Integrating the Healthcare Enterprise

IHE Radiation Oncology
Technical Framework Supplement

Quality Assurance with Plan Veto Profile

Draft ~~in preparation for Public Comment~~ with comments after Public Comment, review by Test Tool Authors

Date: January~~October~~ 16~~2~~, 2014~~3~~

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Foreword

This is a supplement to the IHE Radiation Oncology Technical Framework <VX.X>. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

<For Public Comment:> This supplement is published on <Month XX, 201x> for Public Comment. Comments are invited and may be submitted at http://www.ihe.net/<domain>/<domain>comments.cfm. In order to be considered in development of the Trial Implementation version of the supplement, comments must be received by <Month XX, 201X>.

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 Radiation Oncology domain can be found at: http://www.ihe.net/Domains/index.cfm.

Information about the organization of IHE Technical Frameworks and Supplements and the process used to create them can be found at: http://www.ihe.net/About/process.cfm and http://www.ihe.net/profiles/index.cfm.

The current version of the IHE Radiation Oncology Technical Framework can be found at: http://www.ihe.net/Technical_Framework/index.cfm.

CONTENTS

Introduction to this Supplement

This supplement adds the Quality Assurance with Plan Veto (QAPV) profile to the IHE-RO Domain. The QAPV Profile describes the interaction between a Quality Check Requester and a Quality Check Performer that will force evaluation of radiation treatment data to detect and avoid severe treatment errors.

Open Issues and Questions

1. Transaction numbers are suggested at this time and should be given appropriate numbers and letter codes.

2. [In Progress] CP 1288 to add QAPV codes and structured report to DICOM standard

3. [2014-01-16] Edits to be reviewed:

    a. Workitem Code Inclusion

    b. Leftover COORDINATE reference should be deleted from table 3.4

    ~~2.~~c. Clarify update conditions: only state updates allowed

Formatted

Closed Issues

1. [Closed]Until it is clear that the two types of safety checks can be handled under one profile, the current aim is to create a generic profile with the ability to extend it to more specific applications if the transactions and objects needed cannot be handled under one profile. If multiple profiles are needed, section 2.1 below may need to be filled in. Modified: 4/16/2011 – added Appendices to discuss specific formatting and data for different evaluations. Will now try to cover both in this document, although the positioning evaluation will remain TBD for now.

   Added Appendices to discuss specific formatting and data for different evaluations. Will now try to cover both in this document, although the positioning evaluation will remain TBD for now

2. [Closed] The name of this profile should be reviewed and commented on.

   The name has been presented in various arena with no negative comments

3. [Closed]Can we use the verification information objects defined in Supplement 74 to express the evaluation of information at risk in objects? Do we have to limit this to plans? Do they need to be extended in some way?

   See issue 5 below.

4. [Closed] How do the changes outlined in Beam Dose Depth DICOM CP affect this profile? Additionally, the Beam Dose additions are associated at the dose reference sequence, not at the control point sequence, and so are not in line with what was intended. Some implementations already have these in place. Discussions

continue with Christof, Bruce, Chris P, and Craig L. [Update] Examples discussed in December to try to clarify how this can be specified for the profile.

5. [Closed]Supplement 74 has a lot to say on this model, although there have been issues with the 74 approach brought up at WG-6. These should be reviewed and taken into account.

   Not investing in the machine verification model of Supplement 74, but much of the document is useful in framing the data interactions here. Instead, the reporting of what failed a test is currently following the recommendation of DICOM WG-7, of using a structured report.

6. [Closed]We need more discussion on how the quality check rules are formulated, tested, reviewed and enforced. A Quality Check Performer actor should comply with which of the following? Section 1 in the supplement below will need to be modified depending on what we arrive at.

   a. Level 1 of Rule Visibility: The quality check rules are considered to be fully under the control of application implementation, and so it is up to each vendor to develop, market and publicize how effective they are in implementing their safety checks. Testing for profile compliance is limited to forcing a vetoable set of data to be sent, and a fail result being returned.

   b. Level 2 of Rule Visibility: The actor needs to make the rules set viewable in a common way. Testing and modification of the rules are closed to outside parties. Contents of the rules are part of the application implementation and are the reponsibility of the vendor to develop and market how effective they are in implementing their safety checks. Compliance checking includes those tests in Level 1, and that the product also allows rule review in a common way.

   c. Level 3 of Rule Visibility: Rules are viewable in a common way, and testing of the rules is structured and repeatable. Rules can be added in defined, automated way to make the Quality checks more restrictive than the initial set that the vendor supplies. Content of the initial rules is under complete control of the application vendor. Testing for compliance would follow those under level 1 and 2, but also include tests to add and exercise new rules to the QA checks.

   d. Level 4 of Rule Visibility: Rules are viewable in a common way, and testing of the rules is structured and repeatable. The initial set of rules is defined in a standard set as the responsibility of xxxx. Actor compliance at this level means they will implement the rules that are defined in this standard, and structured testing will demonstrate that they force compliance to these checks or rules when operating as the Quality Check Performer. Testing for compliance will use the standard set of rules to formulate data that can exercise the actor, as well as the tests referred to in level 1, 2 and 3.

