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IHE Radiology Technical Framework Supplement

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Contrast Administration Management (CAM)

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Revision 1.1 – 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 V19.0. 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 30, 2021 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://www.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://ihe.net/Technical_Frameworks.

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Introduction to this Supplement

This supplement adds a Contrast Administration Management Profile to record and distribute contrast agent administration details for imaging and image-guided procedures.

- 150 The profile standardizes storage, query, and retrieval of Imaging Agent Administration SR (IAASR) instances. It is intended to provide the necessary infrastructure for reporting and analysis, such as tracking of adverse reactions. The transactions are intentionally analogous to the IHE Radiation Exposure Monitoring Profile.

- 155 This profile does NOT address managing and reporting the activity of infusion pumps used for medication delivery. Those devices differ from the devices addressed here, are used for different purposes, and use different technical standards.

Several topics are out of scope for this profile but might be addressed as an extension or named option in the future:

- Managing planned contrast administration protocols
- 160 • Selecting contrast administration protocols for individual studies
- Tracking contrast administration using (M)PPS messages
- See “Phase 2” in the CAM Proposal for more detail
https://wiki.ihe.net/index.php/Contrast_Administration_Management_-_Proposal

165 IHE Technical Frameworks General Introduction

The [IHE Technical Framework General Introduction](#) is shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to this document where appropriate.

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210 IHE Technical Frameworks General Introduction Appendices

The [IHE Technical Framework General Introduction Appendices](#) are components shared by all of the IHE domain technical frameworks. Each technical framework volume contains links to these documents where appropriate.

Appendix A – Actor Summary Definitions

215 *Add **new** actors to the IHE Technical Frameworks General Introduction Appendix A:*

New (or modified) Actor Name	Definition
Infusion Manager	Controls devices administering contrast agent(s) for imaging studies. Sometimes referred to as a Smart Power Injector.
Contrast Information Consumer	Consumes contrast administration information, e.g., to display or analyze.

The table below lists *existing* actors that are utilized in this profile.

Complete List of Existing Actors Utilized in this Profile

Existing Actor Name	Definition
Image Manager	Manages and provides access to stored imaging objects.
Image Archive	Provides long term storage of imaging data such as images, measurements, presentation states, and manifests (e.g., a PACS).

220 Appendix B – Transaction Summary Definitions

*Add **new** transactions to the IHE Technical Frameworks General Introduction Appendix B:*

New (or modified) Transaction Name and Number	Definition
Store Contrast Information [RAD-138]	Send instances containing information about a planned or performed imaging contrast administration for storage.
Query Contrast Information [RAD-139]	Request metadata about contrast administration information instances matching a specified filter.
Retrieve Contrast Information [RAD-140]	Retrieve contrast administration information instances.

Appendix D – Glossary

*Add **new** glossary terms to the IHE Technical Frameworks General Introduction Appendix D.*

225

IHE Radiology Technical Framework Supplement – Contrast Administration Management (CAM)

New (or modified) Glossary Term	Definition
Contrast Administration	The controlled delivery of a contrast agent in the context of an imaging procedure.
IAASR Instance	An instance of a DICOM Imaging Agent Administration Structured Report (IAASR). It is a DICOM object containing details of a planned or performed administration of imaging agents, such as radiopaque contrast, in the context of an imaging procedure.

Volume 1 – Profiles

Add new Section 51

51 Contrast Administration Management (CAM) Profile

230 The CAM Profile records contrast agent administration details for imaging and image-guided procedures. CT, MRI, Ultrasound, and Projection X-ray (including angiography, fluoroscopy) commonly use contrast agents. Captured contrast details can be useful for investigating adverse events, driving regular QA processes, serving as evidence for medicolegal activities, or supporting charging and management of drugs and consumables.

235 The profile focuses on “smart injector” systems and refers to the source of administration details as the Infusion Manager. The profile does not, however, exclude manual administrations (e.g., hand injection for radiography and MR, oral or inhaled administration for CT and fluoroscopy, etc.) but in those cases, entry of details would also need to be done manually. The manual entry system would participate in this profile as an Infusion Manager, although it would likely be implemented on a modality or standalone application.

240 Note: Administration of radiopharmaceuticals is excluded since those are addressed by the REM-NM Profile.

Contrast media is a valuable tool in diagnostic imaging to help detect, characterize, and assess biological structures and processes, such as lesions and blood flow. It is also used in image-guided biopsy and therapy to identify target structures, to guide devices, and to assess therapeutic effect.

245 Administration of contrast can, however, cause severe adverse reactions including patient death, so it is important for the medical record to accurately capture what was administered, how it was administered, and what happened during the administration. In a busy clinical practice, it is challenging to manually create and store such detailed record. This profile aims to automate recording and storage of detailed, accurate contrast information so as to avoid a significant administrative burden on staff otherwise occupied with caring for patients.

250 Although the profile does not describe a contrast usage registry, it does standardize storage, query, and retrieval of Imaging Agent Administration SR (IAASR) instances that provide necessary infrastructure for such a database.

255 Similarly, the profile ensures robust sets of contrast records are readily available to Contrast Information Consumers, but it does not mandate any specific reporting or analysis, such as tracking the frequency of adverse reactions, rather leaving such choices to product designers and their customers. With the full details of individual contrast administrations in hand, such features to promote patient safety and healthcare quality should become easily provided.

51.1 CAM Actors, Transactions, and Content Modules

260 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.

IHE Transactions can be found in the Technical Frameworks General Introduction Appendix B. Both appendices are located at http://ihe.net/Technical_Frameworks/#GenIntro

265 Figure 51.1-1 shows the actors directly involved in the CAM Profile and the relevant transactions between them.

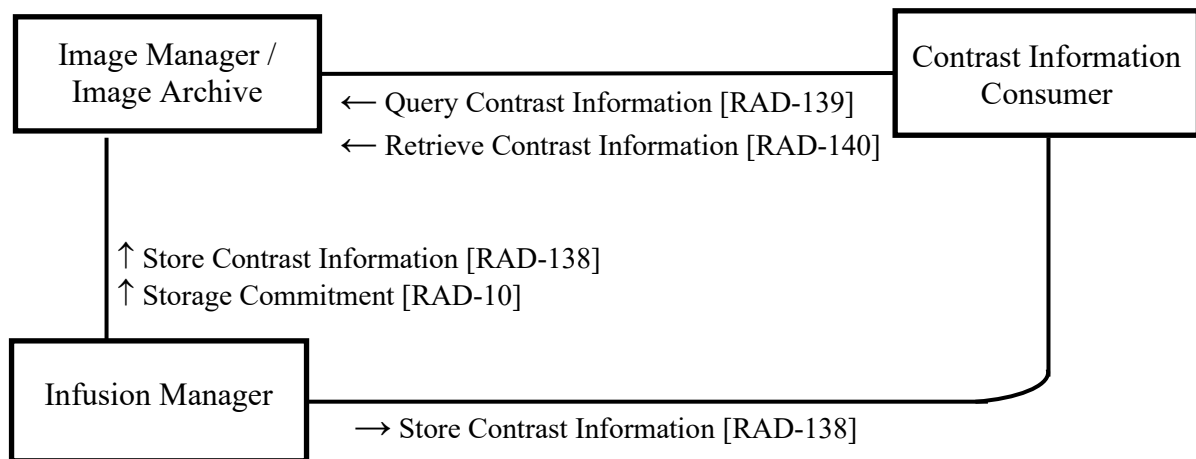


Figure 51.1-1: CAM Actor Diagram

270 Table 51.1-1 lists the transactions for each actor directly involved in the CAM Profile. To claim compliance with this profile, an actor shall support all required transactions (labeled “R”) and may support the optional transactions (labeled “O”).

