive.

Role: Accept and Store DICOM RRDSR objects received from the Radiopharmaceutical Activity Supplier.

Actor: Dose Information Consumer.

Role: Accept and process DICOM RRDSR objects received from the Radiopharmaceutical Activity Supplier.

Actor: Dose Information Reporter.

Role: Accept and process ~~Dose~~ DICOM RRDSR objects received from the Radiopharmaceutical Activity Supplier.

4.110.3 Referenced Standard

DICOM PS 3.3: A.35.14 Radiopharmaceutical Dose SR IOD

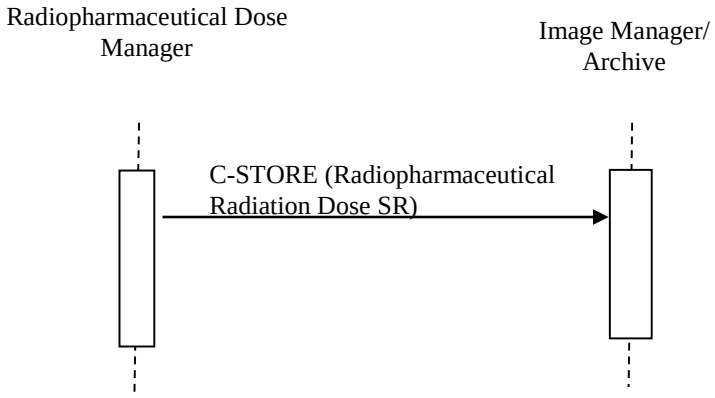
DICOM PS 3.4: Storage Service Class

DICOM PS 3.4: Structured Reporting Storage SOP Classes

DICOM PS 3.16: Radiopharmaceutical Dose SR IOD Templates

DICOM PS 3.17: Annex OOO: Radiopharmaceutical Radiation Dose Structured Report (Informative)

4.110.4 Interaction Diagram



Note: In the above diagram, the Dose Information Consumer and the Dose Information Reporter may also receive the C-STORE message.

4.110.4.1 Store Radiopharmaceutical Dose Information

The Radiopharmaceutical Activity Supplier shall implement the Radiopharmaceutical Radiation Dose SR Storage SOP Class in the role of SCU. The Image Manager/Archive, Dose Information Reporter and Dose Information Consumer shall implement the Dose Storage SOP Class in the role of SCP.

Table 4.110.4.1-1: Radiopharmaceutical Dose Storage SOP Classes

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.88.68	Radiopharmaceutical Radiation Dose SR

4.110.4.1.1 Trigger Events

A radiopharmaceutical administration is one radioactive pharmaceutical administered to a patient.

A Radiopharmaceutical Activity Supplier shall record the relevant details for each radiopharmaceutical administration event. These details will be included in Radiopharmaceutical Radiation Dose Structured Reports as described below.

The Radiopharmaceutical Activity Supplier shall compose an appropriate DICOM RRDSR Object containing the radiopharmaceutical administration event and send the DICOM RRDSR object to the configured destinations.

When two or more radiopharmaceuticals are administered, each constitutes a separate administration event, and corresponds to a separate RRDSR.

4.110.4.1.2 Message Semantics

The Radiopharmaceutical Activity Supplier Actor shall use the DICOM C-STORE message to send DICOM RRDSR objects encoded as DICOM SR objects. These objects serve as a record of irradiation performed by the device.

The Radiopharmaceutical Activity Supplier shall be capable of sending the Dose object to multiple destinations. The primary storage destination is generally an Image Manager/Archive. However, Dose Information Reporters or Dose Information Consumers may also appear as configured destinations when they need to receive timely DICOM RRDSR objects without having to repeatedly poll the Image Manager/Archive.

The Radiopharmaceutical Activity Supplier is responsible for delivery of DICOM RRDSR objects to the destination in spite of intermittent connections (e.g., due to mobile modalities, network trouble, or the destination being down).

Radiopharmaceutical Activity Suppliers which report on radiopharmaceutical administration events shall be capable of producing an SR compliant with TID 10021.

The Radiopharmaceutical Administration Event UID in the template allows receiving systems to recognize duplicate events.

The Synchronization Module shall be included in the RRDSR.

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Table 4.110.4.1.2-1 describes how some attributes in the RRDSR shall be populated by the Radiopharmaceutical Activity Supplier:

Table 4.110.4.1.2-1: Radiopharmaceutical Administration Dose Context Attributes

Attribute Name	Tag	Requirement
Series Description	(0008,103E)	Shall have a value in the appropriate language for local use that means the equivalent of "Radiation Dose Information", or similar.
Referenced Performed Procedure Step Sequence	(0008,1111)	Shall be empty.
Performed Procedure Code Sequence	(0040,A372)	Shall be copied from the Requested Procedure Code Sequence in the Modality Worklist, unless the procedure is changed, in which case this shall be empty.
Referenced Request Sequence (0040,A370) >Requested Procedure Description	(0032,1060)	Shall be copied from the relevant acquisition Modality Worklist entry
Admitting Diagnoses Description	(0008,1080)	Shall be copied from the relevant acquisition Modality Worklist entry. This can facilitate checking compliance to indication-based dose policies.
Admitting Diagnoses Code Sequence	(0008,1084)	
Referenced Request Sequence (0040,A370) >Reason for the Requested Procedure	(0040,1002)	
Referenced Request Sequence (0040,A370) >Reason for Requested Procedure Code Sequence	(0040,100A)	
Patient's Weight	(0010,1030)	Shall be populated with a value that is not zero. May be copied from the relevant acquisition Modality Worklist entry, if present, only if it is not provided by the Radiopharmaceutical Activity Supplier (e.g., via operator entry). The intent is to use the most recent date, though the date of the weight measurement is not provided by the Worklist entry.
Patient's Size	(0010,1020)	I.e., height. Shall be populated with a value that is not zero. May be copied from the relevant acquisition Modality Worklist entry, if present, only if it is not provided by the Radiopharmaceutical Activity Supplier (e.g., via operator entry).
Patient's Age	(0010,1010)	Shall be present. May be filled from any valid source (e.g., computed from Patient's Birthdate and Study Date, copied from the relevant

Attribute Name	Tag	Requirement
		acquisition Modality Worklist entry, if present, only if it is not provided by the Radiopharmaceutical Activity Supplier (e.g., via operator entry).
Patient's Sex	(0010,0040)	Shall be present. May be copied from the relevant acquisition Modality Worklist entry, if present, only if it is not provided by the Radiopharmaceutical Activity Supplier via operator entry.

4.110.4.1.2.1 Cross-referencing DICOM RRDSR Objects and Image Objects

See RAD TF-2: 4.8.4.1.2.4, which requires Acquisition Modalities to record the Radiopharmaceutical Administration Event UID (0008,3012) in related image instances.

The Radiopharmaceutical Radiation Dose Template (TID 10021) does not include references to images since the instances sent to the Image Manager/Archive are typically generated some time after the irradiation is complete.

Note that it is possible for a study to have DICOM RRDSR objects but no image objects. For example, a radioactive iodine uptake test, or thyroid uptake test, involves administration of radioactive iodine but does not include an imaging step (i.e., no acquisition modality).

4.110.4.1.3 Expected Actions

The Image Manager/Archive shall support Level 2 (Full) storage, which means all DICOM Type 1, 2 and 3 attributes (public and private) are stored. It shall accept the DICOM RRDSR objects, store them, and make them available for query/retrieval.

The Dose Information Reporter and Dose Information Consumer shall accept the DICOM RRDSR objects. The DICOM RRDSR objects shall be processed according to the features, configuration, and business logic of the Dose Information Reporter or Dose Information Consumer product. Possibilities include display, processing, analysis, printing, export, etc. At a minimum, the Dose Information Reporter shall provide the capability to the review and do summary analysis of the dose data.

