Integrating the Healthcare Enterprise

IHE Radiology
Technical Framework Supplement

Management of Acquisition Protocols (MAP)

Rev. 1.0 – Draft for Public Comment

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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 15.0. 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 March 17, 2017 for public comment. Comments are invited and can be submitted at http://www.ihe.net/Radiology_Public_Comments. In order to be considered in development of the trial implementation version of the supplement, comments must be received by April 16, 2017.

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.

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Introduction to this Supplement

This supplement introduces the Management of Acquisition Protocols Profile.

The Management of Acquisition Protocols Profile supports the collection of scan protocols from acquisition modalities, their review on a protocol manager and re-distribution to modalities. Protocol managers are permitted to edit attributes marked safe by the creating modality. Such attributes will likely include protocol names, dose notification thresholds and series names for generated images.

The transactions are based on storage, query and retrieval of DICOM®[1] instances containing scan procedure protocols and protocol approvals. Although the profile is agnostic to the type of modality, as of 2016 DICOM has only published the specification for a CT Protocol Storage object. Other modalities are being investigated but the specifications have not yet been published.

Open Issues and Questions

1a. Should collection of protocols from Modalities be push, pull, or both? **A: This draft only requires push. Feedback is requested.** Requiring both increases implementation burden but arguably increases flexibility of use. Modality Push (Store) requires either automation on the Modality to immediately push any new or edited protocol, and/or some trigger to send all protocols (e.g., manual send, automated periodic upload, trigger message from Protocol Manager?) Manager Pull (Query/Retrieve) is convenient for an operator at the central Manager to ensure they have all/newest protocols from all devices. But it requires Modalities to implement a C-FIND SCP which they do not typically do. OTOH it could be a very simplistic SCP since the Manager really only needs a list of instances to retrieve; the Manager is probably not going to as the Modality to do advanced filtering. Also, if the Manager already has most of the protocols, it could choose to only retrieve the ones it doesn't have rather than retrieving everything all the time. Modalities don't like to respond to async requests which can be disruptive. The Protocol Manager/Store will be purpose built.
1b. Should distribution of reviewed protocols to Modalities be push, pull, or both? **A: This draft only requires push. Feedback is requested.** On one hand, the Manager knows when it has new information available for any given modality. Manager Push (Store) would likely involve sending the entire set of protocols "assigned" to a given modality. The modality would need to reject the association if the transmission came at an inopportune time. How would the transmission be re-initiated?

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

Modality Pull (Query/Retrieve) would let the Modality know which instances were assigned to it and to retrieve only those it did not already have. The Modality could further subset the list of instances using query filters. The same/similar source code could be used by the Modality to poll a protocol library.

In either case, (although especially in the Push case since it was not initiated by the Modality) it is likely that the modality would hold the distributed protocols in some kind of import hopper until they were accepted for use. Protocols on a modality can't change "by surprise". And the modality may need to do a (re-)validation of the contents of each protocol before it is available for execution.

2. How does a Protocol Manager confirm deprecation of a protocol by a Modality?

A: Can't really tell. Practical suggestions are welcome.

Possible approaches:

- **Human checks the modality at some point. Software methods would depend on how the modality handles deprecations and would likely require implementing extra services.**
- Protocol Manager queries the Modality and looks for the absence of the deprecated protocols. But this would require the modality implement a Q/R SCP just for this.
- Could have a notification of the deletion/deprecation from Modality to the PM
    - But modality might have deleted a protocol just to reduce clutter knowing it can get later.
- Have a deprecated flag in the protocol and the modality could set it and thus the change appears on the PM

3. Are the transactions REST (DICOMWeb/FHIR) or DIMSE or both?

A: This draft profiles and requires REST only. Feedback is requested.

The technical committee preferred REST for several reasons:

- The protocol part of scanner does not currently use the DIMSE stack. Modifying/adopting the DIMSE stack might be more difficult than adding a web-service
- Defined Protocols are Non-Patient Objects which are not necessarily supported in current DIMSE code
- Programming and testing REST is perceived as significantly easier than DIMSE
- RESTful frameworks might have useful change management capabilities relevant to handling a set of continuously evolving protocols
- VNAs may support the profile and although they support REST and DIMSE, some prefer REST

The committee acknowledges that DIMSE Query/Retrieve/Store is widely implemented/familiar already for Patient objects and there is a risk of the profile foundering on unfamiliar/untested interfaces and toolkits.

Note that the profile could also, in theory, mix, e.g., use REST for Store and DIMSE for Query/Retrieve, if the target systems "split".

<Isolate the Security discussion if we decide that otherwise we would want to do DICOMweb>

4. Should any of the Protocol Manager functions in X.4.1.8 be made required?

A: Feedback is requested.

Currently all such functions are optional.

5. Does the profile need to discuss authentication of the authority of people editing protocols?

A: No. Local policy. Merge into above password discussion.
6. Would more specific guidance on the use of RadLex Playbook codes would be helpful?

Closed Issues

1. Are Modalities required to accept protocols created by the Protocol Manager or another make of scanner? **A: No.** DICOM Sup121 presumes that it would be impractical for various vendor modalities to externalize the logic for composing new protocols (e.g., interactions between related parameters, hardware constraints, etc.). Modalities are not prohibited from accepting "foreign" protocols, but can be expected to reject any protocols that were not generated by the same make, and perhaps the same model and version as well. That being said, a helpful modality might supporting displaying the contents of a foreign protocol and help the user compose a "native" protocol that performs similarly. If someone is so inclined, a product could choose to implement one (or more) "Acquisition Modality Actors" that are really scanner console software without a gantry and group them with a Protocol Manager Actor, which would then have the necessary logic but that's beyond this profiles requirements. If we think this may be a common pattern we might create a Protocol Editor Actor.
2. How should version control of protocols be handled? **A: New instances, no "versions"** DICOM does not allow such instances to be modified. New instances must be created. Attributes exist to point to "prior" instances from new instances. Profiling of certain Label/Name attributes might be helpful.
3. How quickly is Modality required to expose an internal protocol as a DICOM object? **A: Push Mode requires the modality to "promptly" dicomize and send new or modified protocols.** In Pull Mode, the modality is permitted to dicomize internal protocols upon retrieve request.
4. Should any actors be required to export Protocols on media? **A: Permitted, but not required.** It is useful, but not vital for any of the use cases. Section X.6 can mention grouping several actors with a Media Creator and/or Importer.
5a. How are decisions (deprecations) made on the Protocol Manager communicated to the Modality? **A: Protocol Manager sends Approval instances to Modality.**

During the review process at the Protocol Manager, decisions will be made about whether some protocols should not be used, and perhaps which protocols are explicitly approved for certain purposes (clinical use, clinical trial use, etc.).

Those decisions (especially deprecation) need to be effected at the point of use, i.e., the Acquisition Modality.

Protocol Manager will likely maintain a persistent internal database of which protocols have been approved or disapproved by what people for what purpose. The PM creates and sends Approval Instances deprecating the specific protocol(s) to the modality.

One Approval instance can approve multiple protocols. One Protocol can be the subject of multiple Approval instances. An Approval instance has a subject sequence that references the Protocol instances being approved. Protocol instances do not maintain a list of Approvals (for obvious practical reasons). Pushing approvals when made would avoid the need for the modality to implement Q/R, although it would have to manage a local cache of the pushed Approval instances.

Possible reasons for deprecation:

- a protocol has been replaced by a new/better protocol
- a protocol created/revised by a tech or radiologist is considered inappropriate because it:
    - violates site policies
    - generates inappropriate dose levels
    - produces images of inadequate quality
    - is inconsistent with other protocols in use

Other approaches considered:

- Protocol Manager sends a "full protocol batch" to the Modality and any omitted protocols are implicitly deprecated. (But that depends on indirect rather than direct semantics and it might not always be clear)
- Protocol Manager sends an IOCM instance deprecating specific protocol(s). (But since IOCM is Study based, it would need to be modified anyway so might as well do an Approval Instance.)
- Modality queries the Protocol Manager for Approval Instances related to a given protocol. (But that raises timing/workflow/performance issues and requires extra implementation)
- Protocol Manager uses the (non-existent) DICOM Request Deletion Service. (But that's non-existent)
- Protocol Manager lists deprecation alongside other edits in the Modality Planned Edits list (X.4.1.4). But that's not very automated.
- Protocol Manager could set the "WIP" flag (or better a Do Not Use flag) on a version of the protocol and sent it out. (But since it needs to specify the UID of the deprecated protocol)

Note that there will inherently be some lag between the decision being made and being communicated to the modalities, communicated to the operator, and acted on.

Note also the interaction between central **evaluation/approval** of a protocol by a chief radiologist, physicist, or chief tech, and local (on the scanner) control by the scanner to accept the revised protocol and by the technologist to confirm the go-live/switchover. Approval does not oblige the scanner to execute a protocol that violates internal controls, and the work of the tech should not be disrupted by things like protocols unexpected changing during setup etc. The profile mandates interoperability features, not local behaviors.

5b. How are deprecation/approval decisions received by a Modality communicated to the operator?

A: Modality required to communicate to operator but how is not constrained.

Note the sequencing issue if you receive a protocol approval before the protocol itself.

Possible approaches considered:

- Modality deletes deprecated protocols completely
- Modality sequesters deprecated protocols on a "deprecated" tab/folder in the protocol user interface so they don't appear in the standard selection list
- Modality identifies deprecated protocols in the list (e.g., color red, strikethrough, deprecation mark)
- Modality notifies the operator (e.g., via popup like Dose Check) when a selected protocol is explicitly disapproved or missing a particular approval
- Modality is not required to do anything, i.e., is permitted to ignore the deprecation and not communicate it to the operator.

See X.1.1.2 and X.4.1.9.

5c. Should the profile describe how protocols are organized/presented to the operator?

A: Not as requirements, but it's useful to understand.

Most modalities allow protocols to be grouped into sets. For example, they may have "folders" and protocols can be moved between the folders. Or it may be presented as tags that can be applied to protocols, then listings of protocols are filtered based on the presence or absence of certain tags. Some sites use these to put protocols into different "states".

This can be used to

- "hide" protocols that are not in common use
- isolate Service/QC, Research or Clinical Trial protocols that should not be used clinically
- indicate that a protocol is being edited as a Work In Progress and not ready for use
- Move protocols around in the interface for selection. Different picklists.

6. How will "planned edits" be conveyed from the Manager to the Modality?

A: Out of band. Describe in Concepts.

7. Should Modalities be required to create Performed Protocols?

A: No. A Named Option might be added later if there is demand.

The profile is primarily focused on managing Defined Protocols that are patient non-specific.

The value and applications of storing Performed Protocols are described in the Concepts section.

Existing query/retrieve transactions would largely work for Performed Protocols since they are patient objects.

8. Should Protocol Managers be required to collect and review Performed Protocols?

A: No. A Named Option might be added later if there is demand.

The value and applications of reviewing Performed Protocols are described in the Concepts section.