Table 51.1-1: CAM Profile - Actors and Transactions

Actors	Transactions	Initiator or Responder	Optionality	Reference
Infusion Manager	Store Contrast Information [RAD-138]	Initiator	R	RAD TF-2: 4.138
	Storage Commitment [RAD-10]	Initiator	O	RAD TF-2: 4.10
Contrast Information Consumer	Store Contrast Information [RAD-138]	Responder	R	RAD TF-2: 4.138
	Query Contrast Information [RAD-139]	Initiator	R	RAD TF-2: 4.139
	Retrieve Contrast Information [RAD-140]	Initiator	R	RAD TF-2: 4.140
Image Manager / Image Archive	Store Contrast Information [RAD-138]	Responder	R	RAD TF-2: 4.138
	Query Contrast Information [RAD-139]	Responder	R	RAD TF-2: 4.139
	Retrieve Contrast Information [RAD-140]	Responder	R	RAD TF-2: 4.140
	Storage Commitment [RAD-10]	Responder	R	RAD TF-2: 4.10

51.1.1 Actor Descriptions and Actor Profile Requirements

275 Most requirements are documented in RAD TF-2 Transactions. This section documents any additional requirements on profile's actors.

51.1.1.1 Infusion Manager

Infusion Managers output contrast information (IAASR instances) about the administration process with which they are associated.

280 Note: Since the primary focus of this profile is the administration of contrast by injection, the actor names and terms used will reflect that. Administration by swallowing or inhalation is also valid and is supported by the IAASR instance templates. Systems that capture details for swallowed or inhaled agents (e.g., modalities or standalone apps) may conform and claim to support this profile as the Infusion Manager. Similarly, imaging agents other than contrast, such as stress agents like dobutamine or medications like propofol, are addressed in the IAASR instance templates and are considered in the scope of this profile.

285 Whether the IAASR instances are generated by the Infusion Manager or by the power injector is up to the product developer. For simplicity, this profile will be worded as if the Infusion Manager is creating the IAASR instances.

290 Infusion Managers 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 an Infusion Manager is able to store IAASR instances relative to the completion of the contrast administration activity).

Upon completion or discontinuation of a procedure step where contrast administration activities occurred, the Infusion Manager shall compose a Performed IAASR instance and send it to the configured destinations.

295 The Infusion Manager is responsible for storing the IAASR instance in the same Study as the corresponding modality images. This is done by using the same Study Instance UID, however the profile does not mandate a specific mechanism for obtaining that UID. Implementing DICOM Modality Worklist is a logical choice (see RAD TF-2: 4.5 Query Modality Worklist [RAD-5]).

300 The Infusion Manager shall be capable of sending the IAASR instance to multiple destinations. The primary storage destination is generally the Image Manager / Image Archive; however, the Contrast Information Consumer may also be a configured destination when it needs to receive timely IAASR instances without having to repeatedly poll the Image Manager / Image Archive.

305 The Infusion Manager is responsible for delivery of IAASR instances to the destinations despite intermittent connections (e.g., due to network trouble, or the destination being down).

The Infusion Manager shall be capable of creating IAASR instances for patient studies and for phantom/calibration studies.

Note: For phantom or calibration studies, it is expected that Quality Control Subject (0010,0200) will be present with a value of YES.

310 51.1.1.2 Contrast Information Consumer

Contrast Information Consumers receive and/or retrieve contrast information (IAASR instances).

Systems that might implement a Contrast Information Consumer include radiology report creators, departmental contrast reporting systems, acquisition modalities, billing/inventory systems, etc.

315 The acquisition modality might receive contrast information for incorporation into the associated image objects (although this would depend on the Infusion Manager promptly creating and sending the IAASR so as not to delay production of the acquired images).

The contrast reporting system might present some form of report to the user based on the retrieved contrast 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. Examples include
320 generating a daily report of imaging agent administration procedures, or a weekly summary of procedure frequency and adverse events. See Section 51.4.1.3 Analysis & Reporting.

51.1.1.3 Image Manager / Image Archive

Image Manager / Image Archives store and manage contrast information (IAASR instances) as
325 part of the imaging record.

51.2 CAM Actor Options

Options that may be selected for each actor in this profile, if any, are listed in the Table 51.2-1. Dependencies between options, when applicable, are specified in notes.

Table 51.2-1: Contrast Administration Management – Actors and Options

Actor	Option Name	Reference
Infusion Manager	No options defined	
Contrast Information Consumer	No options defined	
Image Manager / Image Archive	No options defined	

330

51.3 CAM 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 requirements for the grouped actor (Column 2) (Column 3 in alternative 2).

335 Section 51.5 describes some optional groupings that may be of interest for security considerations and Section 51.6 describes some optional groupings in other related profiles.

Table 51.3-1: Contrast Administration Management - Required Actor Groupings

CAM Actor	Actor(s) to be grouped with	Reference
Infusion Manager	ITI CT / Time Client	ITI-TF-1: 7.1
Contrast Information Consumer	None	--
Image Manager / Image Archive	None	--

51.4 CAM Overview

340 This profile addresses the flow of information on contrast medium usage from the source to the Image Manager / Image Archive for storage and from the Image Manager Image / Archive to the Contrast Information Consumer for retrieval.

51.4.1 Concepts

51.4.1.1 Planned and Performed Imaging Agent Administrations

345 This profile is focused on the storage of instances of the DICOM Performed Imaging Agent Administration SR IOD. These instances record the specific details of administering an imaging agent (typically contrast) to a specific patient during an imaging procedure. As such these instances are part of the patient-study hierarchy.

350 DICOM also defines a Planned Imaging Agent Administration SR IOD which records the details for a specific planned administration (sometimes called a protocol); however, the use of those instances is not yet addressed by this profile.

51.4.1.2 Codesets

For sites to analyze imaging agent administration records and use them to drive QA processes, they will need to use codesets consistently for things like imaging procedure codes, imaging agents, and adverse reactions.

355 This profile does not mandate the use of particular codesets, so agreeing within the local site or organization on common codesets will be a prerequisite for effective deployment of this profile. (See RAD TF-1x: Appendix I.1.1 Code Set Management).

51.4.1.3 Analysis & Reporting

The profile does not mandate, but is intended to facilitate, the ability to do things like:

- 360
- view the usage of imaging agents for a patient (or organs) in a certain type of study in a facility or department
 - calculate the frequency of each kind of adverse reaction, overall and organized by individual imaging agent, modality, technologist, work shift, procedure type, and injection device.

- 365
- calculate the frequency of imaging agent administration, overall and organized by individual imaging agent, modality, technologist, work shift, procedure type, and injection device.

Note: Reporting organized by physical location (room) might also be of interest, but infusion systems are typically mobile and the device does not necessarily know what room it is located in.

370 A proper imaging agent administration management program at an imaging facility would involve radiologists, radiology technologists, and nurses. The program would 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, processing, or constitute a contrast agent administration management program in itself.

375 The profile is intended to support QA (quality assurance) of the technical process (e.g., was the contrast usage appropriate for the procedure performed, or how frequently do extravasations occur), and QA of the operational process (e.g., were there any differences between the procedure as scheduled and the procedure as performed, was the difference appropriate or inevitable, and was it appropriately approved). It is less suited to QA of the ordering process
380 (was the procedure ordered/scheduled appropriate for the indications, did it meet appropriateness criteria). Since this profile does not include Planned Imaging Agent Administration SR objects in detail, QA of the operational process is likely improved but not automatable by this profile.

Recording and analyzing imaging agent usage can facilitate important activities by key healthcare providers such as:

- 385
- Facilities can ensure their policies, procedures, and protocols are being appropriately followed to minimize risks and physical impact on patients, and lower procedure costs.
 - Radiologists can be assisted in determining how changes in techniques and protocols impact diagnostic ability.
 - Radiologists and referring physicians can better judge risk-benefit assessments for
390 imaging agent use in individual patients.
 - Radiology experts can create guidelines for imaging agent use.

395 Data will generally be continuously collected and evaluated on all imaging agent administration procedures. Process improvement and data analysis would focus on local variations attributable to x-ray equipment, operators, procedures, and ordering physicians. The CAM Profile does not define purpose of analysis, analytical methods, and other usage.

As a part of the departmental quality improvement program, the department's medical administrator might access a Contrast Information Consumer to carry out a bi-monthly assessment of contrast usage.

400 When the assessment reveals difference of contrast usage among doctors and departments, the results of the assessment serve as a data source for contrast usage guideline, or for decision of contrast agent selection.

51.4.1.4 Ordering & Workflow

This profile does not include any requirements on the management of infusion protocols or the selection of infusion protocols in the context of specific scheduled procedures; however, an understanding of these concepts provides relevant context for what the profile does address.