Dose Information Reporter Actors shall be capable of processing TID 10021.

When multiple DICOM RRDSR objects are received, the same Radiopharmaceutical Administration Event (as identified by its Radiopharmaceutical Administration Event UID) may be referenced in multiple DICOM RRDSR objects. It is the responsibility of the recipient to recognize such duplicate Radiopharmaceutical Administration Events when processing or generating reports based on the retrieved data.

Modify the RAD-5 transaction to add the RAS Actor as follows:

4.5 Query Modality Worklist

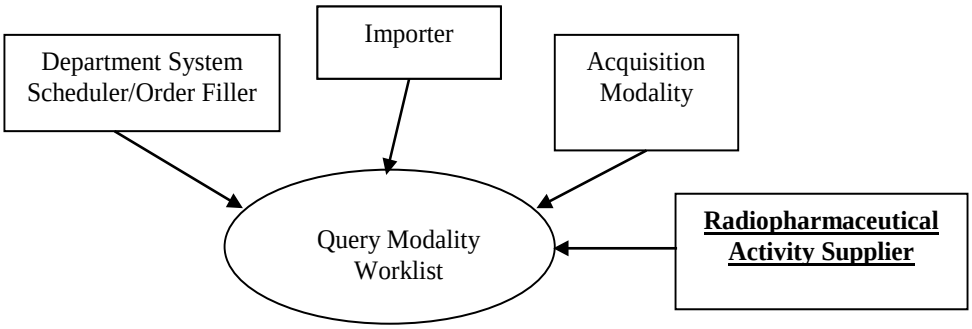
This section corresponds to Transaction RAD-5 of the IHE Technical Framework. ~~**Transaction RAD-5 is used by the Department System Scheduler/Order Filler and worklist clients such as Acquisition Modalities, and Importers**~~.

4.5.1 Scope

This transaction takes place under two circumstances. The first is for the scheduling of an acquisition, the second is for the scheduling of an importation of existing Evidence Objects or Hardcopy. This transaction takes place at the Acquisition Modality at the point of scan/acquisition**, or at the Radiopharmaceutical Activity Supplier (RAS) at the point of radiopharmaceutical administration,** by a technologist. When a patient arrives for the scheduled procedure, the technologist performing the procedure must examine key information elements as they relate to the procedure, the correctness of the procedure that has been ordered, and comments that may have been entered by the referring physician and/or radiologist, among others. The technologist at the Acquisition Modality **or RAS** uses the DICOM Modality Worklist to query the Department System Scheduler/Order Filler for Scheduled Procedure Steps. The list is downloaded to the Acquisition Modality **or RAS** and the technologist verifies the information on the Acquisition Modality **or RAS** console. In the Modality Images Stored transaction this information will be included in the header of the generated images (see Section 4.8 and Appendix A).

An importation may occur with existing DICOM Objects or the creation of DICOM Objects as part of the importation (e.g., the digitization of films into DICOM Objects). The actual scheduling of the importation may vary. For example, the importation may be scheduled as part of an externally referred acquisition, or upon the receipt of a physical PDI media containing patient images required for an upcoming consultation. The User at the Importer uses the DICOM Modality Worklist to query the Department System Scheduler/Order Filler for Scheduled Procedure Steps. The User must be able to verify that Evidence Objects or the Hardcopy data to be imported as DICOM Composite Objects are for the correct Patient and Scheduled Procedure Step. In the Imported Objects Stored transaction this information will be included in the header of the imported Evidence Documents (see RAD TF-3: 4.61. and Appendix A.5).

4.5.2 Use Case Roles



Actor: Acquisition Modality

Role: Responsible for requesting and receiving data from the Department System Scheduler/Order Filler.

Actor: Importer

Role: Responsible for requesting and receiving data from the Department System Scheduler/Order Filler.

Actor: Department System Scheduler/Order Filler

Role: Responsible for accepting requests for MWL from an acquisition modality, performing the query, and sending the response back.

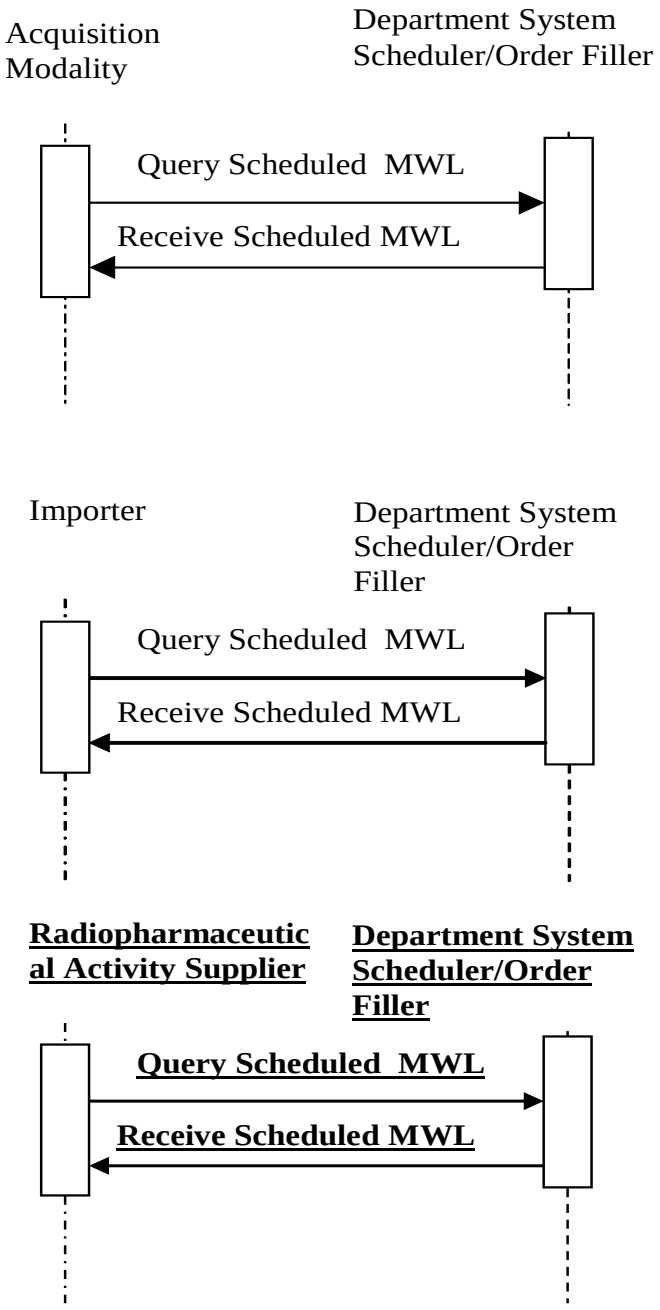
Actor: Radiopharmaceutical Activity Supplier

Role: Responsible for requesting and receiving data from the Department System Scheduler/Order Filler.

4.5.3 Referenced Standards

DICOM ~~**2011**~~ PS 3.4: Modality Worklist SOP Class

4.5.4 Interaction Diagram



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4.5.4.1 Query Scheduled MWL Message

This is the worklist query message sent to the Department System Scheduler/Order Filler.

4.5.4.1.1 Trigger Events

The patient arrives at the Acquisition Modality **or RAS** for a procedure (scan/acquisition).

The trigger event for an importation is a User that wants to perform a scheduled importation. The actual trigger for scheduling the importation is site specific, but may be triggered by such events as:

- Arrival of films as a result of a request for a scheduled consult.
- Patient with a scheduled procedure brings prior Evidence Objects on a PDI Media.
- Other communications not specified further by the IHE Technical Framework which result in the scheduling of an import.

4.5.4.1.2 Message Semantics

The Acquisition Modality**,** ~~**or**~~ Importer **or RAS** uses the C-FIND Request of the DICOM Modality Worklist SOP Class to query for the worklist from the DSS/Order Filler. The Acquisition Modality**, or** Importer **or RAS** performs the SCU role, and the DSS/Order Filler the SCP role.