   Quality checks will be viewable and testable (as per the QA Advisory Group Position Statement)…but are going to be set by the clinical staff. How the rules will be

expressed or set is up to vendor control, but testing of critical check will be exercisable using RT Plan data.

7. [Closed] Any other updates in RO-Q4 that need to be required? None noted.
8. [Closed] Should trigger events for the initial push of the Quality Check UPS be futher detailed? None noted.
9. [Closed]What value do checks other than those done ASAP have? Should it be specified that other interested parties may want a check done, but not necessarily immediately before treatment? Out of band for the profile. Technically, the QCP will probably not be aware whether a check request is ASAP or not, unless it supports some scheduling options that are outside the profile purveyance.
10. [Closed]Should the N-EVENT-REPORT updates be documented in further detail than they are in the high level sequence diagram for clarity? N-Event Report will only be used to note the UPS has been completed/cancelled, not as a mechanism for reporting the success/failure of the check.
11. [Closed]From Stuart:

    In Table A.1 Required Input Sequence Content for Dosimetric QA

    I think that it should be made explicit that the contents of the objects need to adhere to the requirements made inother profiles.

    There is no current mechanism (profile) to enforce that the Treatment Delivery System will receive the list of input objects that are identified (other than RT Plan). The current profile is Treatment Delivery Workflow (TDW). It doesn't address imaging/positioning.
    When IPDW is available, that will, so CT and RT Structure Set will have a specific means of being expressed (perhaps that's true for TDW, but it is never required in TDW). However, not all Treatment Delivery Systems will necessarily support import of volumetric data (2D/2D imaging only), and for sure, not all imaging sessions that are part of a treatment session ("session" is being used in a loose sense here) will demand (be scheduled) volumetric data (CT and RT Structure Set).

    One can make the argument that the RT Plan created by the TPS will have an RT Structure Set (required for the Basic RT Objects Interoperability Profile, and at least by inference in Advanced RT Objects Interoperability), so that even if it isn't an explicit part of the scheduled Treatment Delivery, the information is available to a device that needs to construct the Input Sequence Specification. And one can go even further and insist that because the RT Structure Set is referenced, a device can retrieve the object, inspect it, and identify which CT are required.

    But I don't see how one can ensure that the RT Dose will be uniquely referenced within the scope of an existing profile, nor how that RT Dose instance will be specified in the chain (from the Treatment Management System to the Treatment Delivery System).

If it is necessary for the TMS to identify which RT Dose is involved "out of band", then that should be made explicit.
(As a TMS vendor, I can see utility in having the TMS maintain the associations between RT Dose and RT Plan in a database).

However, there still isn't an explicit mechanism for getting this information over to the TDS utilizing a profile.

I suppose one can say that "it can go in the input sequence in TDW or IPDW", but that puts a burden on a device that is *not* in the profile. I don't know if RT Dose is actually needed for the use case (the QA vendors would need to weigh in). Beam Dose and Beam Meterset are part of the RT Plan. If that *can* be enough, I believe that *should* be all that is required.

Chris's note: The current set of attributes specified have been reviewed by those vendors expressing interest in creating a Quality Check Performer for Dose Check, and have been found to be sufficient.

12. [Closed]MLC leaf opening data: This would seem to be important in calculating dose delivered to the patient, but for the purposes of this profile, two things should be considered: 1) leaf pattern is not a attribute of the RT Plan. (At least the current generation) 2) Is it possible that the condition of a leaf that will be closed during a treatment would make the difference between a life-threatening delivery and a clearly non-life threatening delivery? If the answer to 2 is "no", then it seems we can ignore MLC leaf data. Are there other attributes missing from the DICOM objects in play that can make the calculation of critical levels of dose delivery be wildly inaccurate? Leaf pattern IS part of the RT Plan. Leaf Position Boundaries (300A,00BE)
13. [Closed]Radiosurgery and hypofractionated treatment – Arguments against usefulness of this safety profile approach:
    a. Hypofractionated doses might look like dangerous treatments and be flagged.
    b. To exempt hypfractionated dose levels, the dose levels that are judged dangrous will be so high as to be:
        i. Ludicrous
        ii. Never detected in any plan anywhere.
    c. The RT industry doesn't have the facility to reliably have a third party machine understand a structure whose dose limits are much lower (such as "spinal column" or "optic nerve"), and so extremely dangerous treatments can still slip through, and giving a false sense of security is really more dangerous than being clear that assessment and assurance needs to happen through a human agency every time.