In some medical imaging practices, a radiologist reviews orders for imaging procedures in the coming hours or days and decides whether it is appropriate to use a contrast agent and may prescribe details such as the type of contrast and the amount. The following describes an example of the data flows that might be used to support this task.

An order for an imaging study is placed and transmitted to the DSS/Order Filler via the IHE Placer Order Management [RAD-2] transaction. A radiologist checks the order on a DSS/OF terminal to select an imaging protocol that fits the order. The order may include recent lab values for serum creatinine and eGFR (indicators of kidney function and ability to tolerate injected contrast) or the radiologist may consult the EMR to also check history of allergy, renal function, purpose of study. The radiologist may use a standard contrast protocol or tailor the contrast usage for the specific patient and study. The radiologist decisions may be captured as text notes or the details may be encoded digitally for use by the imaging modality and the infusion manager.

Similar to imaging modalities, Infusion Managers may be capable of storing user-defined infusion protocols including protocol name, protocol ID, and infusion parameters which can then be invoked based on operator selection or details in the procedure worklist entry.

An extension to this profile (“Phase 2”) is under consideration which would profile the use of the modality worklist service by the Infusion Manager. Until then, the Infusion Manager is responsible for the patient and procedure metadata in the injection record being accurate, but the support of a specific mechanism is not required.

51.4.1.5 Injector-Modality Interaction

The diagnostic quality of images can depend on the relative timing of contrast injection and image acquisition. Imaging modalities and injectors often use electronic signals to synchronize these activities and/or communicate operational status. A common standard for this is the CANopen CiA 425 specification (<https://www.can-cia.org/can-knowledge/canopen/cia425/>)

Acquisition Modalities and Infusion Managers are recommended to consider supporting CANopen; however, since no interoperability issues have been raised with this signaling and since the reporting covered by this profile is independent of these controls and interlocks, no CANopen requirements have been included in this profile.

It should also be noted that even with such control signals, an independent power injector with its own operating console is usually preferred because of higher degree of freedom in setting injection parameters and prompt response in situation change or in emergency. Unexpected situations arise (see Extravasation and Discontinuation Use Cases), so even if coordination is partially automated, some degree of flexibility and manual intervention will be needed.

51.4.1.6 Relating Performed Contrast Administrations and Images

440 As described in RAD TF-2: 4.139.4.1.2.1 Filtering Strategies, a coarse correlation between Performed IAASR instances and potentially related images is implicitly established by being part of the same Study.

Note: It is possible for a study to have IAASR instances but no image instances, for example, due to termination of the study after contrast administration but before image acquisition successfully produced images.

445 More fine correlation between IAASR instances and specific images depends on matching the DateTime Started and Duration values for the contrast administration phases and activities in the IAASR instances to corresponding frame times in the images in the same study. The encoding of frame time depends on the image SOP Class.

450 Performed IAASR instances provide detailed information directly from the device managing the imaging agent administration. Many DICOM images types may also include the Contrast/Bolus Module, or the Enhanced Contrast/Bolus Module, which can provide selected details known to the modality at the time the image was created.

455 This profile does not include any requirements on Acquisition Modalities to populate contrast/bolus details in the image or to ensure consistency with the content of corresponding IAASR instances if they do so.

Contrast Information Consumers are recommended to preferentially use contrast information from Performed IAASR instances rather than what may be derived from the contrast/bolus module or other metadata in image instances.

51.4.2 Use Cases

460 Typically, contrast administration activities occur during an imaging study or a session of image-guided therapy. The Infusion Manager associated with the modality device(s) records the usage of imaging agent(s) and other relevant information to generate IAASR instances that are part of the same study as the images. The Infusion Manager stores the instances to the Image Manager / Image Archive where they are available to Contrast Information Consumers.

465 51.4.2.1 Use Case #1: Uneventful Case

The Uneventful Case represents the typical pattern of capturing and storing contrast administration from an imaging procedure for later processing and use.

51.4.2.1.1 Uneventful Case Description

470 For context, it is perhaps useful to understand the contrast administration steps that precede the data transfer steps covered by this profile. Consider a typical imaging procedure (the roles performing the described actions may vary by practice location):

- A CT coronary angiography procedure, which involves administering an injected radiopaque contrast agent, is ordered for the patient.

- 475
 - The patient may be given instructions to fast, to facilitate the effectiveness of the imaging agent or mitigate the effects of contrast-induced nausea, or the patient may be required to perform a preparation procedure such as for colonography.
 - When patient arrives at the scan suite, the technologist selects the corresponding worklist entry on the CT console and on the Infusion Manager terminal.
- 480
 - Based on the requested procedure in the worklist entry, an image acquisition protocol is prepared on the CT and a corresponding infusion protocol is prepared on the Infusion Manager. For example, CT angiography may require a higher volume of contrast, faster rate of infusion, and a larger gauge needle. Increased infusion rates may increase the occurrence of adverse events.
- 485
 - Typically, protocols that have been pre-loaded on the CT and Infusion Manager are used with minor adjustments to suit the individual patient. The technologist or nurse may take into consideration the patient condition and contrast tolerance. The CT and Infusion Manager may automatically pre-select an appropriate protocol based on the requested procedure code.
- 490
 - The technologist or nurse may screen the patient and/or access relevant details from the patient medical record, such as relevant allergies, prior contrast intolerance or lab results relating to kidney function, and input those details into the imaging procedure record. Patients with a history of iodine allergies may require premedication.
- 495
 - The attending nurse inserts an intravenous line into the patient for contrast agent infusion.
 - The technologist and nurse independently verify the infusion protocol, then start the image acquisition and the contrast agent infusion. The acquisition proceeds as defined in the imaging protocol and the contrast agent infusion proceeds as defined in the planned infusion protocol.
- 500
 - Note: The operator of the injector is often the operator of the acquisition modality but this is not always the case.
 - The technologist or nurse may input additional data (such as the needle thickness, syringe lot number, needle placement on the arm, etc.) that the Infusion Manager cannot get from the power injector automatically.
 - The Infusion Manager sends IAASR instances to the Image Manager / Image Archive.
 - Contrast Information Consumers query and retrieve IAASR instances as appropriate from the Image Manager / Image Archive.
- 505
 - In many organizations, the Contrast Information Consumer will collect IAASR instances covering a certain period (e.g., today, this week, or last month), and generate summary reports of imaging agent usage.

51.4.2.1.2 Uneventful Case Process Flow

Figure 51.4.2.1.2-1 shows the Contrast Information Consumer obtaining IAASR instances by querying the Image Manager / Image Archive. Alternatively, the Infusion Manager can be configured to send the IAASR instances directly to various Contrast Information Consumers in addition to, or instead of, sending them to the Image Manager / Image Archive.