9. How will other modalities be added in the future?

A: Will look when we get there. Several reasonable approaches.

The profile currently only addresses CT explicitly. It is intended that other modalities may be addressed in the future when protocol objects are available for them.

Possible approaches

- Modality-specific profiles (most of the content would be cloned/reused/referenced)
- Named option for each modality in this profile
- Generic profile and customers need additional product documentation to know what's supported
- Require all Protocol Managers to retroactively support all (CT, MR, XA, etc.)

All the above approaches permit actors to support multiple modalities in a single product.

Will also consider how "hybrid" modalities are handled. PET/CT and PET/MR are two examples. Once DICOM Contrast Protocols are available, CT-with-Contrast might be a "hybrid" protocol with a CT Protocol and an Injector Protocol.

A Worklist entry could point to both. A mapping table could pair a primary CT protocol to an associated Injector protocol. A combo-protocol might be designed.

10. Should an Order Filler Actor be added to the profile and required to support Protocolling per X.4.1.13?

A: No. Easy to add a new actor later when we understand more details.

This might require a Protocolling actor that could be implemented by the RIS or standalone and would likely Q/R protocol sets from the Protocol Archive. If not grouped with the Order Filler, it would need a way to modify the Modality Worklist.

GUI requirements might also be needed on the Modality to display relevant fields to the operator for this to work.

11. Should Modality push to Protocol Manager or to PACS?

A: Profile a Protocol Archive Actor

Break out the push target as an Archive Actor. A Modality can push to the Archive Actor which might be implemented by a PACS or by a Protocol Manager. The PM would be required to Q/R in case it is not the Archive. If the PACS implements the Archive, you get robust backups/uptime presumably in place for the PACS.

RIS and other actors could Q/R the Archive. The Archive is effectively a Protocol Library.

12. Is splicing/compositing of protocols during a study in scope?

A: No. It really affects Performed Protocols not Defined.

"Slicing/compositing" for a given study means incorporating parts of multiple Defined Protocols, e.g., take Protocol 1 and add Protocol 6 as an extra series.

Sometimes an orderable that comes from the CPOE system is not clear or detailed. Some refinement or clarification may be necessary but that likely falls in the realm of "Protocolling" described in X.4.1.13.

Some (all?) CTs can pull up a second protocol in the middle of doing a first and splice them together. This may be done as a variant of the Group Case concept described in SWF. One can also append additional reconstructions. E.g., for a trauma CAP (Chest-Abdomen-Pelvis) and spine, the CAP acquisition is sufficient and the spine can be handled as additional reformats without doing a second acquisition.

This is a feature of the Acquisition Modality and the Defined Protocols being managed are not directly affected. **The Performed Protocol, if created, will contain elements that represent some combination of Defined Protocol elements but such behavior is not prevented by this profile.** There is also the concept of "sub-protocols" as described in X.4.1.14. If a Defined Protocol uses private attributes to "#include" another sub-protocol, that probably does not conflict with anything in this profile, although it might make it more challenging for the Protocol Manager to display the "effective" contents of the protocol unless it knows to splice in the sub-protocol.
13. Should access control (password) capabilities be required by the profile for changes to saved protocols? **A: No. This is a local policy requirement, not a profile thing.** E.g., require that Acquisition Modalities be capable of restricting access to the ability to modify saved protocols so that sites can decide to use that capability or not? Besides, arguably more important for the approval process on the Protocol Manager anyway.

TODOs

DICOM CP - DICOMDIR supports NPOs but need to add it to the list (PS3.3 Annex F, F.3 and F.4) Also need to specify for the record type what the keys are that go into the dir. There are categories of SOPs that share the same DIR entry (same keys etc.).

DICOM CP – Clarify how to encode in the protocol which (if any) device options the protocol depends on (thus must be present). Might also need to include power injector type and presence of an insufflator or other in room device. E.g., a split bolus CTA protocol will depend on an advanced power injector.

DICOM CP - Add RDSR extensions to audit scan constraint violations in the same way we audit dose check violations.

DICOM CP - Add a MWL field to hold references to specific Defined Procedure Protocol instances.

DICOM CP - Add a WIP flag to Defined Procedure Protocol instances. See discussion in Section X.4.1.12 Generating Protocols.

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 new actors to the IHE Technical Frameworks General Introduction list of actors:

Actor	Definition
Protocol Manager	Manages protocols used by Acquisition Modalities.
Protocol Archive	Stores protocols and supports query and retrieval.

Appendix B - Transaction Summary Definitions

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

Transaction	Definition
Store Protocol [RAD-Y1]	Transfers a DICOM Defined Procedure Protocol object from a Sender to a Receiver.
Query Protocol [RAD-Y2]	Requests and receives metadata about Protocol objects matching a specified filter.
Retrieve Protocol [RAD-Y3]	Retrieves a DICOM Defined Procedure Protocol object.
Store Protocol Approval [RAD-Y4]	Transfers a DICOM Protocol Approval object from a Sender to a Receiver.

Glossary

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

None

Volume 1 – Profiles

Add the following to the IHE Technical Frameworks General Introduction Copyright section:

X Management of Acquisition Protocols (MAP) Profile

The Management of Acquisition Protocols Profile supports the collection of scan protocols from acquisition modalities, their review, approval, archival and re-distribution to modalities. Protocol managers may also edit attributes marked safe by the creating modality, which will likely include protocol names, dose notification thresholds and series names for generated images.

The transactions are based on storage, query and retrieval of DICOM instances containing scan procedure protocols and protocol approvals. Although the profile is agnostic to the type of modality, as of 2016 DICOM has only published the specification for CT Protocol Storage. Other modalities may be investigated but the specifications have not yet been published. This profile lists a single IOD that is supported: CT Defined Procedure Protocol.

X.1 MAP 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://ihe.net/Technical_Frameworks.

Figure X.1-1 shows the actors directly involved in the MAP 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.

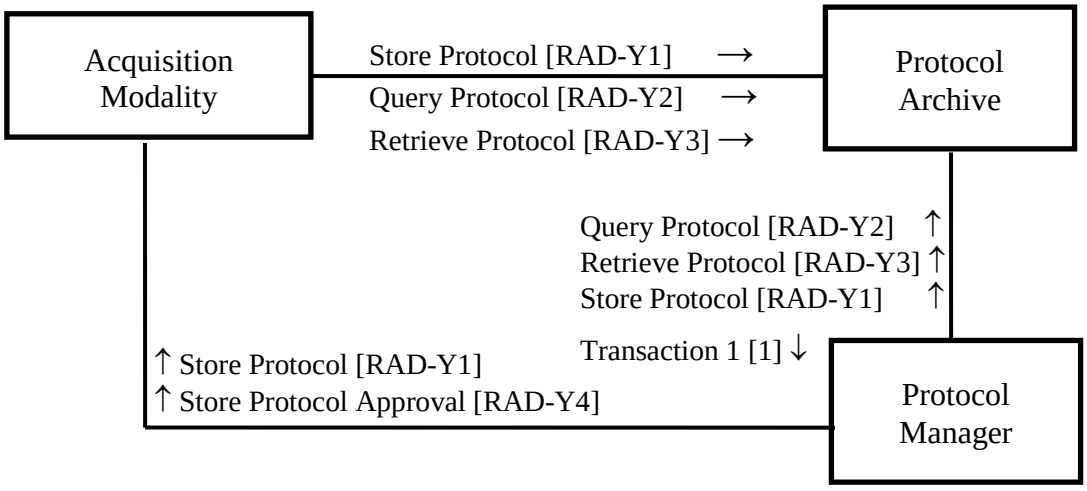

Figure X.1-1: MAP Actor Diagram

Table X.1-1 lists the transactions for each actor directly involved in the MAP 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 X.1-1: MAP Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Protocol Manager	Store Protocol [RAD-Y1]	R	RAD TF-3: 4.Y1
	Query Protocol [RAD-Y2]	R	RAD TF-3: 4.Y2
	Retrieve Protocol [RAD-Y3]	R	RAD TF-3: 4.Y3
	Store Protocol Approval [RAD-Y4]	R	RAD TF-3: 4.Y4
Acquisition Modality	Store Protocol [RAD-Y1]	R	RAD TF-3: 4.Y1
	Query Protocol [RAD-Y2]	R	RAD TF-2: 4.Y2
	Retrieve Protocol [RAD-Y3]	R	RAD TF-3: 4.Y3
	Store Protocol Approval [RAD-Y4]	R	RAD TF-3: 4.Y4
Protocol Archive	Store Protocol [RAD-Y1]	R	RAD TF-3: 4.Y1
	Query Protocol [RAD-Y2]	R	RAD TF-3: 4.Y2
	Retrieve Protocol [RAD-Y3]	R	RAD TF-3: 4.Y3

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in Transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 Protocol Manager

The Protocol Manager is required to support collecting protocols by query/retrieve from a separate Protocol Archive. When the Protocol Manager is grouped with a Protocol Archive, it is still required to support Query/Retrieve but it is permitted to use internal mechanisms to access protocols in the grouped Protocol Archive.

The Protocol Manager shall support distributing protocols as directed by the user to Acquisition Modalities using [RAD-Y1].

The Protocol Manager shall not modify constraints for which the Modifiable Constraint Flag (0082,0038) has been set to NO.

When a Protocol is approved, the Protocol Manager shall send a copy of the corresponding Protocol Approval instance to all appropriate Acquisition Modalities (e.g., ones to which it has distributed a copy of the Defined Procedure Protocol(s) referenced in the disapproval).

X.1.1.2 Acquisition Modality

The Acquisition Modality shall be configurable to activate/deactivate Protocol Update Push Mode and maintain a list of push destinations. When Protocol Update Push Mode is active, the Acquisition Modality shall generate a DICOM Defined Protocol instance and send it to the list of push destinations when a defined protocol is created or modified on the console.

In each Defined Procedure Protocol instance, the Acquisition Modality shall include constraint items with the Modifiable Constraint Flag (0082,0038) set to YES for the following attributes:

- Institution Name (0008,0080)
- Institution Code Sequence (0008,0082)
- Responsible Group Code Sequence (0008,0220)
- Protocol Name (0018,1030)
- Potential Scheduled Protocol Code Sequence (0018,9906)
- Potential Requested Procedure Code Sequence (0018,9907)
- Potential Reasons for Procedure (0018,9908)
- Potential Reasons for Procedure Code Sequence (0018,9909)
- Potential Diagnostics Tasks (0018,990A)
- Contraindications Code Sequence (0018,990B)
- Predecessor Protocol Sequence (0018,990E)
- Content Creators Name (0070,0084)
- Content Creator's Identification Code Sequence (0070,0086)
- Protocol Design Rationale (0018,9910)
- Protocol Planning Information (0018,990F)
- Instance Creation Date (0008,0012)
- Instance Creation Time (0008,0013)
- CTDIvol Notification Trigger (0018,9942)
- DLP Notification Trigger (0018,9943)
- Requested Series Description (0018,9937)
- Destination AE (2100,0140)
- Storage URL (0040,4073)
- Repository Unique ID (0040,E030)

- Home Community ID (0040,E031)

Note: The Acquisition Modality is required to permit modification of the above attributes but is not necessarily required to include any constraints on them. This is intended to allow an operator at the Protocol Manager to set values for the above attributes without giving them permission to add arbitrary attributes to protocol instances.