Acquisition Modalities**,** ~~**and**~~ Importers **and RAS's** shall support individually each one of the required query keys listed in Table 4.5-3 - Matching and Return Keys For Modality Worklist. For Importers, Patient Based Query shall be supported. For Acquisition Modalities, at least one of the ~~**following two combinations of**~~ **Patient Based Query or Broad Query** ~~**keys**~~ shall be supported ~~**by the Acquisition Modality**~~:

1. **The Patient Based Query:** Query for a worklist specific for a particular patient. The SCU shall support all (15) combinations of the matching key attributes listed in Table 4.5-1 by including 1 or more keys.

Table 4.5-1: MWL Keys for Query by Patient

Matching Key Attributes	Tag
Patient's Name	(0010,0010)
Patient ID	(0010,0020)
Accession Number	(0008,0050)
Requested Procedure ID	(0040,1001)

2. The Broad Query: Query for a broad worklist. The SCU shall support all (7) combinations of the matching key attributes listed in Table 4.5-2 by including 1 or more keys.

Table 4.5-2: MWL Keys for Broad Worklist Queries

Matching Key Attributes	Tag
Scheduled Procedure Step Start Date	(0040,0002)

Matching Key Attributes	Tag
Modality	(0008,0060)
Scheduled Station AE-Title	(0040,0001)

3. The Radiopharmaceutical Activity Supplier Query: Query for worklist items related to radiopharmaceutical administration. The SCU shall support all (3) combinations of the matching key attributes listed in Table 4.5-2b by including 1 or more keys.

Table 4.5-2b: MWL Keys for Radiopharmaceutical Activity Supplier Worklist Queries

Matching Key Attributes	Tag
Scheduled Procedure Step Start Date	(0040,0002)
Modality	(0008,0060)

4.5.4.1.2.1 Examples for the Use of Matching Key Attributes

- Using the Scheduled Procedure Step Start Date: query for all the procedures in my department that are scheduled for the start date specified.
- Using the Modality key: query for all the procedures that are scheduled on this type of modality (e.g., all CT exams).
- Using AE Title key: query for all the procedures that are scheduled on the modality with the specified AE Title.
- Using the Scheduled Procedure Step Start Date and Modality keys: query for all the CT procedures that are scheduled for today.
- Using the Patient Name, Patient Birth Date and Patient Sex query for all the procedures that are scheduled for a patient.
- Using the Patient Name and AE Title query for all procedures to be imported for a Patient.

Note: DICOM defines that dates and times are matched by their meaning, not as literal strings. If an application is concerned about how a single value matching of dates and times is performed by another application, it may consider using range matching instead (e.g., "<today>-<today>"), which is always performed by meaning.

Note: Applications are recommended to append a wildcard "*", if one was not previously entered by the user, at the end of each component of the structured Patient Name.

4.5.4.1.2.2 Matching Keys and Return Keys

The Modality is required to query for specific attributes (return keys) that will be inserted into the image objects. The requirements for the attributes in the stored images are defined in Section 4.8 and Appendix A. There are additional attributes that may be queried for use on the

Acquisition Modality (e.g., displayed for the user) but might not be inserted into the composite image object.

The Radiopharmaceutical Activity Supplier is required to query for specific attributes (return keys) that will be inserted into RRDSR objects. The requirements for the attributes in the stored Dose Reports are defined in RAD TF-3: 4.110.

Table 4.5-3 summarizes the matching key requirements and lists the optional and required attributes that may be requested by the SCU and shall be returned by the SCP in order to make these available to the user at the Acquisition Modality **or RAS**. Requirements indicated with R+ or R+* highlight the requirements added by the IHE Technical Framework. See Section 2.2 for more information. All display requirements are an addition to the DICOM Standard requirements for the Modality Worklist SOP Class.

The Importer is required to query for specified attributes (return keys) that will be used to modify the imported objects. The attribute modification requirements are defined in RAD TF-3: 4.61.4.1.2.1 and Appendix A.5.

Table 4.5-3: Return and Matching Keys for Modality Worklist

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
Scheduled Procedure Step					
Scheduled Procedure Step Sequence	(0040,0100)			[IHE-1]	[IHE-2]
>Scheduled Station AE Title	(0040,0001)	R+	R	R+*	R
>Scheduled Procedure Step Start Date	(0040,0002)	R+	R	R+	R
>Scheduled Procedure Step Start Time	(0040,0003)	O	R	R+	R
> Scheduled Procedure Step Location	(0040,0011)	O	O	O	O
>Modality	(0008,0060)	R+	R	R+	R
>Scheduled Performing Physician's Name	(0040,0006)	O	R	O	R
>Scheduled Procedure Step ID	(0040,0009)	O	O	R+*	R
>Scheduled Protocol Code Sequence	(0040,0008)				
>>Code Value	(0008,0100)	O	O	R+*	R
>>Coding Scheme Version	(0008,0103)	O	O	O	O
>>Coding Scheme Designator	(0008,0102)	O	O	R+*	R
>>Code Meaning	(0008,0104)	O	O	R+	R+
>Scheduled Procedure Step Description	(0040,0007)	O	O	R+	R
Requested Procedure					
Requested Procedure Comments	(0040,1400)	O	O	O	O

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
Requested Procedure Description	(0032,1060)	O	O	R+	R
Requested Procedure Code Sequence	(0032,1064)				
>Code Value	(0008,0100)	O	O	R+*	R
>Coding Scheme Version	(0008,0103)	O	O	O	O
>Coding Scheme Designator	(0008,0102)	O	O	R+*	R
>Code Meaning	(0008,0104)	O	O	R+	R+
Requested Procedure ID	(0040,1001)	R+ (Note 1)	R+ (Note 1)	R+	R
Reason for the Requested Procedure [IHE-4]	**(0040,1002)**	**O**	**O**	**R+***	**R+**
Reason for Requested Procedure Code Sequence [IHE-4]	**(0040,100A)**	**O**	**O**	**R+***	**R+**
>Code Value	**(0008,0100)**	**O**	**O**	**R+***	**R+**
>Coding Scheme Version	**(0008,0103)**	**O**	**O**	**O**	**O**
>Coding Scheme Designator	**(0008,0102)**	**O**	**O**	**R+***	**R+**
>Code Meaning	**(0008,0104)**	**O**	**O**	**R+***	**R+**
Names of Intended recipients of results	(0040,1010)	O	O	O	O
Study Instance UID	(0020,000D)	O	O	R+*	R
Referenced Study Sequence **[IHE-3]**	(0008,1110)				
>Referenced SOP Class UID	(0008,1150)	O	O	R+*	R
>Referenced SOP Instance UID	(0008,1155)	O	O	R+*	R
Imaging Service Request					
Imaging Service Request Comments	(0040,2400)	O	O	O	O
Accession Number	(0008,0050)	R+ (Note 1)	R+ (Note 1)	R+	R+ [IHE-3]
Requesting Physician	(0032,1032)	O	O	O	R
Requesting Service	(0032,1033)	O	O	O	O
Referring Physician's Name	(0008,0090)	O	O	R+	R
Visit Identification					
Admission ID	(0038,00100	O	O	O	R
Visit Status					
Current Patient Location	(0038,0300)	O	O	O	R
Visit Relationship					
Referenced Patient Sequence	(0008,1120)				
>Referenced SOP Class UID	(0008,1150)	O	O	O	R
>Referenced SOP Instance UID	(0008,1155)	O	O	O	R