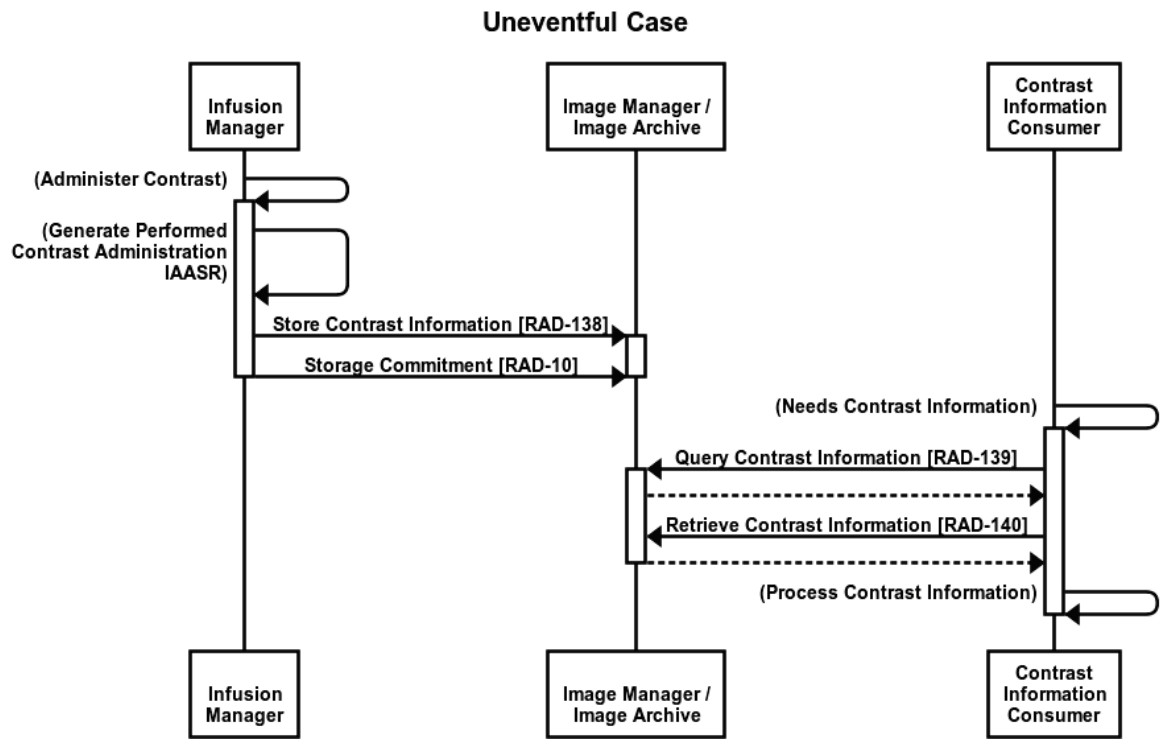


Figure 51.4.2.1.2-1: Uneventful Process Flow

The text in Figure 51.4.2.1.2-2 was used to generate the diagram in Figure 51.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

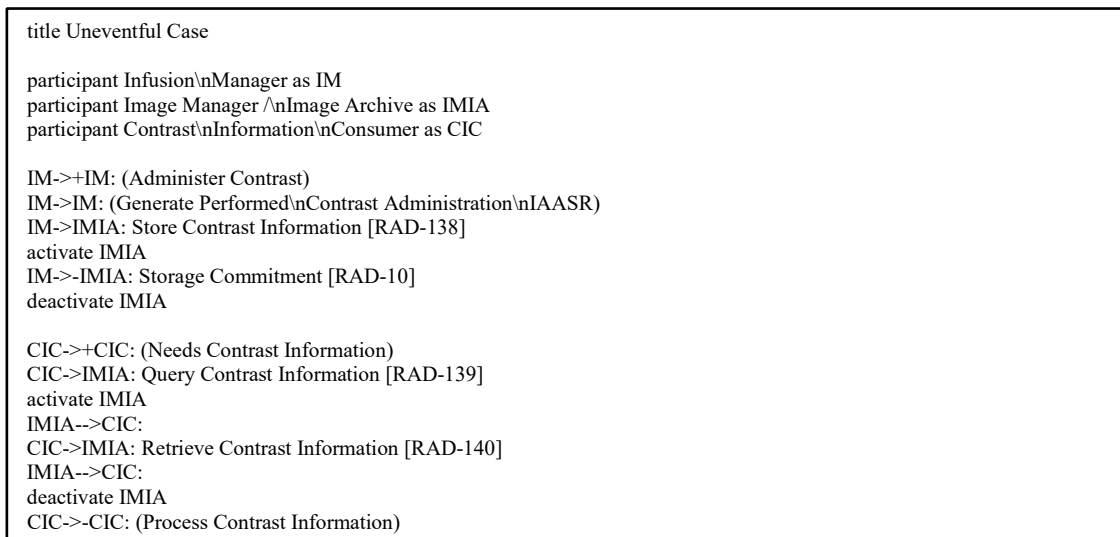


Figure 51.4.2.1.2-2: Diagram Pseudocode for Uneventful Process Flow

51.4.2.2 Use Case #2: Extravasation Case

520 In this deviation from the Uneventful Case, extravasation is detected which requires intervention and/or modification of the contrast administration.

51.4.2.2.1 Extravasation Case Description

525 Extravasation is the unintentional leakage of contrast into the tissue surrounding the intended vein. This means the contrast is not achieving its intended imaging purpose, and may also result in pain and/or injury to the patient.

Extravasation of the contrast agent may be observed by the nurse or may be automatically detected by the power injector, for example based on pressure and flow sensors.

The nurse stops the infusion and the technologist pauses the scan.

530 The nurse assesses the patient. This may lead to administering first aid, or in more severe cases, referring the patient to the emergency department for treatment.

If it is determined that the patient condition permits continuing the study, the intravenous line is reinserted. The technologist and/or the nurse observe that the remaining volume of imaging agent is not enough for the study. They add imaging agent as needed and record the addition in the Infusion Manager. The CT scan and the infusion of the contrast agent are resumed.

535 The technologist or nurse may input additional data or comments describing the nature of the extravasation and re-injection for inclusion in the IAASR instance.

The Infusion Manager may include all the information from before and after the intervention in a single IAASR instance, or may create one IAASR instance describing the administration up to

the point of intervention by the technologist or nurse, and then a second IAASR instance describing the administration after the intervention. Together, the two IAASR instances provide the complete contrast record.

51.4.2.2.2 Extravasation Case Process Flow

Figure 51.4.2.2.2-1 shows the Infusion Manager generating two IAASR instances. Alternatively, it might generate a single IAASR containing all the information.

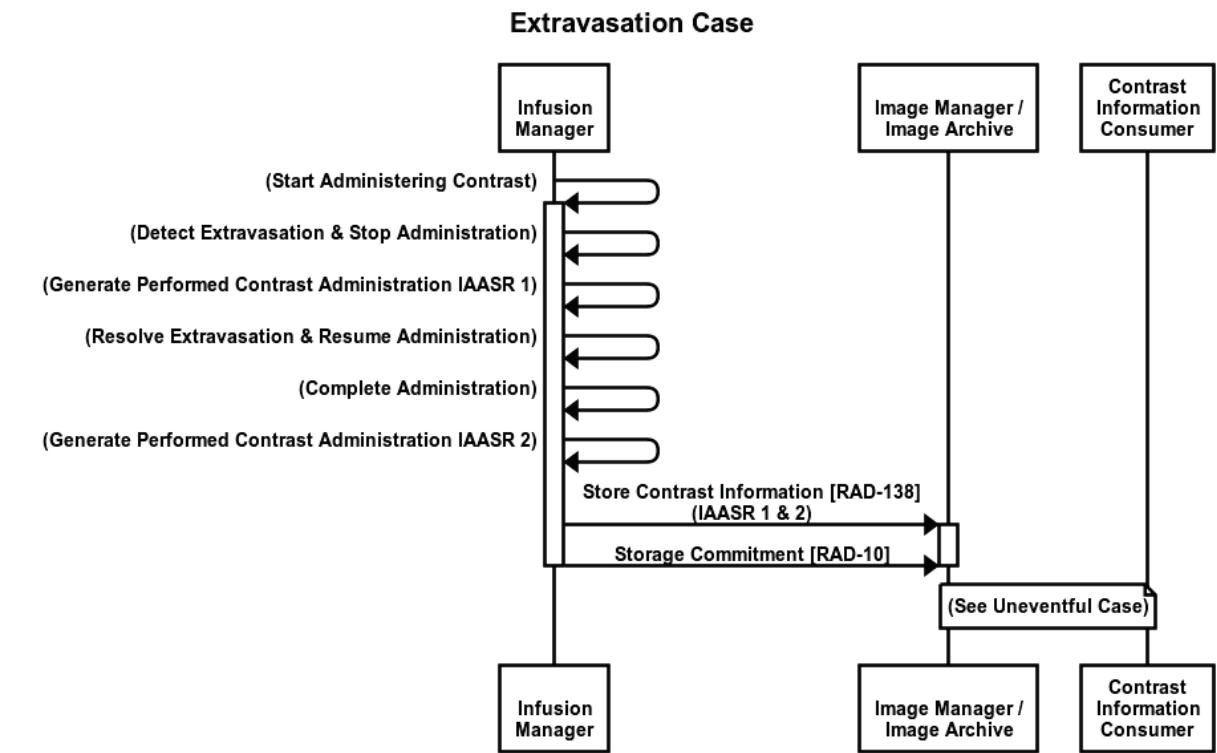


Figure 51.4.2.2.2-1: Extravasation Process Flow

The text in Figure 51.4.2.2.2-2 was used to generate the diagram in Figure 51.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Extravasation Case

participant Infusion\nManager as IM
participant Image Manager /\nImage Archive as IMIA
participant Contrast\nInformation\nConsumer as CIC