The Acquisition Modality is permitted to reject any received protocol instance based on its content (e.g., reject protocols that are designed for other models). The Acquisition Modality shall be capable of informing the operator of protocols that have been received and rejected and the reason for rejection.

The Acquisition Modality is permitted to ignore instances that it receives which have the same SOP Instance UID as instances it already holds. Such instances can be considered duplicates since a modified protocol would need to be sent to the Acquisition Modality with a new SOP Instance UID.

When a protocol is modified, the SOP Instance UID of the instance before it was modified may be recorded in the Predecessor Protocol Sequence (0018,990E) of the new modified protocol instance.

The Acquisition Modality shall communicate to the operator whether any given Defined Procedure Protocol has been disapproved or approved and make available details of the approval/disapproval. The method of communication is not prescribed by this profile. See Section X.4.1.9 Protocol Approvals for further discussion.

The Acquisition Modality shall notify the operator when parameters for the current Defined Procedure Protocol are modified at execution time such that they violate a constraint encoded in the protocol instance. The method of notification is not prescribed by this profile. See Section X.4.1.10 Protocol Constraints for further discussion.

X.2 MAP Actor Options

Options that may be selected for each actor in this profile, if any, are listed in Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: Management of Acquisition Protocols - Actors and Options

Actor	Option Name	Reference
Protocol Manager	No options defined	--
Protocol Archive	No options defined	--
Acquisition Modality	No options defined	--

X.2.1 <Option Name>

<Remove after Public Comment if none. >

X.3 MAP 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 X.5 describes some optional groupings that may be of interest for security considerations and Section X.6 describes some optional groupings in other related profiles.

Table X.3-1: Management of Acquisition Protocols - Required Actor Groupings

MAP Actor	Actor to be grouped with	Reference	Content Bindings Reference
Protocol Manager	ITI Consistent Time / Time Client	ITI TF-1: 7.1	--
	ITI ATNA Secure Node or Secure Application	ITI TF-1: 9.4	
Protocol Archive	ITI ATNA Secure Node or Secure Application	ITI TF-1: 9.4	--
Acquisition Modality	ITI ATNA Secure Node or Secure Application	ITI TF-1: 9.4	--

Note 1: No auditing requirements for the ATNA support beyond the mandatory set.

X.4 MAP Overview

Managing scan protocols is a fundamental part of ensuring appropriate image quality and radiation dose, which in turn directly affect patient and procedure safety and clinical outcomes. Great care goes into tuning protocols to best answer clinical questions.

There is currently no way to manage protocols centrally across devices. This creates inefficiency, inconsistency and chaos in the management of protocols at radiology sites.

DICOM defines SOP classes to distribute planned CT protocols and to record performed CT protocols. IHE Radiology has the Assisted Acquisition Protocol Setting Option in Scheduled Workflow, which enables the operator to use procedure codes provided in the modality worklist to select the acquisition protocol.

A Protocol Manager would enable centralized management of protocols across Acquisition Modality devices.

Several vendors have implemented proprietary protocol management functions. Modality, PACS, RIS and EHR vendors would all benefit from having a standardized method for performing this function.

X.4.1 Concepts

X.4.1.1 Defined Protocols, Performed Protocols and Internal Protocols

Internal Protocols are the set of protocols most Acquisition Modalities have stored on the console, generally using a proprietary format. To import or export them, Internal Protocols are transcoded to/from Defined Protocols.

Defined Protocols are the focus of this profile. Defined Protocols are Internal Protocols that have been transcoded into a DICOM Defined Procedure Protocol Storage IOD structure, e.g., the CT Defined Procedure Protocol IOD (see DICOM PS3.3 A.82.2). Defined Protocols are independent of a specific patient. Defined Protocols are typically specific to a certain scanner model and/or version (identified by device attributes in the protocol). Generic (model-non-specific) protocols are not prohibited, but will depend on the Acquisition Modality choosing to support such things (see Section X.4.1.12 Generating Protocols). A key point is that Defined Protocols describe constraints on the values of various parameters of an acquisition and reconstruction procedure. For example, a parameter is constrained to have a particular value or is constrained to fall within a particular range.

When technologists perform an acquisition (and/or reconstruction), they adjust parameter values for that particular exam based on their instructions and training (presumably staying within the constraints). Performed Protocols can be used to store the value actually used for each parameter in a performed acquisition and/or reconstruction.

Performed Protocols are not addressed by this profile and refer to instances of a DICOM Performed Procedure Protocol IOD. Performed protocols are patient-specific and may be stored in the folder for the corresponding Study.

X.4.1.2 Private Tag Dictionaries

Acquisition Protocols can involve details that are very specific to the design and engineering of the particular model of scanner for which the protocol is intended. Since such details typically go beyond the standard DICOM attributes, the vendors encode those details using DICOM private data elements (see DICOM PS3.5 Section 7.8 Private Data Elements).

The fidelity of the protocol depends on private data elements being preserved so there are requirements in the transaction to that effect.

Reviewing protocols on a Protocol Manager would benefit greatly from being able to display all parameters, including private data elements, to the operator. The Private Data Element Characteristics Sequence (0008,0300) was introduced for just this purpose (see DICOM PS3.3 12.1 SOP Common Module). Acquisition Modalities are strongly encouraged to populate this sequence in the Defined Procedure Protocol instances they create, and Protocol Managers are encouraged to take advantage of this information. The sequence provides details about each private data element including its name and encoding details.

X.4.1.3 Modifiable Parameters

Protocol parameter values often have dependencies on other protocol parameters. For example, changing the table speed might require an adjustment to the pitch, or changing the tube current may affect a tube cooling parameter. The necessary logic to deal with such issues is present in the modality console but would not be present in a 3rd party protocol management workstation.

New protocol instances derived from original protocol instances with different constraints on a given parameter "modify" the constraint. To avoid the risk of patient harm, equipment damage or inadequate image quality, systems such as the Protocol Manager are instructed not to modify constraints unless the corresponding Modifiable Constraint Flag (0082,0038) has been set to YES by the Acquisition Modality.

For example, a CT device that creates a Defined Procedure Protocol, may indicate that the Element Name (0018,9922) of the Acquisition Protocol Element, or the CTDIvol Notification Trigger (0018,9942) constraints may be modified, but the Spiral Pitch Factor (0018,9311) constraint may not since the latter depends on correlated changes by the device to other attributes. By setting the Modifiable Constraint Flag (0082,0038) to YES for the CTDIvol Notification Trigger (0018,9942), the Acquisition Modality permits convenient central management of these dose popup thresholds. Similarly, it is useful to be able to centrally edit Series Names and other parameters such as those listed in Section X.1.1.2.

Note: There is a difference between these "derivation" modifications and what an operator does at the time of protocol execution. At execution time, the operator is using the CT device to change Selector Attribute values and those values are compared to the Constraint Values in the Constraint Macro of the Defined Protocol. The result may (or may not be) stored in a Performed Procedure Protocol instance. At derivation time, an operator is using a workstation to change Constraint Values in the Constraint Macro and store a new Defined Procedure Protocol Instance.

X.4.1.4 Planned Edits

A reviewer working on the Protocol Manager is likely to identify protocol parameters that should be changed, but can only be modified on an appropriate scanner console since they have not been identified as Modifiable Parameters. For example, the reviewer might observe that the protocol is acceptable but it would be desirable to reduce the rotation time and raise the mA to make the scan duration shorter.

The Protocol Manager may support collecting such notes and generating a list of such changes for printing or viewing remotely. This would facilitate making the correct edits later when using the appropriate Acquisition Modality console. Once edited there, the updated protocol is available to the Protocol Manager and can be distributed to other similar scanners as appropriate.

X.4.1.5 Tracking Protocol Changes

Changes to protocols may be driven appropriately by a variety of factors:

- Updates to guidance (e.g., AAPM)
- Merger of imaging centers and merging of preferences

- Updating procedure code sets (e.g., adopting Radlex Playbook)
- Buying a new model scanner and adjusting the default protocols
- Trying to add two protocols together to fit a common order
- Meeting Dose targets
- Adding phases
- Clinical Trials change their imaging requirements
- Seeing a new protocol in the literature

Protocols are also changed inappropriately, for example:

- "N=1 changes" where, based on an observation of a single case, a radiologist modifies and saves a Defined Protocol to address an issue (e.g., noise) that was not actually a problem in typical practice
- Techs may modify the scan protocol name and/or series description to help them remember some detail but the changes disrupt other parts of the workflow such as the hanging protocols and post-processing that also depend on the series description

The frequency of changes vary by setting. Some academic sites might change many protocols each week. Some small sites might only change protocols once a year.

Site policies also vary. Some sites will discourage or prevent techs from making changes to saved protocols. Making scan-by-scan adjustments are a normal, expected part of the technologists work, but those are reflected in the scan, not in the saved protocol. Other sites will allow all techs to freely make changes to saved protocols. This profile does not dictate policy but rather tries to facilitate expected policy variations.

Some sites may wish to proactively monitor individual protocol changes made on modalities (e.g., on a "realtime" basis) in addition to the systematic review described in Use Case #1.

The Protocol Manager might support a configurable notification feature to alert such reviewers when new/changed protocols have been sent from an Acquisition Modality. The reviewer could then use the other features of the Protocol Manager to evaluate and/or log the changes.

DICOM generally requires that modification of an instance results in a new instance, with a new instance UID. It may be useful to identify new instances, that are a modification of an existing instance, as opposed to an instance that is truly created de novo. The Predecessor Protocol Sequence (0018,990E) of the new instance can list a preceding instance from which it was derived, indicating that it may be a version of the predecessor. It may also be useful to compare other attributes from the Protocol Context Module (see DICOM PS3.3 Table C.34.2-1) such as the Protocol Name (0018,1030), the Potential Scheduled Protocol Code Sequence (0018,9906), or the Potential Requested Procedure Code Sequence (0018,9907).

X.4.1.6 Tracking Protocol Usage

It may be useful to identify studies performed with a given Defined Procedure Protocol, for example to evaluate the image quality or dose.

The General Series Module contains the Referenced Defined Protocol Sequence (0018,990C), so the images can reference the Defined Procedure Protocol that was used to create them.

Although an Acquisition Modality is not required by this profile to create Performed Procedure Protocol instances, if it does so, the Acquisition Modality is required to reference the UID of any Defined Procedure Protocol instance(s) that were used. The Acquisition Modality may also include the above sequence in the series level attributes of any images produced.

X.4.1.7 Key Protocol Parameters

Some protocol parameters are particularly useful when managing large sets of protocols.