The intent of the dose check component of this profile is to check for consistency between the dose described for coordinates, volume, site, or point, and the plan that has been formulated to deliver that dose. It will not independantly judge dose level outside of the plan. Under this scheme, a dose can be approved even if it is dangerously high if it is that way consistently in the plan, and matches what the plan delivers. In other words, this check will not protect against bad prescriptions, it intends to check that the plan delivers what it was told to deliverIssue

14. [Closed]The N-EVENT-REPORT usage refers to the Event Information parameter, however, I have difficulty finding a clear definition of how this is encoded.
The best description I could find was in the Print SOP Class, where a set of DICOM elements were in fact the Event Information.
If that is in fact the way that Event Information is encoded, then some choice needs to be made for the element or set of elements to use that constitute the Event Information.

As a strawman, I can imagine using either the Approval Status module or the Substance Approval Module. The N-Event report will not be used to express the check success/failure.

15. [Closed]Insert a note regarding the device types that could fulfill the QCR actor role.
16. [Closed] Check on addition of requirement for High Dose Technique (300A,00C7) in 3.4.5.5. Remove, make equal to DICOM standard. Atrribute removed from those listed as having requirements higher than DICOM standard.
17. [Closed] Need new workitem codes defined for the two types of check requests. RT reviewed and approved to go to WG-6 for CP assignment.
18. [Closed] Review N-Create responses to make sure that appropriate responses are found for 3.1.5.3.7 and 3.1.5.3.8. The response type that can be used for an unsupported or invalid Workitem Code Sequence Code Value would be Annex C.5.23 of Part 7, Unrecognized Operation.
19. [Closed] Progression of states when cancelled. 3.3.5.1 and 3.4.5.1. Progression state modified.
20. [Closed] Review for any other required attributes of RT Plan for 3.4 and 3.6 Sent for approval to move forward with current attribute set 6/22/12
21. [Closed] Decision on whether to include ION transactions or not. Removed Ion Transactions from this track of the document (“A” editions)
22. [Closed] Add precondition regarding readiness of report if stored in place other than the QCP itself
23. [Closed] Object Store Page 43, get rid of references to Object Store
24. [Closed] Check that changes in Quality Check Report are reflected in rest of profile.
25. [Closed] Need CP for templates in QAPV profile – RT 32

26. [Closed] Need CP to add Quality Check Performer descriptor for Item 2 in template XXXX (main body of Check Result Report). – RT 33
27. [Closed] Add "Critical" to item 6 in XXXX
28. [Closed] Value Type should be "Text" for Item 6 (Num assumes a measurement and has units attached.)
29. [Closed] Add "Critical" to item 7 in XXXX.
30. [Closed] Duplicate number 9, make number 10
31. [Closed] Edit item numbers of content items
32. [Closed] Item 2 in TID YYYY (main body of structured report representing the Check Request report) should be code descriptor = IHE-RO.
33. [Closed] Discuss items 1 and 2…they don't seem to both need to be there or at all, if item 3 denotes the Issue Severity of this detail item entry
34. [Closed] Item 3 should just be Issue is Critical - Yes/No
35. [Closed] Item 4 in YYYY, change value type to TEXT (more description, assume this is manufacturer code meaning…
36. [Closed] Need CP for values in value set constraint for item 5 in YYYY – RT 34
37. [Closed] Change item 5 in YYYY type to "CODE"
38. [Closed] Various grammar and spelling issues
39. [Closed] Add Output Info Seq return arrow on X.1-3
40. [Closed] Question on end of 2.3.3 – TMS vs. TPS compliance. Language allowing for TPS or TMS acting as a QCR is still in place in case a treatment delivery device is wholly controlled by one of these devices, and does not have the network or DICOM capability of managing the plan object itself.
41. [Closed] Is Check Report available if the UPS is canceled? "The Quality Check Performer is not required to create an instance of the Quality Check Report or to populate the Output Information Sequence of the Unified Procedure Step Performed Procedure Sequence if the step was CANCELLED"
42. [Closed] R* in Object Requirements
43. [Closed] Reincorporate CP 1138
44. [Closed] ARTI requirements / RT Plan Requirements (Table 3.4) – No
45. [Closed] Comment on Beam Limiting Device Sequence. Any plan items that are actually part of the treatment should be included. We will not force a beam limiting sequence if it is not neede for the treatment.
46. [Closed] N-Get Tags and Requirements
47. [Closed] Changes pending from Use Case review