IM->+IM: (Start Administering Contrast)
IM->IM: (Detect Extravasation & Stop Administration)
IM->IM: (Generate Performed Contrast Administration IAASR 1)
IM->IM: (Resolve Extravasation & Resume Administration)
IM->IM: (Complete Administration)
IM->IM: (Generate Performed Contrast Administration IAASR 2)

IM->IMIA: Store Contrast Information [RAD-138]\n(IAASR 1 & 2)
activate IMIA
IM->-IMIA: Storage Commitment [RAD-10]
deactivate IMIA

note over IMIA,CIC: (See Uneventful Case)
```

550 **Figure 51.4.2.2-2: Diagram Pseudocode for Extravasation Process Flow**

51.4.2.3 Use Case #3: Discontinuation Case

In this deviation from the Uneventful Case, a serious issue occurs that requires the contrast administration and imaging procedure be discontinued.

51.4.2.3.1 Discontinuation Case Description

555 After the data acquisition and contrast agent infusion have started, the procedure is interrupted. This may be due to equipment failures, environmental hazards, or most likely a change in the patient condition making it not possible to acquire a diagnostic set of images. Examples include patient nausea, going into ventricular fibrillation or showing an allergic reaction to the contrast media or an extravasation with severe side effects. The issue may have been detected by either
560 the device, the operator, or the patient. The technologist stops the scanner. The attending nurse stops the infusion and attends to the patient. The study is discontinued.

The Infusion Manger may prompt the technologist or nurse to input additional data describing the nature of the discontinuation for inclusion in the IAASR instance.

565 The Infusion Manager sends to the Image Manager / Image Archive IAASR instances containing information about the completed steps and phases and reasonable estimates for any partially performed steps and phases.

51.4.2.4 Use Case #4: Emulate Prior Protocol Case

570 In this extension to the Uneventful Case, the contrast administration record from a prior imaging procedure is used as the basis for configuring a subsequent administration protocol. The goal is for the subsequent administration to be very similar to the prior administration.

51.4.2.4.1 Emulate Prior Protocol Case Description

A Hospital is performing chest CT scans for patients enrolled in a clinical trial assessing the effect of a thymidine kinase inhibitor for patients with Stage IV non-small cell lung cancer. This trial requires the infusion protocol used for each individual patient be very similar to minimize the impact of contrast infusion differences on the comparison of the tumor imaging between time points for that patient.

- Using a Contrast Information Consumer that is either next to the Infusion Manager or grouped with it, the doctor queries the Image Manager / Image Archive for the Performed IAASR generated during the prior chest CT of the patient.
- The infusion protocol details are displayed or extracted from the retrieved IAASR.
- If the current Infusion Manager is the same as the prior Infusion Manager, or similar enough, the prior details may be able to be used directly. Otherwise the doctor will adapt or compose a new protocol on the current Infusion Manager that achieves a similar effect.
- Infusion for the current procedure then proceeds as described in Use Case #1 Uneventful Case.

It is also possible that the prior Performed IAASR may have a reference to a Planned IAASR on which it was based. If the same Infusion Manager is being used, it may be able to access that Planned IAASR for use again.

51.5 CAM Security Considerations

IAASR instances contain PHI such as patient demographics and details of performed procedures. The security considerations are similar to those for images. Depending on the privacy and security policies of the institution, IAASR instances should be de-identified before sending them outside of the originating institution. Some specific details that may be relevant to consider retaining for certain analysis of contrast administration include approximate patient weight, height, age, sex, and allergies. It may also be appropriate to log the creation, query, and transfer of IAASR instances using the Record Audit Event [ITI-20] transaction defined in the IHE ITI Audit Trail and Note Authentication (ATNA) Profile.

Infusion Managers are typically connected to the same data networks as imaging modality systems and should follow similar data protection practices, such as implementing the Authenticate Node [ITI-19] transaction in ATNA to enable secure connections.

This profile does not address the actual control of Infusion Managers and power injectors, but it is worth noting that injection of large volumes of contrast or injection at high pressures can be harmful to patients so cybersecurity precautions are appropriate.

51.6 CAM Cross-Profile Considerations

605 SWF.b – Scheduled Workflow.b

An Image Manager / Image Archive in Scheduled Workflow.b that also supports Contrast Administration Management is expected to reconcile the IAASR instances along with the rest of the instances in a patient's study.

610 Note: SWF.b addresses reconciliation driven by HL7 v2.5 messages. Reconciliation driven by HL7 v.2.3 messages is handled in the Patient Identification Reconciliation (PIR) Profile which is used in concert with the original SWF Profile.

CHG – Charge Posting

A Department System Scheduler/Order Filler in Charge Posting might be grouped with a Contrast Information Consumer to obtain detailed imaging agent and consumable usage information for billing purposes.

615 RWF – Reporting Workflow

A Report Creator in Reporting Workflow might be grouped with a Contrast Information Consumer to obtain contrast administration details for display to the reporting radiologist in a user-friendly format and for automated insertion into the report.

PDI – Portable Data for Imaging

620 A Portable Media Creator in Portable Data for Imaging might be grouped with any Contrast Administration Management actor to facilitate inclusion of IAASR instances on portable media for sharing with other healthcare providers or with the patient. The media may provide IAASR instances along with the rest of the study data to provide a “complete package”, or on their own as contrast record.

625 TCE – Teaching Files and Clinical Trials Export

An Export Selector in Teaching Files and Clinical Trials Export might be grouped with a Contrast Information Consumer to include IAASR instances in a TCE manifest and export them along with study images for teaching file creation or for clinical trial use. Contrast details such as timing may be relevant for some clinical trial analysis, and teaching files might specifically
630 address the effects of correct (or incorrect) contrast usage on image quality.

XDS-I.b - Cross-Enterprise Document Sharing for Imaging, or

XCA-I - Cross-Community Access for Imaging

635 An Imaging Document Source in XDS-I or XCA-I might be grouped with an Image Manager / Image Archive or Contrast Information Consumer to enable access to IAASR instances across multiple sites along with other DICOM SR instances. Similarly, an Imaging Document Consumer might be grouped with a Contrast Information Consumer.

ATNA – Audit Trail and Node Authentication

640 A Secure Node or Secure Application in ITI Audit Trail and Node Authentication might be grouped with any of the actors in the profile to provide node authentication or logging of audit events.

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

Appendices to Volume 1

Not applicable

645

Volume 2 – Transactions

Modify RAD TF-2: 4.10 as shown to add Infusion Manager as a Requester.

(These updates to RAD-10 presume Final Text CP-RAD-461 “Refactor RAD-10 for easier reuse” is integrated into RAD TF Volume 2 as planned by September 2021.

4.10.1 Actor Roles

650

Table 4.10.1-1: Actor Roles

Role:	Requester: Requests a storage commitment from the Responder for DICOM objects previously transmitted.
Actor(s):	The following actors may play the role of Requester: Acquisition Modality Evidence Creator Importer <u>Infusion Manager</u> Workitem Performer
Role:	Responder: Assumes responsibility for reliable storage, retrieval, and validity of the referenced DICOM objects.
Actor(s):	The following actors may play the role of Responder: Imager Manager/Archive Report Manager Report Repository

Add Section 4.138

4.138 Store Contrast Information [RAD-138]

4.138.1 Scope

655 This transaction is used to send information about contrast administration activities associated with an imaging procedure. The information may describe an administration that has been performed, in whole or in part, or one that is planned.

660 The information is encoded using DICOM Structured Reports with standardized templates for contrast administration (IAASR instances). IAASR models contrast administration as consisting of one or more administration steps which is made up of one or more administration phases which is made up of one or more administration activities.