Acquisition Modalities are encouraged to populate the following attributes if known or applicable, and Protocol Managers are encouraged to support filtering and sorting on them:

- Responsible Group Code Sequence (0008,0220)
- Predecessor Protocol Sequence (0018,990E)
- Protocol Name (0018,1030)
- Potential Scheduled Protocol Code Sequence (0018,9906)
- Potential Requested Procedure Code Sequence (0018,9907)
  - Support for RadLex Playbook Codes is recommended
- Clinical Trial Protocol ID (0012,0020)
- Model Specification Sequence (0018,9912)
- In the Patient Specification Sequence (0018,9911)
  - Patient's Age (0010,1010)
  - Patient's Sex (0010,0040)
  - Patient's Weight (0010,1030)
  - Patient's Size (0010,1020) (i.e., height)
- Anatomic Region Sequence (0008,2218)
- Anatomic Region Modifier Sequence (0008,2220)
- Primary Anatomic Structure Sequence (0008,2228)
- Primary Anatomic Structure Modifier Sequence (0008,2230)
- Requested Series Description (0018,9937)

X.4.1.8 Protocol Management

Section X.1.1.1 requires the Protocol Manager to have certain protocol management features and capabilities.

This section describes capabilities that might be expected on a Protocol Manager; however, this text does not place any explicit requirements on Protocol Managers conforming to this profile.

- Display and compare protocols and highlight differences
  - Compare "Same" protocol for different scanner models
  - Compare Performed Protocols with the original Defined Protocol (what's being adjusted at scan time)
  - Compare protocols with a reference policy or reference protocol set
  - Review all parameters (including Private using Private Dictionary)
- Filter/sort/group protocol sets:
  (note that this refers to the Protocol Manager organizing the instances it has for the person using it, rather than performing instance queries)
  - Make/model/version
  - Responsible Group Code Sequence (0008,0220)
    - Note that this code can identify a department or clinical division as well as an organization such as a hospital or imaging center.
    - This can also be used to distinguish protocols managed by the medical physics department, research group or vendor service.
  - Scanner Location (e.g., Room, Building)
  - Broad procedure type, RPID, Reasons for Procedure
  - Anatomy (multi-valued)
  - Patient Sex, Age, Weight and BMI
  - Protocol name (see Zhang, D., Savage, C.A., Li, X., Liu, B. Data-driven CT protocol review and management experience from a large academic hospital. J Am Coll Radiol. 2015;12:267–272)
  - Date of last change, Date of last review (e.g., list protocols with unreviewed changes)
  - Expected Dose Index value ranges (e.g., CTDIvol, DLP)
  - Key Acquisition parameters
    - E.g., scan duration, kVp=140, or bariatric protocols with kVp=80
- Approve protocols and manage a database of approvals/disapprovals

- Approve/Disapprove for use at this facility, in a specific Clinical Trial, etc.
- Some jurisdictions have regulations requiring that review and approval of protocols be documented and the documents be available to inspectors.

- Edit typical Modifiable Parameters (see Section X.4.1.3) such as:
  - Protocol Name
  - Requested Series Description
  - Dose Check Thresholds
- Edit batches of protocols at once
  - E.g., filter for all routine head protocols across one's fleet and set all of them to have the same CTDIvol notification value
- Generate administrative reports
  - Listing of protocols in use, when they were reviewed and the fact that each was approved by certain people. This will be useful for meeting accreditation requirements).
  - History of protocol changes and associated approvals.
  - Report protocols that match a filter (e.g., pediatric protocols with kVp>=140, protocol with Reason for Procedure=Lung Screening and kVp above AAPM guideline value, etc.).

Protocols will also need to be organized on the Acquisition Modality. This profile does not mandate any particular method or interface for this. Some of the features mentioned above (such as being able to filter or group protocols, or separate out protocols for service or QA procedures) may also be useful on the modality.

X.4.1.9 Protocol Approvals

As part of the review process, Protocol Managers generally allow users to approve/disapprove specific protocol instances for various purposes (e.g., as being approved for use at a particular site, or approved for use in a particular clinical trial).

The Protocol Manager communicates such approval information to the relevant Acquisition Modality devices by sending Protocol Approval objects.

A DICOM Approval instance can contain a particular approval for multiple protocols. One Protocol can be the subject of multiple Approval instances. An Approval instance has a subject sequence that references the Protocol instances being approved. The Protocol instances do not maintain a list of the various Approval instances that they are the subject of (for obvious practical reasons).

Acquisition Modalities are required to communicate to the operator whether any given Defined Procedure Protocol has been disapproved or approved (see Section X.1.1.2). The method of

communication is not prescribed. One could imagine the Acquisition Modality console might identify protocol state by:

- Coloring them (red if disapproved, green if approved, and uncolored if neither is true)
- Marking them with icons (an X if disapproved, a checkmark if approved, and no mark if neither)
- Moving them into tabs or folders (a "disapproved" tab, an "active" tab and an "unreviewed" tab)

The Acquisition Modality might provide access to details such as when the protocol was approved, by whom, and the nature of the approval, via a properties dialog or via a panel in the protocol-editing screen.

The nature of the approval is communicated in the Protocol Approval instance using a code taken from DICOM CID newcid3. Another code of interest in that list is (newcode013,DCM,"Replaced by another protocol"). This can be used by the Protocol Manager to help manage clutter by indicating that a protocol should not be displayed in the active protocol list, but not because the protocol is deficient, but rather it has been superseded by a replacement.

The Acquisition Modality is not required to persist copies of the actual Protocol Approval instances, but is advised to maintain a database of the contents of received approvals (and disapprovals) since the Protocol that is the subject of an approval might not be received until after the Protocol Approval has been received. Similarly, it might receive a copy of the Protocol again in the future.

Note also that it is possible an Acquisition Modality may find that a given protocol is the subject of multiple Protocol Approval instances. Most likely, they will be making different types of approval assertions or it will be different people making the assertions. The meaning of individual assertions is defined by the approval code, but there is no prescribed way to interpret approvals in combination. One might expect more recent approvals to carry more weight than older approvals; or one might consider the relative authority of the different approvers. It may be advisable to notify the operator if any of them are disapprovals.

X.4.1.10 Protocol Constraints

Defined Procedure Protocols contain constraints on parameters. Typically, these are constraints chosen by the protocol designer, for example that the kVp be constrained to the range 100-120 for this protocol. While constraints could represent the end limits of equipment capabilities, more often they are operational guidance to the technologist. The modality is in no way obligated to permit values that are outside its operational envelope just because they conform to the constraints.

Technologists commonly adjust parameters at execution time for example to adapt to the patient body size. The resulting values may or may not violate parameter constraints. The significance of violating constraints can be indicated by the creator of the protocol by using one of the following

values in the Constraint Violation Significance (0082,0036) in the Attribute Value Constraint Macro:

- FAILURE – Violating the constraint is a violation of the Protocol and requires supervisory permission and auditing.
- WARNING – Violating the constraint is a violation of the Protocol and requires operator confirmation and auditing.
- INFORMATIVE – Violating the constraint is not a violation of the Protocol. The constraint represents a guideline. Violation of the guideline may be recorded or shown to the operator.
- If Constraint Violation Significance (0082,0036) is absent for a constraint, a value of INFORMATIVE may be assumed.

Protocol creators should consider carefully whether the use of constraints will be an effective part of their workflow and quality program and use them judiciously.

This profile does not specify the mechanisms by which the Acquisition Modality should audit or interact with the operator; however, implementations are advised to consider mechanisms similar to those used for Dose Check (MITA XR-25).

Note that Acquisition Modalities are not required to create Defined Procedure Protocols that contain constraints, and are permitted to reject received instances that contain them. If, however, the Acquisition Modality does allow a protocol to be executed that contains constraints, it is required to interact with the operator accordingly.

Note also that runtime adjustments do not result in changes to the original Defined Procedure Protocol, and do not result in a new Defined Protocol unless the Technologist explicitly saves the protocol.

X.4.1.11 Performed Procedure Protocols

In addition to the Defined Procedure Protocols that are the focus of this profile, DICOM also has a Performed Procedure Protocol object to store the protocol parameters as they were actually performed for a given study. Performed Procedure Protocol objects would reflect any parameter adjustments made by the technologist or the Acquisition Modality itself in the course of setting up and running the protocol. This object is specific to the study and can be stored inside the Study folder on the Image Archive.

Creation of these objects is not required for an Acquisition Modality to conform to this profile. If an Acquisition Modality does choose to generate these, there are several potentially useful applications:

- A Protocol Manager could retrieve Performed Protocols for scans in the department and compare them to the corresponding Defined Protocol to determine how closely the technologists were adhering to the standard protocols or to understand what kinds of changes are being made at execution time. The interface could highlight changes that

violated Defined Protocol constraints, or analyze how frequently different values were used for certain parameters. Note that doing this would result in the Protocol Manager hosting patient information.

- An Acquisition Modality could retrieve the Performed Protocol for a prior scan of a patient and attempt to make the follow-up scan as similar as possible to support easy comparison. If the prior scan was performed on the same model/version, it could be repeated quite closely. If the prior scan was performed on a different make/model, the Acquisition Modality would need to select or create a new protocol with corresponding parameter values, but that could be quite difficult. Note that some similarity could be achieved by taking a similar Defined Protocol and using some information from image header values or dose reports.

In the absence of Performed Procedure Protocol instances, some acquisition and reconstruction parameters are also available in the attributes of the resulting DICOM images. These parameters can be compared to the Defined Procedure Protocols too.

See also:

- On the Same Page: Physicist and Radiologist Perspectives on Protocol Management and Review; TP Szczykutowicz, and J Siegelman. Journal of the American College of Radiology 12(8) 2015
- Tracking Patterns of Nonadherence to Prescribed CT Protocol Parameters; TP Szczykutowicz. Journal of the American College of Radiology Feb 2017 Volume 14:2 pages 224-230
- Implementation and evaluation of a protocol management system for automated review of CT protocols; Joshua Grimes, Shuai Leng, Yi Zhang, Thomas Vrieze, Cynthia McCollough http://www.jacmp.org/index.php/jacmp/article/view/6164

X.4.1.12 Generating Protocols

Typically, the operator interacts with the Acquisition Modality to generate protocols. Sometimes they may be created from scratch, but most often, they use a copy of an existing protocol as a starting point, modify it and save the result.

For some of the use cases it would be useful for an Acquisition Modality to be able to use other information as a starting point. Some examples of useful starting points include:

- Scan parameters extracted from the header of a prior image
- A protocol object for another scanner
- A partially populated protocol object (or "sketch") that might be a common root protocol used to drive commonality across models, which is desirable to the physics community.

To be clear, it is not expected that an Acquisition Modality would be able to run a protocol from another model or another manufacturer, but it would be useful to allow the operator to use it as a

starting point and help them create a similar protocol that is appropriate for the Acquisition Modality.