48. [Closed] Statement on day / plan relationship and whether QCP is aware of this or checks it
49. [Closed] Review TDW safety list for criteria to EXCLUDE a plan for assessment (patient name is not found, MRNID is not found…etc.)
50. [Closed] Group review of updates for version 1.7A, based on discussion at november face-to-face meeting
51. [Closed] Changes to definitions, transaction 3.3 as per December and January teleconferences. Also, review outstanding changes to 3.7
52. [Closed] Review changes on 1/17/13, to tie down difference check matching. Also, change to structured report to allow other attributes for reporting critical issues
53. [Closed] Changes for Mar 7, 2013 on Object Requirements for Evaluation

General Introduction

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

Appendix A - Actor Summary Definitions

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

Actor	Definition
Quality Check Requester	A system that will be performing treatment, or is in control of treatment on another device. In this role, it requests evaluation of treatment parameters. The evaluation, expressed as a pass or fail, is then accessible to this actor. This actor must implement Plan Veto behavior when the evaluation results in a failure.
Quality Check Performer	A device that evaluates treatment parameters. It compares the treatment attributes to an earlier quality checked version of the same plan, and/ or performs Critical Checks based on the comparison of Critical Values and Supplied Attribute Values.

Appendix B - Transaction Summary Definitions

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

Transaction	Definition
RO-Q1: Create UPS for Quality Check	The Quality Check Performer implements the role of an SCP for UPS Worklist. The Quality Check Requester sends a request to create a UPS for a verification step.
RO-Q2: Subscribe to UPS Progress Update	The Quality Check Requester informs the Quality Check Performer that it wants updates on progress as it does the quality check.
RO-Q3: Workitem Input Objects Retrieval for Difference Check	The Quality Check Performer, using information supplied in the Input Information Sequence of the UPS from the Quality Check Requester, locates and retrieves data needed to do the difference evaluation.
RO-Q4: Workitem Input Objects Retrieval for Dose Check	The Quality Check Performer, using information supplied in the Input Information Sequence of the UPS from the Quality Check Requester, locates and retrieves data needed to do the dose evaluation.
RO-Q5: Update on UPS Progress	The Check Performer reports to the subscriber any important updates.
RO-Q6: Output Information Sequence Retrieval	One the Quality Check Performer has signaled that the UPS is completed, the Quality Check Requester gets the Output Information Sequence of the UPS for the check. This location will describe where to find the structured report containing the detailed information on the findings of the Quality Check and also contains the SOP Instance UID of the report object.
RO-Q7: Quality Check Report Retrieval	After completion or cancellation of the UPS, the Quality Check Requester will perform a C-Move request for the structured report detailing important information about the UPS processing, including the Critical Checks that were performed. The target of the Retrieval is found in the Output Information Sequence that was retrieved in transaction RO-Q6. (The Quality Check Performer is not required to supply a Check Report if the UPS status is CANCELLED, but it may be available)

RO-Q8: Unsubscribe to UPS Progress	The Quality Check Requester unsubscribes to the UPS updates from the Quality Check Performer.

Glossary

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

If these definitions are ambiguous when compared with existing items in the Glossary, please prepend "QAPV Profile" to the term.

Glossary Term	Definition
Supplied Attribute	A specific property, quality or characteristic of data, expressed unambiguously in meaning and units, supplied from some known source. Also can refer to a sequence, set or construct consisting of individual properties, qualities or characteristics.
Calculated Attribute	A specific property, quality or characteristic of data, expressed unambiguously in meaning and units, that is calculate by an acknowledged source from a set of supplied or calculated attributes. Also can refer to a sequence, set or construct consisting of individual properties, qualities or characteristics.
Attribute Value	A particular entry, magnitude, number or amount of an Attribute.
Candidate Treatment Plan	A plan containing a description of device operation to be immediately used to treat a patient with radiation. This is the plan object retrieved from the Quality Check Requester to be used for the Quality Check.
Critical Value	A specific entry, magnitude, number or amount that is a notable or important marker in the allowable range of a specific Attribute Value.
Critical Check	A comparison between a Critical Value and an Attribute Value that will contribute to the safety assessment performed by a Quality Check Performer.
QA Assessed Plan	A treatment plan whose quality has been assessed and recorded by a QA Device that performs a Difference Check, and also checked by a clinical staff member. This assessment and recording happens prior to the transactions in the QAPV profile. The plan and check results are stored on the QA Device for later comparison with candidate treatment plans, and for constructing the resulting structured report.
QA Matched Plan	A single QA Assessed Plan that, through various criteria, has been found to be equivalent to the Candidate Treatment Plan. This plan is used to create the structured report for the current invocation of the profile.