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
Patient Identification					
Patient's Name	(0010,0010)	R+	R	R+	R
Patient ID	(0010,0020)	R+	R	R+	R
Other Patient ID's	(0010,1000)	O	O	O	O
Patient Demographic					
Patients Birth Date	(0010,0030)	O	O	R+	R
Patient's Sex	(0010,0040)	O	O	R+	R
Confidentiality constraint on patient data	(0040,3001)	O	O	O	R
Ethnic Group	(0010,2160)	O	O	O	O
Patient Comment	(0010,4000)	O	O	O	O
Patient Medical					
Patient State	(0038,0500)	O	O	O	R
Pregnancy Status	(0010,21C0)	O	O	O	R
Medical Alerts	(0010,2000)	O	O	O	R
Additional Patient History	(0010,21B0)	O	O	O	O
Contrast Allergies	(0010,2110)	O	O	O	R
Patient's Age [IHE-4]	**(0010,1010)**	**O**	**O**	**R+***	**R+**
Patient Size [IHE-4]	**(0010,1020)**	**O**	**O**	**R+***	**R+**
Patient Weight	(0010,1030)	O	O	O	R
Special Needs	(0038,0050)	O	O	O	R
Admitting Diagnosis [IHE-4]	**(0008,1080)**	**O**	**O**	**R+***	**R+**
Admitting Diagnosis Code Sequence [IHE-4]	**(0008,1084)**	**O**	**O**	**R+***	**R+**
>Code Value	**(0008,0100)**	**O**	**O**	**R+***	**R+**
>Coding Scheme Version	**(0008,0103)**	**O**	**O**	**O**	**O**
>Coding Scheme Designator	**(0008,0102)**	**O**	**O**	**R+***	**R+**
>Code Meaning	**(0008,0104)**	**O**	**O**	**R+***	**R+**

Note 1: The matching performed by the SCP for the Requested Procedure ID and Accession Number attributes shall be single value (SV) matching.

(IHE-1): SCU implementations may choose to obtain the values contained in attributes that are part of the Scheduled Procedure Step sequence in either one of three ways. The first one is to request a universal match on the sequence attribute (zero length attribute). The second one is a universal sequence match (zero length item) for all attributes of the Scheduled Procedure Step sequence. The third one is to request a universal attribute match for selected attributes contained in the Scheduled Procedure Step sequence.

(IHE-2): SCP implementations shall support, per the DICOM Standard, three ways to let the Query SCU obtain the values contained in attributes that are part of the Scheduled Procedure

Step sequence. The first one is to support a universal match on the sequence attribute (zero length attribute), and all managed attributes will be returned. The second one is to support a universal sequence match (zero length item) for all attributes of the Scheduled Procedure Step sequence, and all managed attributes will be returned. The third one is to support a universal attribute match for selected attributes contained in the Scheduled Procedure Step sequence, and the managed attributes that were selected will be returned.

(IHE-3): A value (Non empty field) shall be returned in the Accession Number attribute if the field was requested by the MWL SCU.

(IHE-4): The requirements for the Query Return Key for this attribute apply to SCU and SCP implementations of actors in the REM-NM Profile; see RAD TF-2:4.8.4.1.2.5 and RAD TF-3:4.1.2.1 for requirements on mapping values returned in the worklist into images and RRDSR objects. For actors in all other profiles, the optionality is "O".

4.5.4.1.3 Expected Actions

The Departmental System Schedule/Order Filler performs the query and sends the DICOM Modality Worklist to the Acquisition Modality**,** ~~**or**~~ Importer **or RAS**.

The Importer shall make available to the Operator the information in the Scheduled Procedure Step Description (see Table 4.5-3). This information may include:

- A description of specific Evidence Objects to import (e.g., only a particular study, series or image should be imported).

4.5.4.2 Receive Scheduled MWL Message

This is the message that the Department System Scheduler sends to the modality as a reply containing DICOM Modality Worklist information.

4.5.4.2.1 Trigger Events

The Departmental System Scheduler/Order Filler had received a query for a MWL.

4.5.4.2.2 Message Semantics

C-FIND Response from the DICOM Modality Worklist SOP Class will be used for this message. Some of the attributes queried through the MWL SOP class originate with the Order Placer and ADT, while other attributes are managed internally by the Department System Scheduler/Order Filler.

The DSS/Order Filler will determine the Requested Procedures needed to fulfill the Order, and decompose the Requested Procedures into one or more Scheduled Procedure Steps, assigning proper Scheduled Protocol Codes. The DSS/Order Filler shall support the definition of multiple Protocol Codes in a Scheduled Protocol Code Sequence contained in the Scheduled Procedure Steps for any Requested Procedure. Coded Values shall be used to specify exactly what actions are to be performed at the Acquisition Modality - the DSS/OF shall be configurable to provide such codes.

In addition to these Coded Values further instructions for the technologist may be specified. It is recommended to use the Scheduled Procedure Step Description and the Requested Procedure Description attributes for these additional specific instructions (free text).

The organization operating the DSS/OF and the Modalities is responsible for synchronizing Procedure and Protocol Codes between all the systems that use such codes. IHE does not yet define a common mechanism for code synchronization or access.

Appendix B defines the origin and mappings of the attributes returned in a MWL query.

The details of the C-FIND Response from the DICOM MWL SOP Class are depicted in Table 4.5-3 and ~~a~~**A**ppendix A. At the time images are being created/generated, these attributes will be stored into the DICOM image instance headers. The Acquisition Modality or Importer may need additional information; however this is beyond the scope of this document. Refer to RAD TF-1, Appendix A for a discussion of Accession Number and Procedure ID.

An Order may be cancelled after the corresponding Requested Procedure(s) and Scheduled Procedure Steps have been scheduled, and possibly even after a Performed Procedure Step has been started. In this case the Department System Scheduler/Order Filler shall remove the Scheduled Procedure Steps of the Order from its worklist, and the absence of these Scheduled Procedure Steps in the next C-FIND response to the Acquisition Modality or Importer will indicate that the procedure has been cancelled. In this way the technologist recognizes that the previously scheduled steps no longer need to be performed.

It is the responsibility of the Department System Scheduler/Order Filler to ensure that the patient and procedure information is current in the Modality Worklist response. The Department System Scheduler/Order Filler receives patient and procedure updates through Transactions RAD-2, RAD-3 and RAD-12.

4.5.4.2.2.1 Scheduled Protocol Sequence for Import

The Department System Scheduler/Order Filler has the ability to provide instructions to the Importer on what should be done with the imported Evidence Objects after they are imported through the use of the Scheduled Protocol Sequence (0040,0008). Zero or more items may be present. Table 4.5-4 provides a list of the valid codes that may be used.

If present the codes are intended to be made available for copying into the Performed Protocol Sequence (0040.0260) in order to convey the subsequent use of the instances.

Table 4.5-4: Import Instruction Codes

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
IHERADTF	IRWF001	Import
IHERADTF	IRWF002	To be interpreted
IHERADTF	IRWF003	To be archived
IHERADTF	IRWF004	To be over read

Coding Scheme Designator (0008,0102)	Code Value (0008,0100)	Code Meaning (0008,0104)
IHERADTF	IRWF005	To be post-processed
IHERADTF	IRWF006	To be printed
IHERADTF	IRWF007	To be provided as a prior
IHERADTF	IRWF008	Destroy original media
IHERADTF	IRWF009	Return original media to patient
IHERADTF	IRWF010	Return original media to sender
IHERADTF	IRWF011	Archive original media

4.5.4.2.3 Expected Actions

The technologist checks for the existence of the Scheduled Procedure Steps, validates the displayed patient and procedure information, and checks the given instructions.

When an Acquisition Modality supports the ASSISTED ACQUISITION PROTOCOL SETTING Option**,** it shall provide the means to use the protocol codes specified in the Scheduled Procedure Steps selected from the Modality Worklist (**S**see **s**Section 4.6.4.1.2.4.2 Assisted Acquisition Protocols Setting Option).