Another aspect of generating protocols is that someone may want to distribute a protocol that is still in a "work-in-progress" state. In this context WIP means that the author feels the protocol needs further modification before it can be considered "ready for use" even if a scanner might be able to execute it as is. This can be done by setting the Draft (TBA) attribute to TRUE. When the details are finalized, a new instance would be created with the attribute either absent or set to "FALSE".

X.4.1.13 Protocolling Ordered Patient Studies

"Protocolling" is the activity where a radiologist selects a protocol to be used for a specific patient study and perhaps decides on specific parameter modifications.

Note: In some practices, due to preapproval requirements, it is necessary to fix the correct detailed requested procedure a week or two in advance of the procedure. Protocolling might also be done at the same time

This profile does not protocolling-specific requirements but protocolling could be performed as follows:

- An Order Filler (RIS) or an application that communicates with the Order Filler could start by accessing the modality worklist.
- The actor would likely then use [RAD-Y1] and [RAD-Y2] to query/retrieve a collection of active protocols from the Protocol Archive.
    - The Requested Procedure Description (0032,1060) or Requested Procedure Code Sequence (0032,1064) (which might be drawn from the Radlex Playbook) and other details such as patient age, weight or indications, could be used to match a short-list of protocols.
    - It might also be necessary to know which specific Acquisition Modality device the patient is scheduled to be scanned on to select a protocol appropriate to the make, model and version.
- Once an appropriate protocol is selected by the radiologist, the modality worklist entry could be revised to identify the Scheduled Protocol Code Sequence (0040,0008), or the unique instance UID of the protocol object to be used.
- Comments from the radiologist explaining any patient specific protocol adaptations they would like the tech to make before running the scan (e.g., increase the mA to 60) could be placed in the Imaging Service Request Comments (0040,2400) in the worklist entry.

X.4.1.14 Protocols vs Local System Configurations

Some Acquisition Modalities may have details that affect acquisition, reconstruction or storage, but are configured at a system level rather than being included directly in a protocol as a parameter. For example, a particular Defined Protocol may have a parameter that specifies it will

use "mode X", but the details of mode X are configured on the system (and are the same for all protocols that invoke mode X).

An Acquisition Element in a Defined Protocol might specify an AEC (automatic exposure control) Strength parameter of "Strong", but the curve that maps relative attenuation values to corresponding adjustments of the tube current when the parameter is set to "Strong" is defined on the system.

Similarly, a Reconstruction Element in a Defined Protocol might specify reconstruction kernel "C56", but the details of C56 are defined on the system. If C56 always invokes the same fixed behavior, then it would be similar to specifying a certain kVp and expecting a certain consistent beam characteristic, however if C56 can change, then it would be an example of this configuration issue.

An advantage of this is the ability to "factor out" those details so they can be changed once and affect all the associated protocols, and it avoids having to specify them (and later update them) in each protocol. The disadvantage is that the behavior of the protocol will change, even though the protocol itself has not; and to replicate the behavior on another Acquisition Modality, it will be necessary to also convey the configuration settings.

This has the potential to add significant complexity to protocol management.

One possible approach would be to consider the configurations as "sub-protocols" which can also be exchanged between systems using the Protocol Storage mechanisms. Behavior then depends on having the correct set of protocols.

Another approach would be to replicate relevant configuration settings into each Defined Protocol when it is exported from the system. Similarly, when the system imports a protocol it would need to check such parameters and confirm they match those currently configured on the system, alerting the operator if there is an issue.

Some "sub-protocols" may be visible to the user and configurable, others may be internal to the system and vendor-controlled.

X.4.2 Use Cases

X.4.2.1 Use Case #1: Reviewing Site Protocols

Site policy should require periodic review/approval of protocols. An up-to-date list of protocols are collected on a central Protocol Manager where they can be reviewed by the responsible radiologist/physicist/technologist and re-distributed as needed.

X.4.2.1.1 Reviewing Site Protocols Use Case Description

As part of a combined image quality and radiation safety program, a periodic review is conducted of the protocols installed on all the CT scanners in the organization. The review might occur monthly, semi-annually or annually. The review may be conducted by an individual, such

as the chief radiologist, or maybe a committee (e.g., composed of the chief technologist, a physicist and a radiologist).

Their intention is to monitor changes to protocols, ensure appropriate consistency across the scanners, and periodically re-assess the protocols for currency with respect to guidelines and technology.

The reviewer will likely do things such as:

- organize the protocols by device model, clinical purpose, patient type, etc., e.g., to work through the large number of protocols in logical groups
- see what protocols have been added or changed recently or since the last review, e.g., to confirm the changes are acceptable
- compare parameter values across selected protocols, e.g., to find undesired differences, or confirm necessary differences are in place
- make limited edits (see Section X.4.1.3 Modifiable Parameters)
- make notes of edits which will need to be made on the scanner console
- see what approvals have been applied to each protocol (see Section X.4.1.6 Protocol Approvals)
- manage lists of which protocols are assigned to each device (or each group of devices of the same/similar model)

See Section X.4.1.8 Protocol Management for a more detailed discussion of possible features.

To maintain an up-to-date inventory of all protocols on the Protocol Manager:

- When the Acquisition Modalities and Protocol Manager are initially set up, each modality sends a batch of all protocols, e.g., when the operator pushes a "Send All" button.
- On an ongoing basis, whenever a new protocol is created on an Acquisition Modality or an existing protocol is revised (e.g., when an operator clicks Save) the modality sends a copy of the protocol to the Protocol Archive grouped with the Protocol Manager.

In the particular example scenario shown below, the reviewer decides:

- The protocol name of Protocol A1 from Scanner 1 needs to be aligned with the name normally used in this organization (changing "CTBrWOCon" to "CT Brain without Contrast"). This is a Modifiable Parameter so the reviewer makes the change on the Protocol Manager resulting in a new instance Protocol A2.
- Protocols A2 and B are approved for use at this site (the approval is recorded in the Protocol Manager database).

- Protocol C should be removed from use.

At the end of the review, the reviewer triggers the Protocol Manager to send sets of protocols to the specified scanners or groups of scanners. If the transactions come at an inopportune time for the Acquisition Modality, it might refuse the association in which case the Protocol Manager will need to retry.

In addition to sending the relevant Protocols to each scanner, the Protocol Manager also sends a Protocol Approval object to Scanner 2 indicating that Protocol C is disapproved. That particular model of scanner reflects that by displaying a red X next to Protocol C until an operator chooses to delete it.

X.4.2.1.2 Reviewing Site Protocols Process Flow

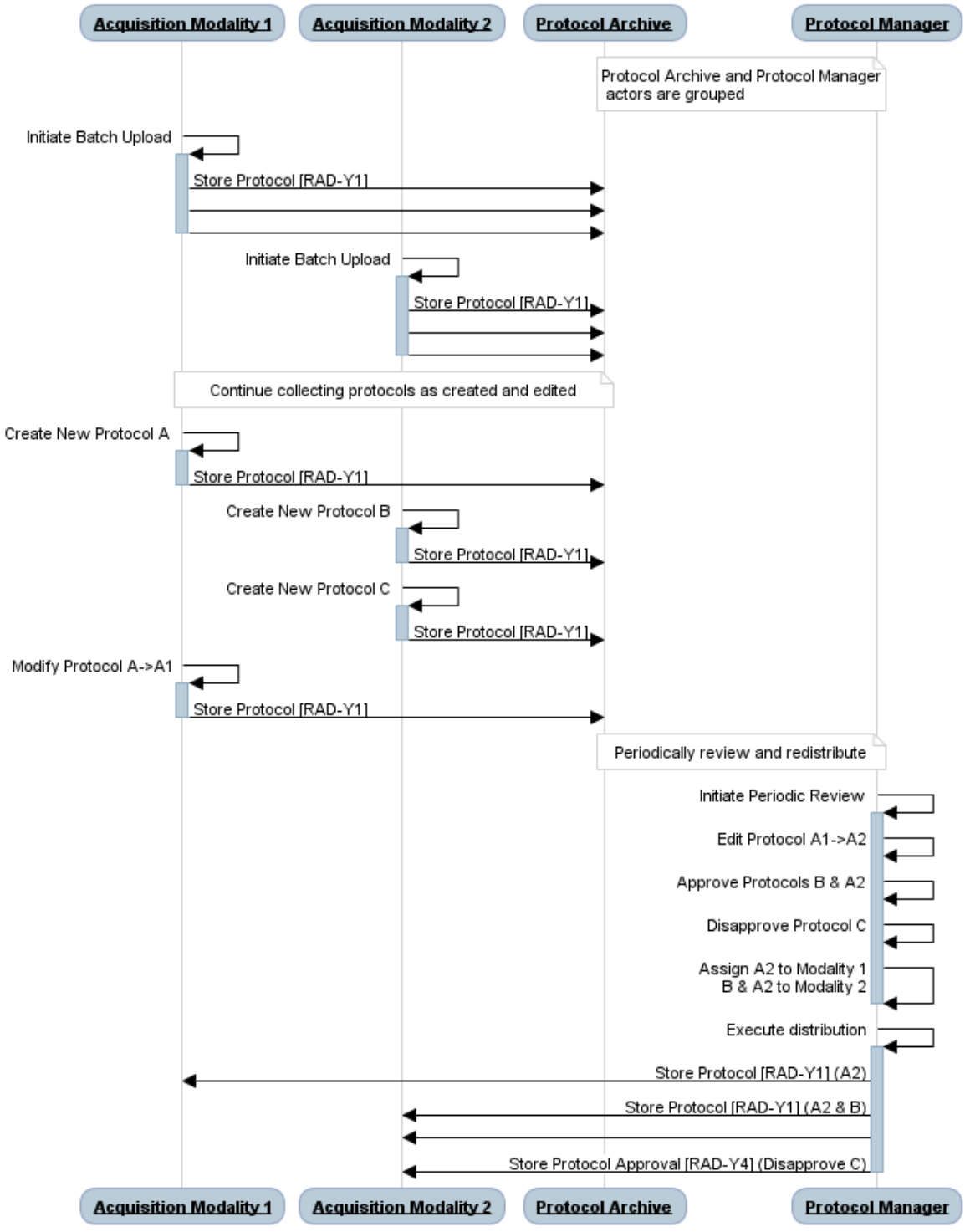

Figure X.4.2.1.2-1: Reviewing Site Protocols Process Flow

The text in Figure X.4.2.1.2-2 was used to generate the diagram in Figure X.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Reviewing Site Protocols

participant Acquisition Modality 1
participant Acquisition Modality 2

note over Protocol Archive, Protocol Manager: Protocol Archive and Protocol Manager\n actors are grouped
Acquisition Modality 1->+Acquisition Modality 1: Initiate Batch Upload
Acquisition Modality 1->Protocol Archive: Store Protocol [RAD-Y1]
Acquisition Modality 1->Protocol Archive:
Acquisition Modality 1->-Protocol Archive:
Acquisition Modality 2->+Acquisition Modality 2: Initiate Batch Upload
Acquisition Modality 2->Protocol Archive: Store Protocol [RAD-Y1]
Acquisition Modality 2->Protocol Archive:
Acquisition Modality 2->-Protocol Archive:
note over Acquisition Modality 1, Protocol Archive: Continue collecting protocols as created and edited
Acquisition Modality 1->+Acquisition Modality 1: Create New Protocol A
Acquisition Modality 1->-Protocol Archive: Store Protocol [RAD-Y1]
Acquisition Modality 2->+Acquisition Modality 2: Create New Protocol B
Acquisition Modality 2->-Protocol Archive: Store Protocol [RAD-Y1]
Acquisition Modality 2->+Acquisition Modality 2: Create New Protocol C
Acquisition Modality 2->-Protocol Archive: Store Protocol [RAD-Y1]
Acquisition Modality 1->+Acquisition Modality 1: Modify Protocol A->A1
Acquisition Modality 1->-Protocol Archive: Store Protocol [RAD-Y1]
note over Protocol Archive, Protocol Manager: Periodically review and redistribute