Volume 1 – Profiles

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

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Add to Section …

X Quality Assurance with Plan Veto Workflow Profile

The Quality Assurance with Plan Veto Profile describes behavior and interactions to allow checking for critical safety issues prior to treatment.

X.1 QAPV Actors, Transactions, and Content Modules

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

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

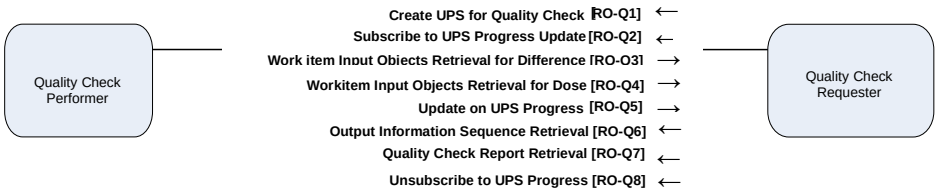

Figure X.1-1: QAPV Actor Diagram

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

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Table X.1-1: QAPV Profile - Actors and Transactions

Actors	Transactions	Optionality	Reference
Quality Check Performer	RO-Q1 Create UPS for Quality Check	R	
	RO-Q2 Subscribe to UPS Progress Update	R	
	RO-Q3 Workitem Input Objects Retrieval for Difference Check	RC – Required if RO-Q4 is not supported	
	RO-Q4 Workitem Input Objects Retrieval for Dose Check	RC – Required if RO-Q3 is not supported	
	RO-Q5 Update on UPS Progress	R	
	RO-Q6 Output Information Sequence Retrieval	R	
	RO-Q7 Quality Check Report Retrieval	R	
	RO-Q8 Unsubscribe to UPS Progress	R	
Quality Check Requester	RO-Q1 Create UPS for Quality Check	R	
	RO-Q2 Subscribe to UPS Progress Update	R	
	RO-Q3 Workitem Input Objects Retrieval for Difference Check	RC – Required if RO-Q4 is not supported	
	RO-Q4 Workitem Input Objects Retrieval for Dose Check	RC – Required if RO-Q3 is not supported	
	RO-Q5 Update on UPS Progress	R	
	RO-Q6 Output Information Sequence Retrieval	R	
	RO-Q7 Quality Check Report Retrieval	R	
	RO-Q8 Unsubscribe to UPS Progress	R	

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 Object Request Failure

If the object request made against the Quality Check Requester fails, either because the object is not found, or some other data inconsistency, the flow of interactions will follow those outlined in Sections 3.3.5.1 and 3.4.5.1: the state of the UPS will move from "SCHEDULED" to "IN PROGRESS" to "CANCELED" with appropriate updates being sent to the Quality Check Requester. A CANCELED status means that the UPS could not be performed. interactions after this point are outside the scope of this profile, but it does mean the check could not be performed, so the appropriate mitigation or exception handling is expected on the part of the Quality Check Requester actor.

X.1.1.2 Plan Veto

A critical requirement of this profile is that the Quality Check Requester relies upon on the Quality Check Performer to deliver a pass/fail judgement on the safety of the plan. The results of Critical Checks are communicated in the Structured Report prepared by the Quality Check Performer. If a critical issue is found, item EV (100000, IHE-RO, "Critical Issues Found") in the structured report will have the value "Yes". The Quality Check Requester must not allow automatic treatment or automatic override if the value of this item is "Yes". Only the EV (100000. IHE-RO, "Critical Issues Found") value should be used to trigger Plan Veto. Other entries in the structured report are for informational use only.

1. The Quality Check must be performed at a point where treatment can be prevented.
2. The benefit of the Critical Check increases the closer in time that the Check occurs to the start of treatment.

Since the plan veto is a capability of the Quality Check Requester itself, and not subject to an interoperable transaction, the implementation of that capability is up to the actor vendor. The testing of the adherence to the profile will exercise and evaluate this capability.