For imports, the User checks for the existence of the Scheduled Procedure Steps, validates the selected Patient Demographics with the Patient demographics of the existing Evidence Objects or the hardcopy, and checks for special instructions given in the Scheduled Procedure Step Description on what Evidence Objects are to be imported (e.g., how many PDI Media or films are associated with the Scheduled Procedure Step). In addition, the Importer shall provide the means to use the protocol codes specified in the Scheduled Procedure Step selected from the Modality Worklist (see RAD TF-3: 4.59.4.1.2.3.3 Import Instruction Codes).

Modify the following sections

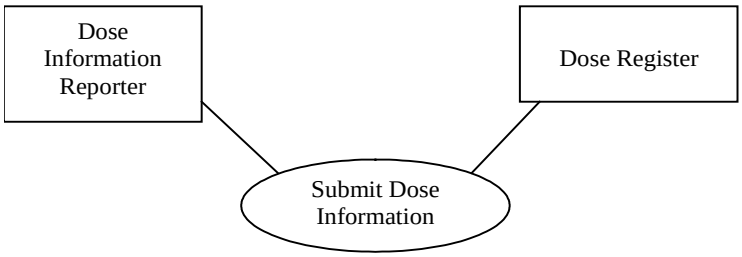
4.63 Submit Dose Information

This section corresponds to Transaction RAD-63 of the IHE Technical Framework. Transaction RAD-63 is used by the Dose Information Reporter and Dose Registry Actors.

4.63.1 Scope

This section describes secure FTP transfers of DICOM Structured Report objects which detail irradiation events. A Dose Information Reporter sends Dose objects to a Dose Registry for subsequent compilation, monitoring and analysis of population and individual radiation exposure and current practices. Dose objects will often be de-identified prior to submission for the population use case.

4.63.2 Use Case Roles



Actor: Dose Information Reporter

Role: Submit (de-identified) Dose objects describing irradiation events performed by Acquisition Modalities **or Radiopharmaceutical Activity Suppliers** in its facility.

Actor: Dose Registry

Role: Accept and store Dose objects received from Dose Information Reporters.

4.63.3 Referenced Standard

DICOM PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

DICOM PS 3.3: A.35.14 Radiopharmaceutical Dose SR IOD

DICOM PS 3.10: Media Storage and File Format

DICOM PS 3.16: X-Ray Radiation Dose SR IOD Templates

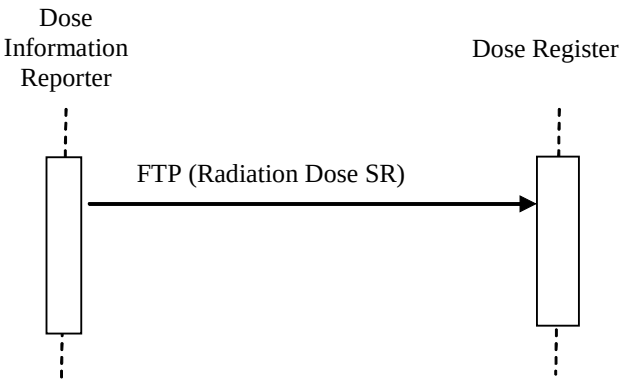
DICOM PS 3.16: CT Radiation Dose SR IOD Templates

DICOM PS 3.16: Radiopharmaceutical Dose SR IOD Templates

DICOM PS 3.17: Annex OOO: Radiopharmaceutical Radiation Dose Structured Report (Informative)

IETF RFC-4217 Securing FTP with TLS

4.63.4 Interaction Diagram



4.63.4.1 Submit Dose Information

4.63.4.1.1 Trigger Events

A Dose Information Reporter shall be capable of periodically submitting Dose objects accumulated since the last submission.

The Dose Information Reporter shall support submitting at a configurable interval, or upon a manual trigger, or both.

Local site policy and preferences will dictate whether periodic submissions take place, at what frequency, whether the Dose objects are first de-identified, and which Dose objects are submitted (e.g., the site might submit a random sample, or just reports for certain types of procedures, etc.)

4.63.4.1.2 Message Semantics

Except for de-identification, the Dose objects submitted by the Dose Information Reporter will generally be copies of reports received via the Store Dose Information or Retrieve Dose Information transactions.

The Dose Information Reporter shall ensure that the attributes described **either** in RAD-62 in Table 4.62-2 Dose Context Attributes**, or in RAD-110 in Table 4.110.4.1.2-1 Radiopharmaceutical Administration Dose Context Attributes,** are populated (i.e., not empty and not zero or some other dummy value), even if this requires a quality control step with additional manual data entry by an operator.

It may also be desirable to send the localizer images to the registry, since size estimates can be produced from these by image processing or manual measurement. An individual registry might require this, so a Dose Information Reporter may have the capability to obtain and include images with a Modality of CT and an Image Type (0008,0008) value 3 of LOCALIZER (for either non-enhanced and enhanced SOP classes).

The Dose Information Reporter shall initiate a (Secure) FTP (File Transfer Protocol) session as a client as specified by IETF RFC-4217 “Securing FTP with TLS”.

When initiating the FTP session, the Dose Information Reporter:

1. Shall use the "firewall-friendly" connection method
2. Shall negotiate TLS first, before any other FTP commands
3. Shall require a protection level of "Private" (i.e., the connection shall fail if a level of “Private” is not successfully negotiated)
4. Shall support AES, although it is acceptable for an alternative encryption to be dynamically negotiated as part of TLS.
5. Shall support and accept certificate authentication. User authentication shall not be required.
6. Shall support X.509 based certificates.
7. Shall disconnect when TLS fails.

Note: Certificate Management by the Dose Information Reporter and the Dose Registry is outside the scope of the REM **and REM-NM** Profile. Dose Registries may find it convenient to make their public certificate available on their web server. Hospitals with Dose Information Reporters might have their public certificate available in a file they could email to the Dose Registry administrator when joining such a project. A detailed discussion of certificate management can be found in the “Management of Machine Authentication Certificates” Whitepaper developed by the NEMA Security and Privacy Committee, available on the NEMA Website at http://www.medicalimaging.org/wp-content/uploads/2011/02/CertificateManagement-2007-05-Published.pdf

The Dose Registry shall be capable of accepting a secure FTP session as documented above.

The Dose Registry may require the Dose Information Reporter to identify itself (for audit purposes) by providing a descriptive string either in the USER login (with no password) or in the PASS of an anonymous USER login. The Dose Information Reporter shall support configuring such details.

The Dose Information Reporter shall use the FTP session to submit Dose objects encoded in DICOM SR and formatted as DICOM Part 10 media files with a Transfer Syntax of Explicit VR Little Endian.

The Dose objects may be transferred as either:

- individual files, or
- composed into Zip File Media as described in DICOM PS 3.12 Annex V.

DICOM Zip File Media requires a valid DICOMDIR be present.

The Dose Information Reporter shall be capable of sending the Dose objects to multiple configured destinations.

The Dose Information Reporter is responsible for delivery of Dose objects in spite of intermittent connections (network trouble, or the destination system being down).

4.63.4.1.2.1 De-identification

The Dose Information Reporter shall be capable of de-identifying Dose objects before submitting them.

There is considerable variation in what attributes need to be removed to achieve sufficient de-identification for any particular purpose. See the discussion in RAD TF-3: Appendix I and DICOM PS 3.15 Annex E.

Accordingly, this transaction does not require the removal of all text attribute values, nor the removal of all private attribute values.

The Dose Information Reporter may provide a mechanism to allow the user to configure those attributes that will be removed or replaced. At minimum the Dose Information Reporter shall support the ability to configure removal and replacement of all those attributes listed in the Basic Application Level Confidentiality Profile in DICOM PS 3.15. It shall be configurable to use:

- the Retain Longitudinal Option
- Retain Patient Characteristics Option
- Retain Device Information Option
- Retain UIDs Option

This configurability is particularly important since details such as patient sex, approximate age and weight, anatomy imaged and type of procedure are typically part of population dose analysis and such analysis would be severely limited without the ability to leave such information in submitted data. If the value in the Patient Birth Date (0010,0030) is removed from a Dose object during de-identification, then the Patient Age (0010,1010) attribute shall be included with an appropriate value.