Protocol Manager->+Protocol Manager: Initiate Periodic Review
Protocol Manager->Protocol Manager: Edit Protocol A1->A2
Protocol Manager->Protocol Manager: Approve Protocols B & A2
Protocol Manager->Protocol Manager: Disapprove Protocol C
Protocol Manager->-Protocol Manager: Assign A2 to Modality 1\nB & A2 to Modality 2
Protocol Manager->+Protocol Manager: Execute distribution
Protocol Manager->Acquisition Modality 1: Store Protocol [RAD-Y1] (A2)
Protocol Manager->Acquisition Modality 2: Store Protocol [RAD-Y1] (A2 & B)
Protocol Manager->Acquisition Modality 2:
Protocol Manager->-Acquisition Modality 2: Store Protocol Approval [RAD-Y4] (Disapprove C)
```

Figure X.4.2.1.2-2: Diagram Pseudocode for Reviewing Site Protocols Process Flow

X.4.2.2 Use Case #2: Protocol Library

A reference set of protocols can be a useful resource to query/retrieve. Such a library might be maintained by a site, a vendor, a professional society, etc.

X.4.2.2.1 Protocol Library Use Case Description

A scanner technologist may receive an order on the worklist for a procedure that needs a protocol not currently stored on the Acquisition Modality (e.g., a pulmonary embolism study for a child). In this use case, there are protocols for a variety of models and a variety of procedures stored on

an organizational protocol library. Similarly, a protocol library operated by the vendor of the Acquisition Modality or by a professional society may be accessible to the Acquisition Modality.

The technologist queries for Protocols matching certain parameters, selects one, and retrieves it from the library. After reviewing it on the Acquisition Modality console, the technologist uses it for the upcoming study. Alternatively, if the worklist includes a protocol code that the modality does not have a matching protocol for, the modality might proactively query/retrieve an applicable protocol from the library and offer it to the technologist for consideration.

In another variant of the use case, the operator of a Protocol Manager might query a library for reference Protocols matching certain parameters so they can compare them to local protocols during the next protocol review.

Lastly, this could also be used to initially populate a newly installed modality with desired protocols from the library.

X.4.2.2.2 Protocol Library Process Flow

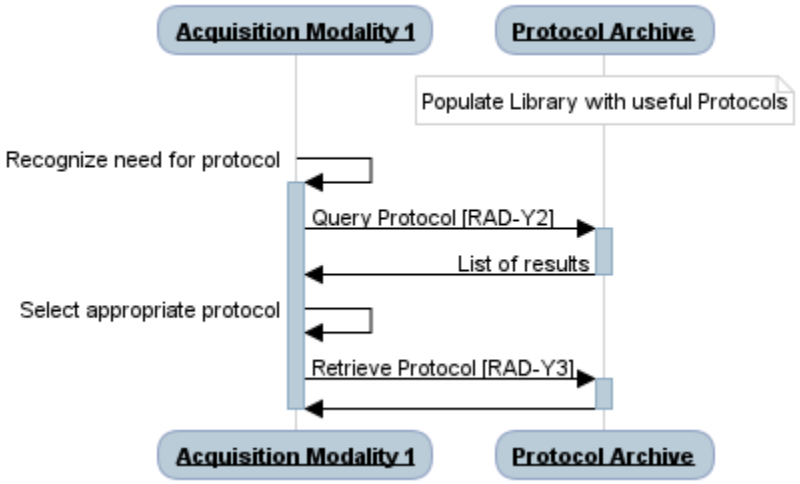

Figure X.4.2.2.2-1: Protocol Library Process Flow

The text in Figure X.4.2.2.2-2 was used to generate the diagram in Figure X.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.


```
title Protocol Library

participant Acquisition Modality 1
note over Protocol Archive: Populate Library with useful Protocols

Acquisition Modality 1->Acquisition Modality 1: Recognize need for protocol
Activate Acquisition Modality 1
Acquisition Modality 1->+Protocol Archive: Query Protocol [RAD-Y2]
Protocol Archive->-Acquisition Modality 1: List of results
Acquisition Modality 1->Acquisition Modality 1: Select appropriate protocol
Acquisition Modality 1->+Protocol Archive: Retrieve Protocol [RAD-Y3]
Protocol Archive->-Acquisition Modality 1:

deactivate Acquisition Modality 1
```

Figure X.4.2.2.2-2: Diagram Pseudocode for Protocol Library Process Flow

X.4.2.3 Use Case #3: Backup/Restore Protocols

X.4.2.3.1 Backup/Restore Protocols Use Case Description

The reviewer may wish to maintain backups of protocols, especially if they were locally modified beyond the baseline set from the vendor. The reviewer could then retrieve/restore copies of protocols that were deleted by an operator or lost during a hard drive failure or a software upgrade of the Acquisition Modality.

Similar to Use Case #3, they would need to be able to query/retrieve one or more protocols, but in this case, they would also push to the Protocol Archive similar to Use Case #1. The Protocol Archive providing backup/restore is not necessarily the same one that provides the protocol library or the one used for protocol review and management.

Note that after an upgrade of an Acquisition Modality, there is a possibility that old protocols might no longer be compatible so the Acquisition Modality might still reject the restored protocols or might support generating new protocols as described in Section X.4.1.12 Generating Protocols.

X.4.2.3.2 Backup/Restore Protocols Process Flow

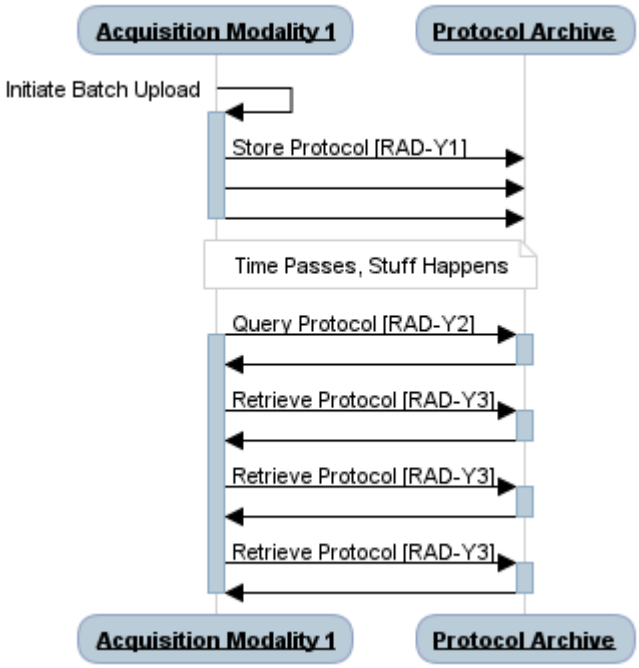

Figure X.4.2.3.2-1: Backup/Restore Protocols Process Flow

The text in Figure X.4.2.3.2-2 was used to generate the diagram in Figure X.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Backup/Restore Protocols

participant Acquisition Modality 1

Acquisition Modality 1->+Acquisition Modality 1: Initiate Batch Upload
Acquisition Modality 1->Protocol Archive: Store Protocol [RAD-Y1]
Acquisition Modality 1->Protocol Archive:
Acquisition Modality 1->-Protocol Archive:

note over Acquisition Modality 1, Protocol Archive: Time Passes, Stuff Happens
Acquisition Modality 1->+Protocol Archive: Query Protocol [RAD-Y2]
Activate Acquisition Modality 1
Protocol Archive->-Acquisition Modality 1:
Acquisition Modality 1->+Protocol Archive: Retrieve Protocol [RAD-Y3]
Protocol Archive->-Acquisition Modality 1:
Acquisition Modality 1->+Protocol Archive: Retrieve Protocol [RAD-Y3]
Protocol Archive->-Acquisition Modality 1:
Acquisition Modality 1->+Protocol Archive: Retrieve Protocol [RAD-Y3]
Protocol Archive->-Acquisition Modality 1:
deactivate Acquisition Modality 1
```

Figure X.4.2.3.2-2: Diagram Pseudocode for Backup/Restore Protocols Process Flow

X.4.2.4 Use Case #4: Peer-to-Peer Protocol Sharing

X.4.2.4.1 Peer-to-Peer Protocol Sharing Use Case Description

Independent of performing site-wide review of protocols, an operator at one Acquisition Modality may have created a new protocol or made a local change to a protocol and may wish to push it to one or more peer Acquisition Modalities.

As described in Use Case #1, the push may come at an inopportune time for the receiving Acquisition Modality and the sender may need to retry later.