The override, if implemented, is expected to be interactive in some engaging way, as opposed to a simple Yes/No button dialog. It is suggested that the override present relevant portions of the Quality Check Report and force entry and persistence of a senior clinical staff member's id and password. The information must be captured in an auditable fashion and this capability will be part of the profile testing.

Note also that even though it is strongly advised that the check happen as closely to, but previous to, treatment as possible, it may not be the Treatment Delivery Device that adheres to the Quality Check Requester actor. The items required for the check may not be present on the Treatment Delivery Device, and so it may be required that the Treatment Management System, or Treatment Planning System has to fulfill the Quality Check Requester role.

X.2 QAPV Actor Options

There are no actor options.

X.3 QAPV Required Actor Groupings

There are no actor groupings for the QAPV profile.

X.4 QAPV Overview

X.4.1 Concepts

X.4.2 Use Cases

X.4.2.1 Use Case #1: Detect Dangerous Plan Specifications or Modifications

X.4.2.1.1 Detection Use Case Description

This profile grew out of a request from ASTRO to address patient safety via an IHE-RO profile. As such, it does not address a current clinical failing or use case that is commonly found, but tries to set up an inter-device check of plan attributes that can detect treatment issues. It cannot do it narrowly, and cannot fix a bad prescription.

The profile also implements a transaction flow that can be used to automate general treatment machine to QA device checks.

X.4.2.1.2 QAPV Process Flow

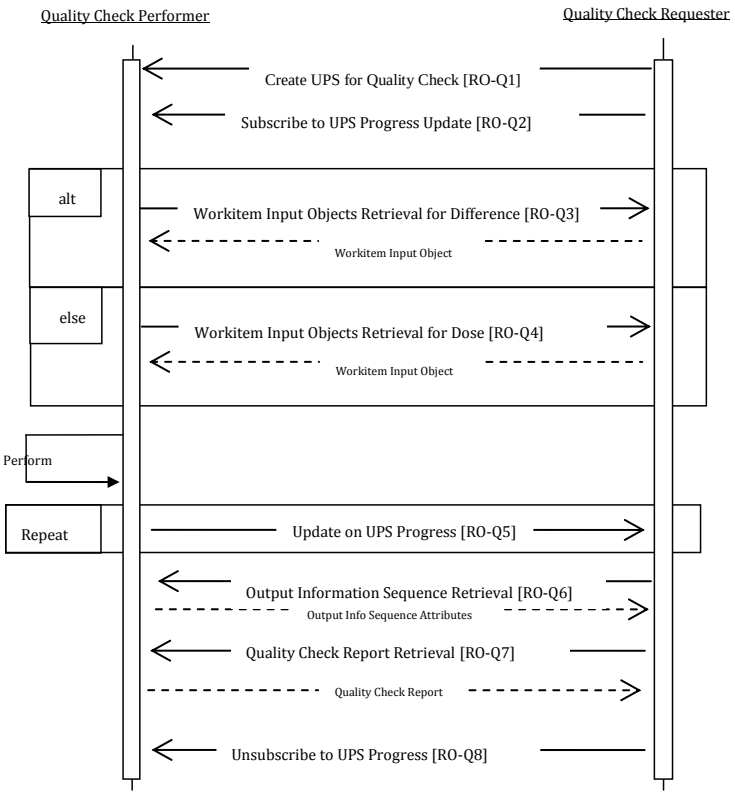


Figure X.4.2.2-1: Basic Process Flow in QAPV Profile

Pre-conditions:

The profile assumes some Critical Values have been defined on the Quality Check Performer. If the Critical Values have not been defined, the Quality Check Performer should accept the request to create a Unified Procedure Step to do a Quality Check, and will be required to cancel it after an initial subscription has been received. The profile also allows for the Quality Check Performer to indicate other required steps before the interactions described here can be supported.

Because of the varied Critical Checks and requirements of different Quality Check Performer products, it would be prudent for Quality Check Requesters to allow for configuration of, and submission to multiple Quality Check Performers for each treatment. It is anticipated that Quality Check Performers will implement models of performing checks which may not be appropriate for all patients at a given site.