When de-identification has been performed, the Dose Information Reporter shall add to the DICOM dataset of each instance the Patient Identity Removed (0012,0062) attribute with a value of YES, and add a value for De-identification Method (0012,0063) or De-identification Method Code Sequence (0012,0064).

The Dose Information Reporter shall be configurable to perform no de-identification at all.

In some scenarios, it may be appropriate to perform no de-identification, such as when the Dose Registry is doing a longitudinal study for specific patients (and necessary consents and/or privacy agreements have been taken care of). In such cases, if the Patient Identity Removed (0012,0062) attribute is present in the dataset it shall not be changed before submitting the dataset; if the attribute is absent it shall be added with a value of NO.

The Dose Information Reporter shall be capable of different de-identification configuration settings for each submission destination.

In some de-identification scenarios, the UIDs might need to be replaced. This transaction does not require that the Dose Information Reporter have the ability to replace UIDs, but if UIDs are replaced, internal consistency within the exported set of instances and across multiple exports over time shall be maintained. This entails adherence to the following rules:

- The same replacement UID is used for all composite instances of the same entity within the set, e.g., if the Study Instance UID is replaced, it is replaced with the same value in all dose objects within the same original study.
- References by UID to other instances or entities within the set are updated, e.g., references to the SOP Instance UIDs of predecessor documents, reference images and source images.
- References by UID to other instances or entities not included within the set are removed or replaced with consistent, well-formed, dummy references.

If the same instances are exported multiple times on different occasions, the identifying attributes and UIDs therein shall be replaced with the same values on each occasion. That is, this transaction requires deterministic behavior for replacement of identifying attributes and UIDs. This assures that the receiving Dose Registry can detect duplicate submissions and not accumulate the same dose multiple times. The safest way to assure detection of duplicate submissions from a single or multiple sites is not to replace the UIDs in the first place, but local regulations or policy may not permit this.

The Dose Information Reporter performing de-identification shall not create invalid IODs. Specifically:

- Mandatory and conditional attributes may not be removed, but rather must be replaced.
- Type 1 attributes must be given a value.
- Type 2 attributes may be encoded zero length, but it is often advisable to encode a value, especially for attributes likely to be used in browsers such as Patient Name, Patient ID, Study ID and Accession Number.
- UIDs shall have valid roots and be genuinely globally unique.

The Dose Information Reporter is not required to be able to pseudonymize Dose objects. For a description of pseudonymization, see RAD TF-3: 4.51.4.1.4.

4.63.4.1.3 Expected Actions

The Dose Registry shall accept the received Dose objects. What it does with the Dose objects will depend on the features, configuration, and business logic of the product. Some details of several Dose Registry projects are discussed in RAD TF-1: Appendix I – Deployment of Dose Registries.

Although the Dose Information Reporter may keep track of which Dose objects have been previously submitted to avoid duplicates or missing objects, the Dose Registry cannot depend on every object being sent, and should also be prepared to check for duplicates (by checking the Irradiation Event UIDs, though these may have been affected by de-identification during the current and previous submission, particularly if the same information is received multiple times from different Dose Information Reporters).

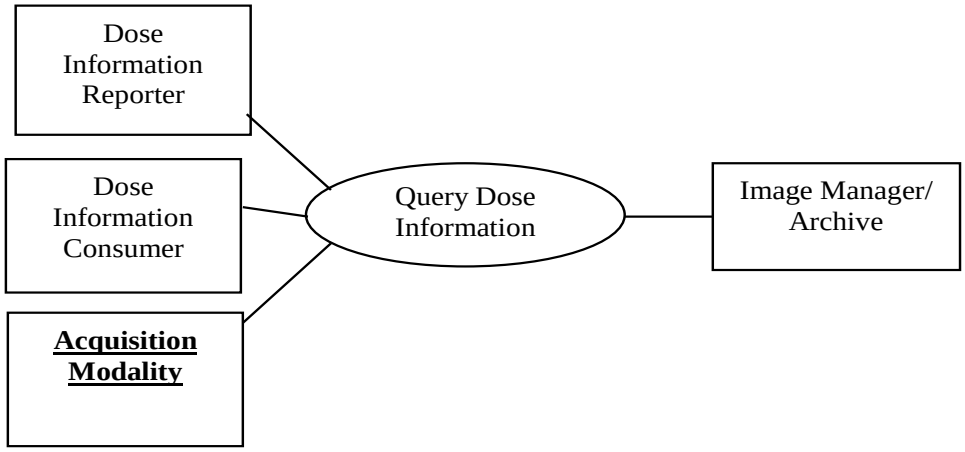
4.64 Query Dose Information

This section corresponds to Transaction RAD-64 of the IHE Technical Framework. Transaction RAD-64 is used by the Dose Information Reporter, Dose Information Consumer**, Acquisition Modality** and Image Manager/Archive Actors.

4.64.1 Scope

A Dose Information Reporter**, ~~or~~** Dose Information Consumer**, or Acquisition Modality** requests and receives from the Image Manager/Archive a list of instance metadata describing Dose objects matching a specified filter.

4.64.2 Use Case Roles



~~Actor: Dose Information Reporter~~

~~Role: Query for a list of Dose objects (generally in order to retrieve them).~~

~~Actor: Dose Information Consumer~~

~~Role: Query for a list of Dose objects (generally in order to retrieve them).~~

~~Actor: Image Manager/Archive~~

~~Role: Respond to queries from Dose Information Reporters and Dose Information Consumers for Dose objects matching the specified filter.~~

Role:	**Requestor:** **Query for a list of Dose objects.**
Actor(s):	**The following actors may play the role of Requestor:** **Dose Information Reporter** **Dose Information Consumer** **Acquisition Modality**

Role:	**Manager:** **Respond to queries for Dose objects matching the specified filter.**
Actor(s):	**The following actors may play the role of Manager:** **Image Manager/Archive**

4.64.3 Referenced Standard

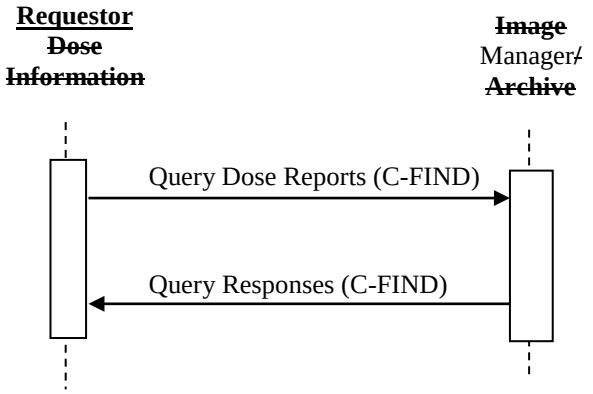
DICOM PS 3.4: Query/Retrieve Service Class

DICOM PS 3.4: Structured Reporting Storage SOP Classes

DICOM PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

DICOM PS 3.3: A.35.14 Radiopharmaceutical Dose SR IOD

4.64.4 Interaction Diagram



~~**Note: In the above diagram, the Dose Information Consumer may also receive and respond to the C-FIND message.**~~

4.64.4.1 Query Dose Information

The Query (Study Root – FIND and optionally Patient Root – FIND) SOP Classes shall be supported. Refer to DICOM PS 3.4: Query/Retrieve Service Class for detailed descriptive semantics.

4.64.4.1.1 Trigger Events

The Dose Information Reporter needs to obtain information about Dose objects.