X.4.2.4.2 Peer-to-Peer Protocol Sharing Process Flow

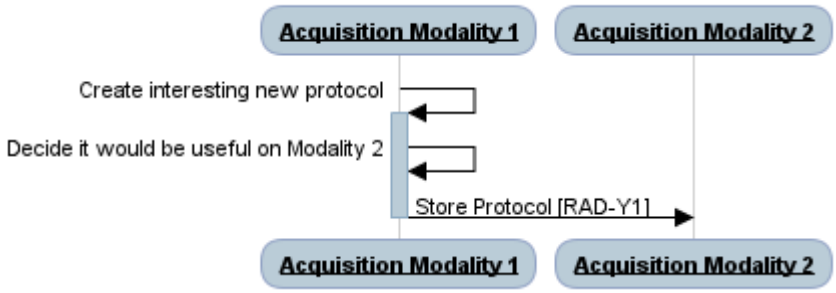

Figure X.4.2.4.2-1: Peer-to-Peer Protocol Sharing Process Flow

The text in Figure X.4.2.4.2-2 was used to generate the diagram in Figure X.4.2.4.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
title Peer-to-Peer Protocol Sharing

Acquisition Modality 1->+Acquisition Modality 1: Create interesting new protocol
Acquisition Modality 1->Acquisition Modality 1: Decide it would be useful on Modality 2
Acquisition Modality 1->-Acquisition Modality 2: Store Protocol [RAD-Y1]
```

Figure X.4.2.4.2-2: Diagram Pseudocode for Peer-to-Peer Protocol Sharing Process Flow

X.5 MAP Security Considerations

Defined Procedure Protocols are not patient-specific and thus do not normally contain PHI. This limits the privacy related issues.

Tampering with protocols by unauthorized persons is a potential concern. Facilities commonly have various forms of access control limiting scanner control access to authorized personnel and often have further controls limiting who can make changes to protocols. Similar considerations may apply to the Protocol Manager.

This profile requires implementation of ATNA Secure Node or Secure Application Actors to further ensure the integrity of transactions. Implementers are advised to take advantage of the authentication and communication encryption capabilities ATNA provides between secure nodes and to take advantage of TLS when communicating over the internet.

The ITI profiles for Enterprise User Authentication (EUA), Internet User Authorization (IUA) and Cross-Enterprise User Assertion (XUA) may be useful both for authentication of operators and for accurately logging events about those users.

X.6 MAP Cross Profile Considerations

SWF.b – Scheduled Workflow.b

An Acquisition Modality in Scheduled Workflow.b might be grouped with an Acquisition Modality to support coordinated management of the protocols being used in SWF.b. This might be particularly useful if the Assisted-Protocol Setting Option is also supported.

PDI – Portable Data for Imaging

A Portable Media Creator or Portable Media Importer might be grouped with an Acquisition Modality or a Protocol Manager to export/import DICOM protocol objects to/from media for sharing with another facility or organization.

Implementers may consider use cases for sharing individual protocols of interest (e.g., between collaborators), sets of protocols (e.g., protocols for multiple models in a given clinical trial, or reference protocols for a particular diagnostic task), or a full catalog of protocols (e.g., a backup of a particular system or library).

Note that Defined Protocol instances would go in the root directory of the media since they are not part of the Patient-Study Hierarchy.

REM – Radiation Exposure Monitoring

A Dose Information Reporter or a Dose Consumer in Radiation Exposure Monitoring might be grouped with a Protocol Manager to incorporate study dose information (RDSR objects) into the evaluation and management process for protocols.

For example, unusual doses might trigger review of the constraints in the Defined Protocol used for that scan. Or when a protocol is revised with the intention of achieving a dose target, the dose data corresponding to the original and revised protocol could confirm if the goal is being met. Or when an interesting difference in dose levels is noticed between two types of scans, the

corresponding Defined Protocols might be pulled up to dig deeper into the root of the differences.

If the Acquisition Modality has chosen to create Performed Protocols, those would also be available for the Dose Information Reporter to retrieve from the PACS to see the actual acquisition parameter values.

<Alternative Table Format for the material above – What do people prefer?>

Table X.6-1 describes various actors in various other profiles which might be useful to group with MAP Profile actors.

Table X.6-1: Management of Acquisition Protocols - Optional Actor Groupings

MAP Actor	Actor to group with	Potential Purpose
Acquisition Modality	SWF.b Acquisition Modality	To support coordinated management of the protocols being used in SWF.b. This might be particularly useful if the Assisted-Protocol Setting Option is also supported.
	PDI Portable Media Creator	To export DICOM protocol objects to media for sharing with another facility or organization. Consider use cases for sharing individual protocols of interest (e.g., between collaborators), sets of protocols (e.g., protocols for multiple models in a given clinical trial, or reference protocols for a particular diagnostic task), or a full catalog of protocols (e.g., a backup of a particular system or library). Note that Defined Protocol instances would go in the root directory of the media since they are not part of the Patient-Study Hierarchy.
	PDI Portable Media Importer	To import DICOM protocol objects from media. See above.
Protocol Archive		
Protocol Manager	PDI Portable Media Creator	To export DICOM protocol objects from media. See above.
	PDI Portable Media Importer	To import DICOM protocol objects from media. See above.

MAP Actor	Actor to group with	Potential Purpose
	REM Dose Information Reporter	To incorporate study dose information (RDSR objects) into the evaluation and management process for protocols. For example, unusual doses might trigger review of the constraints in the Defined Protocol used for that scan. Or when a protocol is revised with the intention of achieving a dose target, the dose data corresponding to the original and revised protocol could confirm if the goal is being met. Or when an interesting difference in dose levels is noticed between two types of scans, the corresponding Defined Protocols might be pulled up to dig deeper into the root of the differences. If the Acquisition Modality has chosen to create Performed Protocols, those would also be available for the Dose Information Reporter to retrieve from the PACS to see the actual acquisition parameter values.
	REM Dose Information Consumer	To retrieve study dose information. See above.

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Volume 3 – Transactions (cont.)

Add Section 4.Y1

4.Y1 Store Protocol [RAD-Y1]

4.Y1.1 Scope

This transaction transfers a DICOM Defined Procedure Protocol object from a Sender to a Receiver.

Note: This transaction currently only references the CT Defined Procedure Protocol Storage SOP Class.

4.Y1.2 Actor Roles

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

Table 4.Y1.2-1: Actor Roles

Role:	Sender: Sends a procedure protocol object.
Actor(s):	The following actors may play the role of Sender: Protocol Manager – when distributing reviewed protocols Acquisition Modality – when pushing new/modified protocols
Role:	Receiver: Receives a procedure protocol object.
Actor(s):	The following actors may play the role of Receiver: Acquisition Modality Protocol Archive

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.

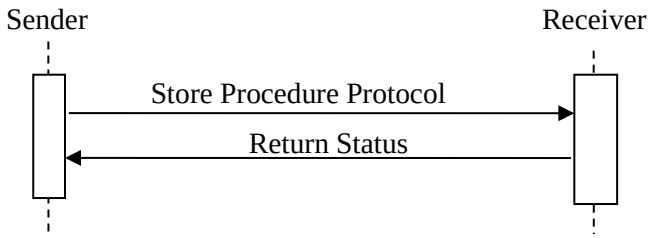
4.Y1.3 Referenced Standards

DICOM PS 3.3: A.82.2 CT Defined Procedure Protocol IOD

DICOM PS3.18 Section 6.10: RS Non-Patient Instance (NPI) Storage

DICOM PS3.18 Section 6.10.3.3: Store Transaction

4.Y1.4 Interaction Diagram



4.Y1.4.1 Store Procedure Protocol Message

The Sender sends a Procedure Protocol instance to the Receiver for storage.

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

4.Y1.4.1.1 Trigger Events

A user or an automated function on the Sender determines that a Procedure Protocol object should be sent to the Receiver.

4.Y1.4.1.2 Message Semantics

The message is a Store transaction request of the RESTful DICOM Non-Patient Instance (NPI) Service. The Sender is the User Agent, and the Receiver is the Origin Server. The content is one of the Storage SOP Classes listed in Table 4.Y1.4.1.2-1.

Note: Although support of the Store transaction is optional to claim DICOM Conformance to the NPI RESTful Service, this [RAD-Y1] transaction makes it required

Table 4.Y1.4.1.2-1: Store Procedure Protocol SOP Classes

DICOM SOP Class Name	SOP Class UID
CT Defined Procedure Protocol Storage SOP Class	1.2.840.10008.5.1.4.1.1.200.1

Note: Protocols recorded as a result of performance of a patient procedure are instances of the CT Performed Procedure Protocol Storage SOP Class that exist in the Patient/Study/Series hierarchy. They would be stored using Store Instances over the Web [RAD-108].

The Sender shall encode the instances using either the binary DICOM method or the DICOM PS3.18 metadata and bulk data method.

Note: Protocol objects will typically not have bulk data unless one of the Private Data Elements is unusually large.

The Sender shall encode the metadata and bulk data request as an array of DICOM JSON Model Object as defined in DICOM PS3.18 Annex F.

Note: STOW-RS specifies Native DICOM Model as a baseline and JSON Model Object is optional.

The Sender shall include all attributes available in the instances, including Type 3 attributes and private attributes.

The Sender shall encode each DICOM instance as a separate message part.

4.Y1.4.1.3 Expected Actions

The Receiver shall accept and process the message payload.

The Receiver shall accept metadata and bulk data encoded in DICOM JSON Model Object. The Receiver shall at least support the SOP Classes defined in Table 4.Y1.4.1.2-1.

The Receiver shall store the protocol instances in a fashion meeting the requirements defined for a DICOM Level 2 (Full) Storage SCP (refer to DICOM PS3.4 Section B.4.1). This means all DICOM Type 1, 2 and 3 attributes (public and private) are stored.

The Protocol Manager processes received Protocol objects according to its features, configuration, and business logic. Possibilities include display, processing, analysis, printing, export, etc. At a minimum, the Protocol Manager shall provide the capability to review and approve the Protocols (see RAD TF-1: X.4.1.8 Protocol Management).

The Acquisition Modality shall promptly process received Protocol objects.

4.Y1.4.2 Return Status Message

The Receiver reports the outcome of the Store Procedure Protocol Message.

4.Y1.4.2.1 Trigger Events

The Receiver receives a Store Procedure Protocol Message.

4.Y1.4.2.2 Message Semantics

The message is a Store transaction response of the RESTful DICOM Non-Patient Instance (NPI) Service. The Receiver is the Origin-Server. The Sender is the User-Agent.

The Receiver shall return a response to the Sender according to DICOM PS3.18 Section 6.10.3.3.3.

Note: The Receiver will honor the HTTP Accept header field for encoding of the response message. However, if the Sender accepts both XML and JSON, then the Receiver can choose either format for the response message.

4.Y1.4.2.3 Expected Actions

The Sender has no expected actions.

4.Y1.5 Security Considerations

4.Y1.5.1 Security Audit Considerations

This transaction is not associated with an ATNA Trigger Event.

The Defined Procedure Protocol instances conveyed by this transaction are generic and do not contain personal health information.

Add Section 4.Y2

4.Y2 Query Protocol [RAD-Y2]