Main Flow:

The Quality Assurance with Plan Veto profile describes behavior and interactions to augment safety checks during a patient's treatment in radiation therapy:

- The QAPV Check Performer accepts a UPS Workitem for a verification action from a Check Requester
- The Check Requester subscribes to updates on the workitem.
- The Check Performer actor requests the data specified in the UPS Workitem as required to perform the evaluation. If the data is not available, or deemed insufficient, the evaluation is not performed.
- The Check Performer performs the check and prepares the resulting structured report for retrieval by the Check Requester.
- The Check Performer updates subscribers on the work that was done, including final state.
- The Check Requester gets the Output Information Sequence from the UPS maintained by the Check Performer.
- The Check Requester requests retrieval of a structured report from the Check Performer using the SOP Instance and AE Title specified in the Output Information Sequence.
- The Check Requester unsubscribes to the workitem.

Post-conditions:

The Check Requester allows or prevents the treatment to proceed based on the information found in the structured report. Specific requirements on the treatment approval and override behavior can be found in section X.1.1.2

X.5 QAPV Security Considerations

X.6 QAPV Cross Profile Considerations

Quality Assurance with Plan Veto	Advanced RT Integration (ARTI)	Plan (Beam) types defined in ARTI that are supported by a Quality Check Performer should be documented in their Integration Statement	It is anticipated that different beam models will have different requirements and safety checks, and using the ARTI to drive the attribute requirements is appropriate to insure this occurs correctly.

Appendices

Appendix A – Actor Summary Definitions

Quality Check Requester – A system that will be performing treatment, or is in control of treatment on another device. In this role, it requests evaluation of treatment parameters. The evaluation, expressed as a pass or fail, is then accessible to this actor. This actor must implement Plan Veto behavior when the evaluation results in a failure.

Quality Check Performer – A device that evaluates treatment parameters. It performs Critical Checks based on the comparison of Critical Values and Supplied Attribute Values.

Appendix B – Transaction Summary Definitions

RO-Q1: Create UPS for Quality Check

The Quality Check Performer implements the role of an SCP for UPS Worklist. The Quality Check Requester sends a request to create a UPS for a verification step.

RO-Q2: Subscribe to UPS Progress Update

In this transaction, the Quality Check Requester informs the Quality Check Performer that it wants updates on progress as it does the quality check.

RO-Q3: Workitem Input Objects Retrieval for Difference Check

In the Workitem Input Objects Retrieval for Difference Check transaction, the Quality Check Performer, using information supplied in the Input Information Sequence of the UPS from the Quality Check Requester, locates and retrieves data needed to do the difference evaluation.

RO-Q4: Workitem Input Objects Retrieval for Dose Check

In the Workitem Input Objects Retrieval for Dose Check transaction, the Quality Check Performer, using information supplied in the Input Information Sequence of the UPS from the Quality Check Requester, locates and retrieves data needed to do the dose evaluation.

RO-Q5: Update on UPS Progress

In the Update on UPS Progress transaction, the Check Performer reports to the subscriber any important updates.

RO-Q6: Output Information Sequence Retrieval

Once the Quality Check Performer has signaled that the UPS is Completed, the Quality Check Requester gets the Output Information Sequence of the UPS for the check. This location will describe where to find the structured report containing the detailed information on the findings of the Quality Check and also contains the SOP Instance UID of the report object.

RO-Q7: Quality Check Report Retrieval

After Completion or Cancellation of the UPS, the Quality Check Requester will perform a C-Move request for the structured report detailing important information about the UPS processing, including the Critical Checks that were performed. The target of the Retrieval is found in the Output Information Sequence that was retrieved in transaction RO-Q6. (The Quality Check Performer is not required to supply a Check Report if the UPS status is CANCELED, but it may be available)

RO-Q8: Unsubscribe to UPS Progress

In this transaction, the Quality Check Requester unsubscribes to UPS updates from the Quality Check Performer.

Volume 2 – Transactions

Add section 3.Y

3.Y RO-Q1: Create UPS for Quality Check

3.Y.1 Scope

In the Create UPS for Quality Check transaction, a Quality Check Performer receives a request from a Quality Check Requester to create a UPS with an appropriate verification workitem type.