4.138.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

665 **Table 4.138.2-1: Actor Roles**

Role:	Sender: Sends information about planned or performed contrast administrations.
Actor(s):	The following actors may play the role of Sender: Infusion Manager
Role:	Receiver: Receives and stores information about planned or performed contrast administrations.
Actor(s):	The following actors may play the role of Receiver: Imager Manager/Archive Contrast Information Consumer

Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

4.138.3 Referenced Standards

- 670
- DICOM PS3.3 Section A.35.19: Planned Imaging Agent Administration SR IOD

- DICOM PS3.3 Section A.35.20: Performed Imaging Agent Administration SR IOD
- DICOM PS3.4: Storage Service Class
- DICOM PS3.16 TID 11001: Planned Imaging Agent Administration
- DICOM PS3.16 TID 11020: Performed Imaging Agent Administration
- DICOM PS3.17: Annex LLLL Imaging Agent Administration Report Template (Informative)
- DICOM PS3.17: Annex MMMM Performed Imaging Agent Administration Structured Report (Informative)

4.138.4 Messages

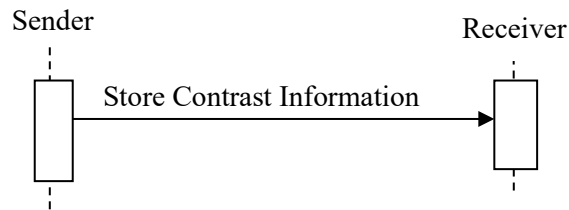


Figure 4.138.4-1: Interaction Diagram

4.138.4.1 Store Contrast Information Message

The Sender sends contrast administration information to the Receiver.

The Receiver shall support handling such messages from more than one Sender. The Sender shall support making requests to more than one Receiver.

4.138.4.1.1 Trigger Events

A user or an automated function on the Sender determines that information about a contrast administration should be sent to the Receiver.

4.138.4.1.2 Message Semantics

The message is a DICOM C-STORE request. The Sender is the SCU, and the Receiver is the SCP. The Sender shall support at least one of the Storage SOP Classes listed in Table 4.138.4.1.2-1. The Receiver shall support both of the Storage SOP Classes listed in Table 4.138.4.1.2-1.

Table 4.138.4.1.2-1: Store Contrast Information SOP Classes

DICOM SOP Class Name	SOP Class UID
Planned Imaging Agent Administration SR	1.2.840.10008.5.1.4.1.1.88.74

DICOM SOP Class Name	SOP Class UID
Performed Imaging Agent Administration SR	1.2.840.10008.5.1.4.1.1.88.75

695

The Sender shall record the relevant details for each performed contrast administration activity. These details will be included in the IAASR instances as described below.

700 A contrast administration step is associated with a single imaging study or a single image-guided biopsy or therapy session. A contrast administration step is made up of one or more administration phases which are made up of one or more administration activities.

The content of Planned Imaging Agent Administration SR instances and Performed Imaging Agent Administration SR instances are based on TID 11001 “Planned Imaging Agent Administration” and TID 11020 “Performed Imaging Agent Administration Baseline Template” respectively.

705 Note: DICOM may extend these templates (and the sub-templates they contain). Implementers are reminded that they are responsible for monitoring such changes and keeping their implementations current.

In the event of discontinuation, administration steps and phases which were not started may be omitted and values in partially completed steps and phases shall reflect reasonable estimates of what was actually performed rather than what was originally planned.

710 If no administration activity was started, the Sender is permitted, but not required, to create an IAASR instance with a single activity containing appropriate values (e.g., EV (122091, DCM, "Volume Administered") = 0ml).

715 Note: Since the information in the IAASR may affect inventory management and clinical records, and since policies may vary between sites and countries and depending on whether contrast media has been loaded and/or administered, providing configurable behavior for what is recorded and what instances are created during discontinued procedures may be desirable.

720 If the content of the IAASR instance has been populated by manual entry (rather than directly generated by the Infusion Manager), this is indicated by including TID 1002 Observer Context with (121005, DCM, "Observer Type") = (121006, DCM, "Person") and identifying the person in TID 1003 Person Observer Identifying Attributes.

Table 4.138.4.1.2-3 describes how some attributes shall be populated if present with a value in the IAASR instance. These attributes are Type 1C, 2, and Type 3 in the Performed Imaging Agent Administration SR IOD. The use of “shall” in this table does not make these attributes required, it only constrains their value when the implementation chooses to provide one.

725

Table 4.138.4.1.2-3: Contrast Administration Attributes

Attribute Name	Tag	Requirement
Series Description	(0008,103E)	When provided, shall have a value in the appropriate language for local use that means the equivalent of “Imaging Agent Information”, or similar.

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Attribute Name	Tag	Requirement
Referenced Performed Procedure Step Sequence	(0008,1111)	When provided, shall list the SOP Class UID and Instance UID of the image acquisition PPS. Typically, only a single PPS is associated with an IAASR. Since DICOM only permits a single value in this sequence, in the case where an IAASR covers several PPS (e.g., of a whole multi-step study), this attribute shall be left empty.
Performed Procedure Code Sequence	(0040,A372)	When provided, shall contain the codes for the acquisition procedures performed by the modality (i.e., not a code for “Create IAASR”). Creation of the IAASR instance is to be considered part of the imaging procedure, not a separate procedure in itself.
Referenced Request Sequence (0040,A370) >Requested Procedure Description	(0032,1060)	When provided, shall be copied from the relevant acquisition SPS (Modality Worklist entry). This can facilitate checking compliance to indication-based imaging agent usage. Note: This means that if a Modality Worklist entry is not available, the attribute should not be provided.
Admitting Diagnoses Description	(0008,1080)	
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)	When provided, shall be copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry and may be approximate. This may be necessary for future analysis of adverse reactions to the imaging agent.
Patient’s Size	(0010,1020)	I.e., height. When provided, shall be copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry, and may be approximate. This may be necessary for future analysis of adverse reactions to the imaging agent.
Patient’s Age	(0010,1010)	When provided, shall be filled from any valid source (e.g., computed from Patient’s Birthdate and Study Date, copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry) and may be approximate. This may be necessary for future analysis of adverse reactions of imaging agent
Patient’s Sex	(0010,0040)	When provided, shall be copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry.

In the event of a Group Case acquisition (see RAD TF-2: 4.6.4.1.2.3.4), the IAASR instance generated shall reflect the single physical acquisition procedure step performed. The procedure type would reflect the combined acquisition. The Infusion Manager shall not allocate subsets of the IAASR to the pseudo-sub-procedures of the group. The Infusion Manager may choose to replicate the IAASR instance under each component of the group case, and if it does so, it shall populate the Identical Documents Sequence.

When an adverse reaction has occurred, the Sender shall populate the concepts in Table 4.138.4.1.2-2 in TID 11004 in addition to those mandated by the template in DICOM PS3.16. If the information cannot be obtained from an RFID or barcode reader, the Sender may require the operator to enter the information.

Table 4.138.4.1.2-2: Adverse Reaction Concepts

Concept Name	Note
EV (113510, DCM, "Drug Product Identifier")	Even with the same principal component and concentration, contrast composition can vary with product/brand, thus adverse reactions may differ.
EV (C0947322, UMLS, "Manufacturer Name")	
EV (111529, DCM, "Brand Name")	
EV (121149, DCM, "Lot Identifier")	Supports analysis of lot on frequency of adverse reactions.

4.138.4.1.3 Expected Actions

The Image Manager / Image 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 IAASR instances, store them, and make them available for query/retrieval.

The Contrast Information Consumer shall accept the IAASR instances when it is configured to do so. The IAASR instance shall be processed according to the features, configuration, and business logic of the Contrast Information Consumer. Possibilities include display, processing, analysis, printing, export, etc.