Often this will be triggered by the Dose Information Reporter preparing to produce reports, preparing to perform analyses or preparing to submit data to a dose registry based on local

policies. Examples of such triggers might include generating a daily report of procedures exceeding Diagnostic Reference Levels for certain procedure types, producing a summary of dose to a particular patient over the past year, or submitting reports for all procedures performed in the past week to a national dose registry.

The Dose Information Consumer needs to obtain information about Dose objects.

Often this will be triggered by the Dose Information Consumer preparing to display or further process the contents of one or more Dose objects. Examples of such triggers might include processing the contents of a dose object together with the generated images in order to produce a dose map. Refer to the Use Cases in RAD TF-1: 22.3 Radiation Exposure Monitoring Process Flow for more details.

The Acquisition Modality needs to obtain administered dose information from a Dose object.

This will be triggered by the modality that will perform the imaging procedure. It will read the Dose object to determine information about the radiopharmaceutical that was administered to the patient for an imaging procedure, including the actual administered dose, and the date and times it was assayed and administered.

4.64.4.1.2 Message Semantics

The message semantics are defined by the DICOM Query/Retrieve SOP Classes.

The ~~**Dose Information Reporter and Dose Information Consumer actors**~~**Requestor** shall implement the Query/Retrieve SOP Classes in the role of SCU. The ~~**Image**~~ Manager~~**/Archive Actor**~~ shall implement the Query/Retrieve SOP Classes in the role of SCP.

A C-FIND Request from the DICOM Study Root Query/Retrieve Information Model – FIND SOP Class or the DICOM Patient Root Query/Retrieve Information Model – FIND SOP Class shall be sent from the ~~**Dose Information Reporter or Dose Information Consumer**~~ **Requestor** to the ~~**Image**~~ Manager~~**/Archive**~~.

The ~~**Dose Information Reporter or Dose Information Consumer**~~ **Requestor** uses one or more matching keys as filter criteria to obtain the list of matching entries in the Image Manager/Archive at the selected level (Patient & Study/Series/Instance).

In addition to the required and unique keys defined by the DICOM Standard, the Dose Report Query SCU and SCP shall support the matching and return keys defined for Study, and Series level queries as defined in RAD TF-2: 4.14.4.1.2 and Table 4.14-1.

The ~~**Dose Information Reporter (SCU), the Dose Information Consumer**~~ **Requestor** (SCU) and the ~~**Image**~~ Manager~~**/Archive**~~ (SCP) shall also support the Dose Report Instance-specific keys defined in Table 4.64-1.

Table 4.64-1: Dose Report Instance Specific Query Matching and Return Keys

Attribute Name	Tag	Query Keys Matching	Query Keys Return

		SCU	SCP	SCU	SCP
Dose Report Instance Specific Level					
SOP Class UID	(0008,0016)	O	R+	O	R+
SOP Instance UID	(0008,0018)	O	R	O	R
Content Date	(0008,0023)	O	O	O	R+
Content Time	(0008,0033)	O	O	O	R+
Referenced Request Sequence	(0040,A370)				
>Study Instance UID	(0020,000D)	O	O	R+*	R+
>Accession Number	(0008,0050)	O	O	R+	R+
>Requested Procedure ID	(0040,1001)	O	O	R+	R+
>Requested Procedure Code Sequence	(0032,1064)				
>>Code Value	(0008,0100)	O	O	O	R+
>>Coding Scheme Designator	(0008,0102)	O	O	O	R+
>>Coding Scheme Version	(0008,0103)	O	O	O	R+
>>Code Meaning	(0008,0104)	O	O	O	R+
Content Template Sequence	(0040,A504)				
>Template Identifier	(0040,DB00)	O	O	R+	R+
Concept Name Code Sequence	(0040,A043)				
>Code Value	(0008,0100)	O	O	R+*	R+
>Coding Scheme Designator	(0008,0102)	O	O	R+*	R+
>Coding Scheme Version	(0008,0103)	O	O	O	R+
>Code Meaning	(0008,0104)	O	O	R+	R+

The requirement conventions for key usage in the above table are defined in RAD TF-2: 2.2.

4.64.4.1.2.1 Filtering Strategies

Since it may not be immediately obvious how to perform certain dose object filtering based on the available matching keys, return keys and object content, some suggestions are provided here.

Filtering can occur at three points. Matching keys allow filtering on the server side; only instances that pass the filter have metadata returned. Return keys allow filtering on the client side; only instances whose metadata passes the filter are subsequently retrieved. Finally object attributes or content tree elements allow further client side filtering; only retrieved instances that pass the filter are processed further.

Client-side filtering of the object attributes and content is the most flexible, but to avoid retrieving an unnecessarily large number of objects, the use of matching and return keys is very helpful.

To filter for Dose objects:

- Matching key - SOP Class UID (0008,0016) allows selection of the X-ray Radiation Dose SR Storage SOP Class **or the Radiopharmaceutical Administration Radiation Dose SR Storage SOP Class**.

To filter for a specific date range:

- Matching key – Study Date (0008,0020) and/or Performed Procedure Step Start Date (0040,0244) allows selection of a particular date or range.

To filter for specific modalities:

- Matching key - Modalities in Study (0008,0061) allows selection of a desired modality (e.g., CT, XA, DR, DX, CR, MX**, NM, PT, SR**)

Note: Some studies might have multiple irradiating modalities so it will still be necessary to confirm the modality in the dose report. Note also that the series level Modality attribute will always be SR for dose reports.

- Return key - Template ID (0040,DB00) allows identification of either CT**,** ~~**or**~~ Projection X-Ray **or Radiopharmaceutical Administration** dose reports. Future dose reports will also be identifiable by new Template ID values, making this a potentially valuable attribute for the Archive to support as a matching key.
- Object Content Tree - Procedure Reported allows differentiation of Mammography from other types of projection x-ray**.**

To filter for specific procedure types:

- Object Attribute - Performed Procedure Code Seq. (0040,A372) is Type 2, but if filled in the Dose object, will contain the acquisition procedures performed, allowing identification of the procedure. Since these are local codes and tend to change, systems will likely need to use a lookup table to map the variety of procedure/anatomy codes to a smaller set for performing analysis and reporting.
- Object Content Tree – Acquisition Protocol, if present, may also help identify the procedure type.

Note: Series Description (0008,103E) is a Type 3 attribute which, if present, in a Dose object will have a value of "Radiation Dose Information".

To filter for specific body regions:

- Object Content Tree – Target Region allows identification of body regions.

Note: Some implementations may provide a very specific region and the filter will want to generalize; other implementations may be unable to identify the exact region and will provide an overly generalized region instead.

- Object Content Tree – Anatomical Structure, if present, may also identify body regions in projection x-ray dose reports.

To filter for patient age category:

- Return key – Patient's Birth Date (0010,0030) allows identification of patients in an age range.
- Return key - Patient's Age (0010,1010) is a Type 3 attribute and an optional return key but may allow identification of some patients in an age range.

To filter for patient weight category:

- Return key - Patient's Weight (0010,1030) is a Type 3 attribute and an optional return key but may allow identification of some patients in a weight range.

To filter for patient sex:

- Return key – Patient's Sex (0010,1040) allows identification of patient's sex (e.g., for monitoring policies relating to women of childbearing age).

4.64.4.1.3 Expected Actions

The **~~Image~~** Manager**~~/Archive~~** receives the C-FIND request, performs the matching on the provided keys and sends the list of matching records back to the **Requestor** **~~Dose Information Reporter or Dose Information Consumer~~** via C-FIND responses.

The **~~Dose Information Reporter or Dose Information Consumer~~** **Requestor** may use the value of certain return keys to identify specific Dose objects for subsequent retrieval. See Section 4.64.4.1.2.1**, or 4.110.4.1.2.1** for details. Some details are only available by first retrieving and then parsing the dose objects.