4.Y2.1 Scope

This transaction requests and receives a list of instance metadata describing Protocol objects matching a specified filter.

4.Y2.2 Actor Roles

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

Table 4.Y2.2-1: Actor Roles

Role:	Requester: Queries for a list of procedure protocol objects.
Actor(s):	The following actors may play the role of Requester: Protocol Manager: when collecting Protocols from Modalities Acquisition Modality: when checking a Protocol Library
Role:	Responder: Responds to queries for Protocol objects matching the specified filter.

Actor(s):	The following actors may play the role of Responder: Protocol Archive

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.

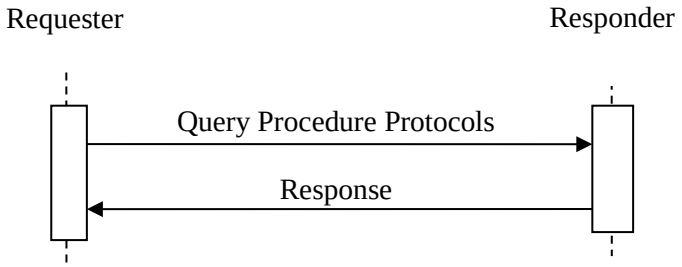
4.Y2.3 Referenced Standards

DICOM PS 3.3: A.82.2 CT Defined Procedure Protocol IOD

DICOM PS3.18 Section 6.10: RS Non-Patient Instance (NPI) Storage

DICOM PS3.18 Section 6.10.3.4: Search Transaction

4.Y2.4 Interaction Diagram



4.Y2.4.1 Query Procedure Protocols Message

The Requester sends a filter to the Responder in a request for matching Procedure Protocol 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.Y2.4.1.1 Trigger Events

A user or an automated function on the Requester needs to obtain information about Protocol objects on the Responder.

Typically, the trigger is associated with an intention of the Requester to later retrieve Protocol objects of interest.

4.Y2.4.1.2 Message Semantics

The message is a Search transaction request of the RESTful DICOM Non-Patient Instance (NPI) Service. The Requester is the User Agent, and the Responder is the Origin Server. The Requester and the Responder shall support the Defined Procedure Protocol Resource Category (See DICOM PS3.18 6.10.3.4.1.2.1).

4.Y2.4.1.3 Expected Actions

The Responder shall accept and process the message payload.

4.Y2.4.2 Response Message

The Responder reports the outcome of the Query Procedure Protocols Message.

4.Y2.4.2.1 Trigger Events

The Responder receives a Query Procedure Protocol Message.

4.Y2.4.2.2 Message Semantics

The message is a Query transaction response of the RESTful DICOM Non-Patient Instance (NPI) Service. The Responder is the Origin-Server. The Requester is the User-Agent.

The Responder shall return a response to the Requester according to DICOM PS3.18 Section 6.10.3.4.3.

4.Y2.4.2.3 Expected Actions

The Requester has no expected actions.

4.Y2.5 Security Considerations

4.Y2.5.1 Security Audit Considerations

This transaction is not associated with an ATNA Trigger Event.

The Defined Procedure Protocol instance information conveyed by this transaction are generic and do not contain personal health information.

Add Section 4.Y3

4.Y3 Retrieve Protocol [RAD-Y3]

4.Y3.1 Scope

This transaction retrieves a DICOM Defined Procedure Protocol object.

4.Y3.2 Actor Roles

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

Table 4.Y3.2-1: Actor Roles

Role:	Requester: Requests a procedure protocol object from the Responder.
Actor(s):	The following actors may play the role of Requester: Protocol Manager Acquisition Modality
Role:	Responder: Provides the requested procedure protocol object.
Actor(s):	The following actors may play the role of Responder: Protocol Archive

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.

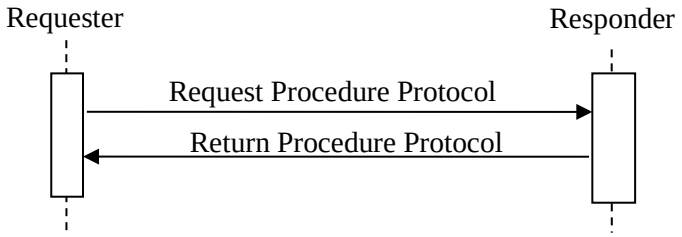
4.Y3.3 Referenced Standards

DICOM PS 3.3: A.82.2 CT Defined Procedure Protocol IOD

DICOM PS3.18 Section 6.10: RS Non-Patient Instance (NPI) Storage

DICOM PS3.18 Section 6.10.3.2: Retrieve Transaction

4.Y3.4 Interaction Diagram



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4.Y3.4.1 Request Procedure Protocol Message

The Requester requests that the Responder return a Procedure Protocol 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.

1055 **4.Y3.4.1.1 Trigger Events**

A user or an automated function on the Requester determines that it needs a Procedure Protocol object that is stored on Responder.

4.Y3.4.1.2 Message Semantics

The message is a Retrieve transaction request of the RESTful DICOM Non-Patient Instance
1060 (NPI) Service. The Requester is the User Agent, and the Responder is the Origin Server.

The Requester identifies a single Defined Procedure Protocol instance with its UID.

4.Y3.4.1.3 Expected Actions

The Responder shall accept and process the message.

4.Y3.4.2 Return Procedure Protocol Message

1065 The Responder returns the requested Procedure Protocol instance.

4.Y3.4.2.1 Trigger Events

The Responder receives a Request Procedure Protocol Message.

4.Y3.4.2.2 Message Semantics

The message is a Retrieve transaction response of the RESTful DICOM Non-Patient Instance
1070 (NPI) Service. The Responder is the Origin-Server. The Requester is the User-Agent.

The Responder shall return a response to the Requester according to DICOM PS3.18 Section 6.10.3.2.3.

Note: The Responder will honor the HTTP Accept header field for encoding of the response message. However, if the Requester accepts both XML and JSON, then the Responder can choose either format for the response message.

The content is one of the Storage SOP Classes listed in Table 4.Y3.4.2.2-1.

Table 4.Y3.4.2.2-1: Retrieve Procedure Protocol SOP Classes

DICOM SOP Class Name	SOP Class UID
CT Defined Procedure Protocol Storage SOP Class	1.2.840.10008.5.1.4.1.1.200.1

Note: Protocols recorded as a result of performance of a patient procedure are instances of the CT Performed Procedure Protocol Storage SOP Class that exist in the Patient/Study/Series hierarchy. They would be retrieved using WADO-RS Retrieve [RAD-107] (see MHD-I Trial Implementation Supplement).

The Responder shall include all attributes available in the requested instance, including Type 3 attributes and private attributes. The Responder shall encode attributes in the Native DICOM Model or DICOM JSON Model Object.

The Responder shall encode the requested DICOM instance as a single message part.

4.Y3.4.2.3 Expected Actions

The Requester shall accept metadata and bulk data encoded in DICOM JSON Model Object. The Requester shall at least support the SOP Classes defined in Table 4.Y3.4.2.2-1.

The Requester shall store the protocol instances in a fashion meeting the requirements defined for a DICOM Level 2 (Full) Storage SCP (refer to DICOM PS3.4 Section B.4.1). This means all DICOM Type 1, 2 and 3 attributes (public and private) are stored.

4.Y3.5 Security Considerations

4.Y3.5.1 Security Audit Considerations

This transaction is not associated with an ATNA Trigger Event.

The Defined Procedure Protocol instances conveyed by this transaction are generic and do not contain personal health information.

Add Section 4.Y4

4.Y4 Store Protocol Approval [RAD-Y4]

4.Y4.1 Scope

This transaction transfers a DICOM Protocol Approval instance from a Sender to a Receiver.

4.Y4.2 Actor Roles

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

1105

Table 4.Y4.2-1: Actor Roles

Role:	Sender: Sends a protocol approval object.
Actor(s):	The following actors may play the role of Sender: Protocol Manager
Role:	Receiver: Sends a protocol approval object.
Actor(s):	The following actors may play the role of Receiver: Acquisition Modality

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.

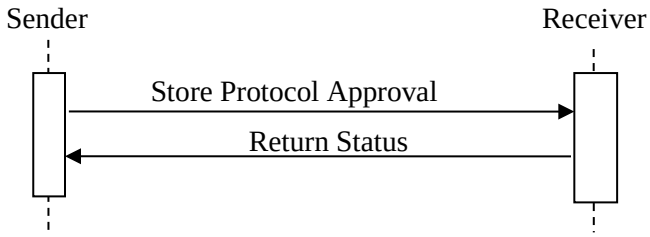
1110 ### 4.Y4.3 Referenced Standards

DICOM PS 3.3: A.X1.1 Protocol Approval IOD (see Supplement 192 Letter Ballot)

DICOM PS3.18 Section 6.10: RS Non-Patient Instance (NPI) Storage

DICOM PS3.18 Section 6.10.3.3: Store Transaction

4.Y4.4 Interaction Diagram



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4.Y4.4.1 Store Protocol Approval Message

The Sender sends a Protocol Approval instance 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.Y4.4.1.1 Trigger Events

A user or an automated function on the Sender determines that a Protocol Approval object should be sent to the Receiver.

4.Y4.4.1.2 Message Semantics

The message is a Store transaction request of the RESTful DICOM Non-Patient Instance (NPI) Service. The Sender is the User Agent, and the Receiver is the Origin Server. The content is instances of the Protocol Approval Storage SOP Class (1.2.840.10008.5.1.4.1.1.X.0.1).

Note: Although support of the Store transaction is optional to claim DICOM Conformance to the NPI RESTful Service, this [RAD-Y4] transaction makes it required.

The Sender shall encode the instances using either the binary DICOM method or the DICOM PS3.18 metadata and bulk data method.

Note: Protocol Approval objects will typically not have bulk data unless one of the Private Data Elements is unusually large.

The Sender shall encode the metadata and bulk data request as an array of DICOM JSON Model Objects as defined in DICOM PS3.18 Annex F

Note: STOW-RS specifies Native DICOM Model as a baseline and JSON Model Object is optional.

The Sender shall include all required attributes in the DICOM JSON Model Object according to DICOM PS3.4 Section B.5 for the appropriate DICOM SOP Class.

The Sender shall encode each DICOM instance as a separate message part.

4.Y4.4.1.3 Expected Actions

The Receiver shall accept and process the message payload.

The Receiver shall accept metadata and bulk data encoded in either Native DICOM Model or DICOM JSON Model Object. The Receiver shall support the Protocol Approval Storage SOP Class.

If the message contents are not binary DICOM instances, the Receiver shall convert the DICOM metadata and bulk data into DICOM binary instances according to the SOP Class UID specified in the metadata.

The Acquisition Modality shall parse and apply the approvals and disapprovals to the associated Defined Procedure Protocols. Although Acquisition Modalities are not required to retain the Protocol Approval instances, they are advised to retain the information contained in them, for

example in an internal database. It is possible that a Procedure Protocol instance that has been approved or disapproved might arrive at the Acquisition Modality after the Protocol Approval instance.

See RAD TF-1: X.4.1.9 Protocol Approvals for further discussion.

4.Y4.4.2 Return Status Message

The Receiver reports the outcome of the Store Protocol Approval Message.

4.Y4.4.2.1 Trigger Events

The Receiver receives a Store Protocol Approval Message.

4.Y4.4.2.2 Message Semantics

The message is a Store transaction response of the RESTful DICOM Non-Patient Instance (NPI) Service. The Receiver is the Origin-Server. The Sender is the User-Agent.

The Receiver shall return a response to the Sender according to DICOM PS3.18 Section 6.10.3.3.3.

Note: The Receiver will honor the HTTP Accept header field for encoding of the response message. However, if the Sender accepts both XML and JSON, then the Receiver can choose either format for the response message.

4.Y1.4.2.3 Expected Actions

The Sender has no expected actions.

4.Y4.5 Security Considerations

4.Y4.5.1 Security Audit Considerations

This transaction is not associated with an ATNA Trigger Event.

The Protocol Approval instances conveyed by this transaction are generic and do not contain personal health information.