The Contrast Information Consumer shall recognize duplicate steps and phases based on the corresponding UIDs in the received IAASR instances (e.g., not catalog a step twice when the same step appears in two instances).

Note: IAASR instances include content items for EV (130246, DCM, "Imaging Agent Administration Performed Step UID") and EV (130261, DCM, "Imaging Agent Administration Performed Phase UID") which uniquely identify performed administration steps and phases. It is possible for the same step or phase to appear in multiple IAASR instances. For example, the same step might appear in both an SR reporting the completion of that step, and an SR reporting all the contrast administration steps for the entire procedure.

4.138.5 Security Considerations

The DICOM objects conveyed typically constitute personal health information.

4.138.5.1 Security Audit Considerations

This transaction is associated with a Begin-storing-instances ATNA Trigger Event on the Sender and an Instances-Stored ATNA Trigger Event on the Receiver.

760 The Radiology Audit Trail Option in the ITI Audit Trail and Node Authentication Profile (ITI TF-1:9) defines audit requirements for IHE Radiology transactions. See RAD TF-3: 5.1.

<i>Add Section 4.139</i>

4.139 Query Contrast Information [RAD-139]

4.139.1 Scope

765 This transaction requests and receives a list of instance metadata describing contrast information records (IAASR instances) matching a specified filter. The information may describe an administration that has been performed, or one that is planned.

The information is encoded using DICOM Structured Reports with standardized templates for contrast administration events.

770 4.139.2 Actor Roles

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.139.2-1: Actor Roles

Role:	Requester: Requests metadata describing contrast information records matching a specified filter.
Actor(s):	The following actors may play the role of Sender: Contrast Information Consumer
Role:	Responder: Responds to the query and returns matching results.
Actor(s):	The following actors may play the role of Receiver: Imager Manager/Archive

775 Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

4.139.3 Referenced Standards

- DICOM PS3.4: Query/Retrieve Service Class
- DICOM PS3.3 Section A.35.19: Planned Imaging Agent Administration SR IOD
- 780 • DICOM PS3.3 Section A.35.20: Performed Imaging Agent Administration SR IOD

4.139.4 Messages

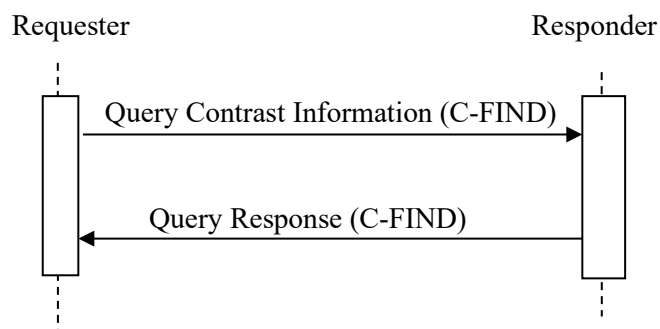


Figure 4.139.4-1: Interaction Diagram

4.139.4.1 Query Contrast Information Message

785 The Requester sends a filter to the Responder in a request for matching IAASR instances. The Responder shall support handling such messages from more than one Requester. The Requester shall support making requests to more than one Responder.

4.139.4.1.1 Trigger Events

790 A user or an automated function on the Requester needs to obtain information about IAASR instances on the Responder.

Typically, the trigger is associated with an intention of the Requester to later retrieve IAASR instances of interest. See Section 4.140 Retrieve Contrast Information.

4.139.4.1.2 Message Semantics

795 The message is a DICOM C-FIND request. The Requester is the SCU, and the Responder is the SCP. The Responder shall support both SOP Classes listed in Table 4.139.4.1.2-1. The Requester shall support at least one of the SOP Classes listed in Table 4.139.4.1.2-1.

Refer to DICOM PS3.4: Query/Retrieve Service Class for detailed description of the semantics.

Table 4.139.4.1.2-1: Query Contrast Information SOP Classes

DICOM SOP Class Name	SOP Class UID
Study Root Query/Retrieve Information Model – FIND	1.2.840.10008.5.1.4.1.1.88.74
Patient Root Query/Retrieve Information Model – FIND	1.2.840.10008.5.1.4.1.1.88.75

800 The Requester uses one or more matching keys as filter criteria to obtain the list of matching entries in the Responder at the selected level (Patient & Study/Series/Instance).

In addition to the required and unique keys defined by the DICOM Standard, the 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. (Query Images [RAD-14])

805 The Requester and Responder shall also support the IAASR Instance-specific keys as defined in Table 4.139.4.1.2-2. The requirement conventions for key usage in the following table are defined in RAD TF-2: 2.2.

Table 4.139.4.1.2-2: IAASR Instance Specific Query Matching and Return Keys

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
IAASR 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+

810 Note: CID 12 is a relevant Context Group for Contrast/Bolus Agent Sequence, CID 13 is a relevant Context Group for Contrast/Bolus Ingredient Code Sequence, and CID 11 is a relevant Context Group for Contrast/Bolus Administration Route Sequence.

4.139.4.1.2.1 Filtering Strategies

815 Since it may not be immediately obvious how to perform certain IAASR instance filtering based on the available matching keys, return keys, and instance content, some informative suggestions are provided here. The transaction does not require support for any of these in particular beyond requiring support for certain matching and return keys in Table 4.139.4.1.2-2.

Filtering can occur in three ways.

- Matching key filtering: the Responder only returns metadata for instances whose Matching key metadata passes the filter.
- 820 • Return key filtering: the Requester only retrieves instances whose Return key metadata passes the filter.

- Attribute/content filtering: the Requester retrieves all likely matching instances then only processes instances whose instance attribute values and instance content tree values pass the filter.

825 Notes: 1. Attribute/content filtering has access to the most details, but to avoid retrieving an unnecessarily large number of instances, it is useful for the Requester to also use the matching and return keys as a pre-filter.
2. The retrieval of matching instances is not part of C-FIND, but would use C-STORE or C-GET.

To filter for IAASR instances:

- 830 • Matching key - SOP Class UID (0008,0016) allows selection of the Planned Imaging Agent Administration SR Storage SOP Class and Performed Imaging Agent Administration SR Storage SOP Class.

To filter for contrast procedures in 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.

835 To filter for contrast procedures associated with specific modalities:

- Matching key - Modalities in Study (0008,0061) (e.g., CT, XA, MR, US)

Note: Some studies might have multiple procedures and even multiple modalities. The acquisition time attributes in the images can be matched to timestamps in the IAASR contrast instances to confirm which IAASR instances correspond to which images/modalities

840 To filter for contrast procedures associated with a specific study:

- Matching key – Study Instance UID (0020,000D) and/or Accession Number (0008,0050) allows selection of contrast procedures for a specific study.

To filter for contrast details associated with particular study images:

- 845 • Matching key – Study Instance UID (0020,000D) and/or Accession Number (0008,0050) allows selection of contrast procedures for the same study as the images.
- Return Key – Content Date (0008,0023) and Content Time (0008,0033) allows selection of contrast instances at roughly the same time as the frame time of the image.
- 850 • Instance Content Tree – (111526, DCM, "DateTime Started") and (C0449238, UMLS, "Duration") in the Imaging Agent Administration Activity container and the Imaging Agent Administration Phase container provide precise times for matching with images (noting that there may be some delay for the contrast bolus to appear in images and more time before the contrast washes out as well as details such as whether a saline chaser is administered, etc.)

To filter for specific infusion manager devices:

- 855 • Return key – Manufacturer (0008,0070), Manufacturer's Model Name (0008,1090), and/or Device Serial Number (0018,1000) allows selection of specific devices.

Note: Image Managers may not support these as Return keys, so it may be necessary to do Attribute/Content filtering.

To filter for specific imaging procedure types:

- 860 • Return Key – Study Description (0008,1030) might give a sense of which body region was the focus of the imaging.
- 865 • Instance Attribute - Performed Procedure Code Sequence (0040,A372) is Type 2, but if filled in the IAASR instance, 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.
- Instance Content Tree – Acquisition Protocol, if present, may also help identify the procedure type.

To filter for specific Infusion protocols:

- 870 • Instance Attribute – Scheduled Procedure Step Description (for planned IAASRs) and Performed Procedure Step Description (for performed IAASRs) may include description text about the infusion protocol.