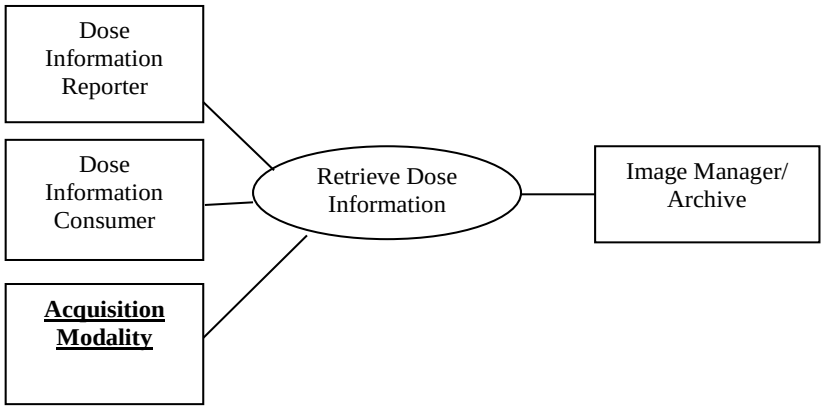
4.65 Retrieve Dose Information

This section corresponds to Transaction RAD-65 of the IHE Technical Framework. Transaction RAD-65 is used by the Dose Information Reporter, Dose Information Consumer**, Acquisition Modality** and Image Manager/Archive Actors.

4.65.1 Scope

A Dose Information Reporter**, ~~or~~** Dose Information Consumer **or Acquisition Modality** requests and receives from the Image Manager/Archive specified instances of Dose objects.

4.65.2 Use Case Roles



Actor: Dose Information Reporter

Role: Request and receive specific Dose objects from the Image Manager/Archive.

Actor: Dose Information Consumer

Role: Request and receive specific Dose objects from the Image Manager/Archive.

Actor: Acquisition Modality

Role: Request and receive specific Dose objects from the Image Manager/Archive.

Actor: Image Manager/Archive

Role: Provide specified Dose objects requested by Dose Information Reporters and Dose Information Consumers.

4.65.3 Referenced Standard

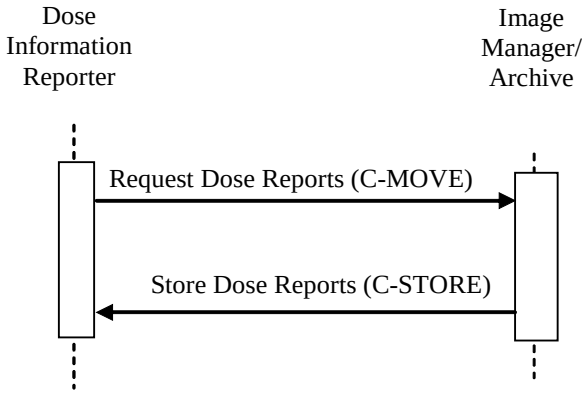
DICOM PS 3.4: Query/Retrieve Service Class

DICOM PS 3.4: Structured Reporting Storage SOP Classes

DICOM PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

DICOM PS 3.3: A.35.14 Radiopharmaceutical Dose SR IOD

4.65.4 Interaction Diagram



Note: In the above diagram, the Dose Information Consumer **or Acquisition Modality** may also submit a C-MOVE request and receive a C-STORE message.

4.65.4.1 Retrieve Dose Information

The Retrieve (Study Root – MOVE and optionally Patient Root – MOVE) SOP Classes shall be supported. This requires that C-MOVE also be supported at the Series Level. Refer to the DICOM PS 3.4 Annex C for detailed descriptive semantics.

Actors that claim support of the Radiation Exposure Monitoring (REM) Profile or the Radiation Exposure Monitoring for Nuclear Medicine (REM-NM) Profile ~~**The Image Manager/Archive, Dose Information Reporter, and Dose Information Consumeractors**~~ shall support the SOP Classes shown in Table 4.65-1 below **as indicated by the Profile Supported column**.

Table 4.65-1: Dose Storage SOP Classes

SOP Class UID	SOP Class Name	Profile Supported
1.2.840.10008.5.1.4.1.1.88.67	X-Ray Radiation Dose SR	**REM**
1.2.840.10008.5.1.4.1.1.88.68	**Radiopharmaceutical Administration Radiation Dose SR**	**REM-NM**

4.65.4.1.1 Trigger Events

The Dose Information Reporter**, or** Dose Information Consumer **or Acquisition Modality** decides it needs a specific Dose object.

4.65.4.1.2 Message Semantics

The message semantics are defined in the DICOM Query/Retrieve Service Class Section of the DICOM PS 3.4: Query/Retrieve Service Class. The Dose Information Reporter**, or** Dose Information Consumer **or Acquisition Modality** is the DICOM C-Move SCU and DICOM Storage SCP and the Image Manager/Archive is the DICOM C-Move SCP and DICOM Storage SCU.

The contents of the X-Ray Radiation Dose SR objects are **generally** based on Baseline Template TID 10001 "Projection X-ray Radiation Dose" or Baseline Template TID 10011 "CT Radiation Dose"**. The contents of the Radiopharmaceutical Administration Radiation Dose SR objects are based on Baseline Template TID 10021 "Radiopharmaceutical Radiation Dose". However, but** it should be noted that those templates are extensible, and the use of additional templates is not prohibited.

It is the responsibility of the Image Manager/Archive to assure that the patient and procedure information is current in the Dose objects when they are retrieved from the Image Manager/Archive.

The Image Manager/Archive receives the C-MOVE request, establishes a DICOM association with the Dose Information Reporter**, or** Dose Information Consumer **or Acquisition Modality**, and uses the DICOM C-STORE command to transfer the requested Dose objects.

4.65.4.1.3 Expected Actions

The Dose Information Reporter and Dose Information Consumer shall accept the Dose objects. The Dose objects shall be processed according to the features, configuration, and business logic of the Dose Information Reporter or Dose Information Consumer product. Possibilities include display, processing, analysis, printing, export, etc.

Dose Information Reporters **that claim support of the REM Profile** shall be capable of processing both TID 10001 and TID 10011**. Dose Information Reporters that claim support of the REM-NM Profile shall be capable of processing TID 10021** .

The Dose Information Reporter or Dose Information Consumer shall not return an error to the Archive due to not recognizing the template used or the retrieved document content. The retrieved results may simply be discarded instead.

X-Ray Irradiation Events are identified by an Irradiation Event UID (0008,3010). Radiopharmaceutical Administration Events are identified by a Radiopharmaceutical Administration Event UID (0008,3012). The same ~~**Irradiation**~~ Event ~~**(as identified by its Irradiation Event UID)**~~ may be referenced in multiple Dose objects. For example, the same dose event might appear in both an SR summarizing a procedure and an SR summarizing the whole study.

The Dose Information Reporter and Dose Information Consumer shall recognize duplicate ~~**Irradiation**~~ Events based on the ~~**Irradiation**~~ Event UIDs in the Dose object.

The Dose Information Reporter shall be capable of presenting some form of report to the user based on the retrieved dose information. The format, contents and analysis of such reports are not defined by the IHE. Such details should be worked out as part of the product design.

Modify RAD TF-3: Table 5.1-2 as follows

Table 5.1-2: IHE Radiology transactions and resulting ATNA trigger events

IHE Radiology Transaction	ATNA Trigger Event(s)	Actor(s) that shall be able to record audit event
Retrieve Dose Information [RAD-65]	Instances-Stored	Image Manager/Image Archive
	Study-used	Dose Information Reporter, Dose Information Consumer, **Acquisition Modality**
Store Radiopharmaceutical Activity Information [RAD-110]	**Begin-storing-instances**	**Radiopharmaceutical Activity Supplier**
	Instances-Stored	**Image Manager/Image Archive, Dose Information Reporter, Dose Information Consumer, Acquisition Modality**