To filter for specific contrast agents:

- 875 • Instance Content Tree – Drug Administered (coded value) or Brand Name (text) indicates a specific contrast agent or product name (e.g., (109218004,SCT,"Iohexol") or "Omnipaque")

To filter for a “bad lot” of contrast (e.g., after a recall):

- 880 • Matching Key – a Study Date filter for a specific date range (see above) might initially narrow the list of instances. The manufacturing date and expiration date of the recalled contrast lot might provide an initial coarse range. The hospital inventory system might narrow the dates to when the lot in question was in stock or removed for use.
- Instance Content Tree – the (130238, DCM, "Imaging Agent Component") container includes a variety of identifiers including (121149, DCM, "Lot Identifier"), (128739, DCM, "UDI") and (130231, DCM, "Barcode Value")

To filter for adverse events:

- 885 • Instance Content Tree – (C41331, NCI, "Adverse Event") indicates adverse patient events, and EV (130234, DCM, "Imaging Agent Administration Injector Event Type") indicates injector related events which can include specific values from CID 71 Imaging Agent Administration Injector Event Type for events such as (110501, DCM, "Equipment failure") or (130156, DCM, "Terminated due to pressure above termination limit")
- 890

To filter for specific route of administration and/or injection site:

- Instance Content Tree – (410675002, SCT, "Route of Administration") combined with (272737002, SCT, "Site Of") indicates how and where contrast was administered (e.g., (47625008, SCT, "Intravenous Route") and (260590008, SCT, "Via femoral artery").

895 Note: This may be of interest for infection control procedures or analysis.

To filter for patient age category:

- Return key – Patient's Birth Date (0010,0030) identifies 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.

900 **4.139.4.1.3 Expected Actions**

The Responder receives the C-FIND request, performs the matching on the provided keys and sends the list of matching records back to the Requester via C-FIND responses.

4.139.4.2 Query Response Message

The Responder returns the list of matching records to the Requester.

905 **4.139.4.2.1 Trigger Events**

The Responder receives a C-FIND request.

4.139.4.2.2 Message Semantics

The message is a DICOM C-FIND response. The Requester is the SCU, and the Responder is the SCP.

910 Refer to DICOM PS3.4: Query/Retrieve Service Class for detailed description of the semantics.

4.139.4.2.3 Expected Actions

The Requester may use the value of certain return keys to identify specific IAASR instances for subsequent retrieval. See Section 4.138.4.1.2.1 for details. Some details are only available by first retrieving and then parsing the IAASR instances.

915 **4.139.5 Security Considerations**

The patient demographics and clinical record details returned in the response, and potentially matching details contained in the query, typically constitute personal health information.

4.139.5.1 Security Audit Considerations

This transaction is associated with a Query Information ATNA Trigger Event on the Receiver.

920 The Radiology Audit Trail Option in the ITI Audit Trail and Node Authentication Profile (ITI TF-1:9) defines audit requirements for IHE Radiology transactions. See RAD TF-3: 5.1.

<i>Add Section 4.140</i>

4.140 Retrieve Contrast Information [RAD-140]

925 **4.140.1 Scope**

This transaction requests and receives a specific contrast information record (IAASR instance). The information may describe an administration that has been performed, or one that is planned.

The information is encoded using DICOM Structured Reports with standardized templates for contrast administration events.

930 **4.140.2 Actor Roles**

The roles in this transaction are defined in the following table and may be played by the actors shown here:

Table 4.140.2-1: Actor Roles

Role:	Requester: Requests a specific contrast information record instance.
Actor(s):	The following actors may play the role of Sender: Contrast Information Consumer
Role:	Responder: Provides the requested instance.
Actor(s):	The following actors may play the role of Receiver: Imager Manager/Archive

935 Transaction text specifies behavior for each role. The behavior of specific actors may also be specified when it goes beyond that of the general role.

4.140.3 Referenced Standards

- DICOM PS3.4: Query/Retrieve Service Class
- DICOM PS3.3 Section A.35.19: Planned Imaging Agent Administration SR IOD

- 940 • DICOM PS3.3 Section A.35.20: Performed Imaging Agent Administration SR IOD

4.140.4 Messages

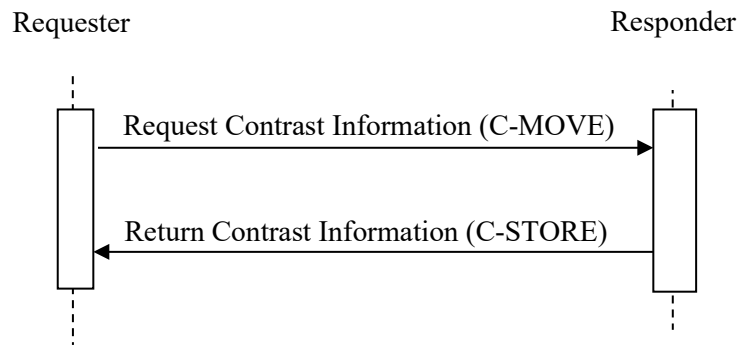


Figure 4.140.4-1: Interaction Diagram

4.140.4.1 Request Contrast Information Message

- 945 The Requester requests that the Responder return an IAASR instance to the Requester.
The Responder shall support handling such messages from more than one Requester. The Requester shall support making requests to more than one Responder.

4.140.4.1.1 Trigger Events

- 950 A user or an automated function on the Requester determines that it needs an IAASR instance that is stored on the Responder.

4.140.4.1.2 Message Semantics

The message is a DICOM C-MOVE request. The Requester is the SCU, and the Responder is the SCP.

- 955 The Requester and Responder shall support the Study Root Query/Retrieve Information Model - MOVE SOP Class. This requires that C-MOVE also be supported at the Series Level. Refer to the DICOM PS3.4 Annex C for detailed message semantics.

4.140.4.1.3 Expected Actions

The Responder returns a C-MOVE response as described in DICOM PS3.4 C.4.2.3.

4.140.4.2 Return Contrast Information Message

- 960 The Responder returns an IAASR instance requested by the Requester.

4.140.4.2.1 Trigger Events

The Responder receives a C-MOVE request for IAASR instances.

4.140.4.2.2 Message Semantics

The message is a DICOM C-STORE. The Responder is the SCU, and the Requester is the SCP.

- 965 The Responder shall support both SOP Classes listed in Table 4.140.4.2.2-1. The Requester shall support at least one of the SOP Classes listed in Table 4.140.4.2.2-1.

Table 4.140.4.2.2-1: Retrieve Contrast Information SOP Classes

DICOM SOP Class Name	SOP Class UID
Planned Imaging Agent Administration SR	1.2.840.10008.5.1.4.1.1.88.74
Performed Imaging Agent Administration SR	1.2.840.10008.5.1.4.1.1.88.75

- 970 The contents of the IAASR instances are based on TID 11001 “Planned Imaging Agent Administration” or TID 11020 “Performed Imaging Agent Administration” depending on the SOP Class.

Note: these templates are extensible. See DICOM PS3.16 Section 6.2.5 Extension of Templates.

The Responder establishes a DICOM association with the Requester and uses the DICOM C-STORE command to transfer the requested IAASR instances.

975 4.140.4.2.3 Expected Actions

The Requester shall accept the IAASR instances.

The IAASR instances will be processed according to the features, configuration, and business logic of the Requester. Possibilities include display, processing, analysis, printing, export, etc.

- 980 The Requester shall recognize duplicate steps and phases based on the corresponding UIDs in the retrieved IAASR instances (e.g., not catalog a step twice when the same step appears in two instances).

- 985 Note: IAASR instances include content items for EV (130246, DCM, "Imaging Agent Administration Performed Step UID") and EV (130261, DCM, "Imaging Agent Administration Performed Phase UID") which uniquely identify performed administration steps and phases. It is possible for the same step or phase to appear in multiple IAASR instances. For example, the same step might appear in both an SR reporting the completion of that step, and an SR reporting all the contrast administration steps for the entire procedure.

4.140.5 Security Considerations

The DICOM objects conveyed typically constitute personal health information.

4.140.5.1 Security Audit Considerations

- 990 This transaction is associated with an Instances-Stored ATNA Trigger Event on the Sender and a Study-used ATNA Trigger Event on the Receiver.

Volume 3 – Cross-Transaction Specifications and Content Specifications

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

5.1 Record Audit Event [ITI-20]

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
Patient Registration [RAD-1]	Patient-record-event	ADT Order Placer, DSS/OF - when PHI is presented
...		
<u>Store Contrast Information [RAD-138]</u>	<u>Instances-stored</u>	<u>Receiver: Image Manager</u>
<u>Query Contrast Information [RAD-139]</u>	<u>Query Information</u>	<u>Responder: Image Manager</u>
<u>Retrieve Contrast Information [RAD-140]</u>	<u>Instances-stored</u>	<u>Responder: Image Manager</u>
	<u>Study-used</u>	<u>Requester</u>
...		

Volume 4 – National Extensions

1000 *No national extensions are currently defined by this profile.*