3.Y.2 Actor Roles

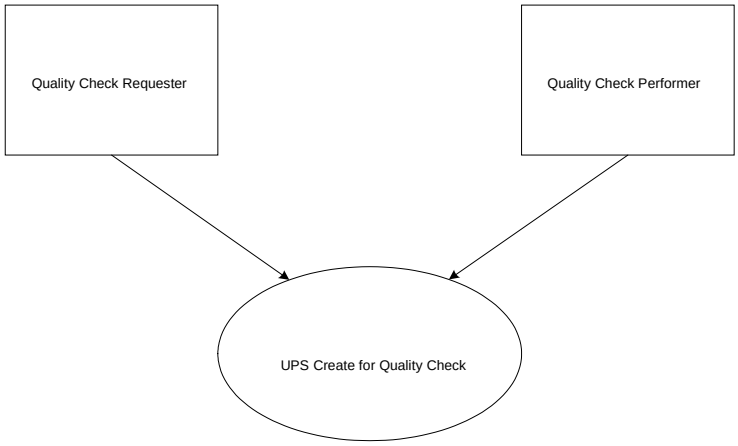


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

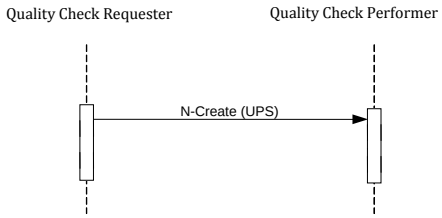
Actor:	Quality Check Requester
Role:	Uses the N-CREATE DIMSE service with a UPS Push SOP class to create a procedure to perform a quality check on the Quality Check Performer
Actor:	Quality Check Performer
Role:	Receives request for the UPS Push of a UPS Worklist object from a Quality Check Requester and creates the Unified Procedure Step

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.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4-2011 Annex CC.2.1

3.Y.4 Interaction Diagram



3.Y.4.1 N-Create Message

This is a UPS Push worklist message sent to the Quality Check Performer.

3.Y.4.1.1 Trigger Events

Either automatically triggered by treatment workflow, or by a specific user gesture on the Quality Check Requester, or one of the devices it is controlling.

3.Y.4.1.2 Message Semantics

The Quality Check Requester uses the N-CREATE request of the DICOM Unified Procedure Step – Push SOP Class to push a workitem onto the worklist of the Quality Check Performer. The Quality Check Requester performs the SCU role, and the Quality Check Performer performs the SCP role. The message contains a formatted UPS under the UPS Push SOP class indicating the desired evaluation.

3.Y.4.1.2.1 Preconditions

The Quality Check Performer can stipulate requirements of its choosing before accepting requests for creating a Quality Check procedure step. In general, these requirements are meant to cover configuration steps or other critical settings that need to be in place before a quality check can be performed. These requirements are outside the scope of this profile. The requirements stipulated cannot violate the specific details or general intention of the profile.

The Quality Check Performer should specify if it needs to limit active subscribed UPSs for Quality Check to some number at any given time.

3.Y.4.1.2.2 SOP InstanceUID

This value is required by the standard in the SOP Common Module Attributes, but the DICOM Standard states that in an N-CREATE request message, it is "not allowed". This should be left unassigned, and is the task of the Quality Check Performer to assign, and return a valid SOP Instance UID.

3.Y.4.1.2.3 Scheduled Procedure Step Start

The earliest Scheduled Procedure Step Start Date and Time (0040,4005) of the UPS can be used by the Quality Check Performer to set the order of checks if processing more than one Quality Check Request at a time.

3.Y.4.1.2.4 Scheduled Procedure Step Priority

Quality Check Performer should in general ignore this attribute, and process check requests in the order received.

3.Y.4.1.2.5 Input Readiness State

Shall be READY. This indicates that the Workitem needed for the Quality Check is available for retrieval by the Performer via C-MOVE

3.Y.4.1.2.6 Input Information Sequence Specification

The Input Information Sequence (0040,4021) shall contain reference to one of the following items :

The RT Plan SOP Instance to be delivered. The specified location should contain the plan in a state exactly as it is planned to be treated.

Table 3.Y.1 Required Input Sequence Content for Quality Check

SOP Class Name	SOP Class UID	Condition
RT Plan Storage	1.2.840.10008.5.1.4.1.1.481.5	If transaction RO-Q3 or RO-Q4 is supported

3.Y.4.1.2.7 Required Attribute Values

The Scheduled Workitem Code Sequence (0040,4018) Code Value shall be ~~equal~~ either value 121731 (RT Treatment QA with RT Plan Dose Check) or 121732 (RT Treatment QA with RT Plan Difference Check) under Context ID 9241 in the DICOM standard.

and~~to xxxx and~~ Coding Scheme Designator shall be equal to 'DCM'. ~~[New Workitem codes go here]~~

3.Y.4.1.2.8 Return Value

If the N-CREATE request cannot be handled by the Quality Check Performer, because of missing references, invalid message formatting, invalid workitem code or other reasons, an error response should be returned as per DICOM Part 7 Annex C. Because the subscription request has not been received from the Check Requester at this point, there is no other facility to signal a canceled workitem at this point. Canceling a request because of the existence of a prior UPS for Quality Check is not acceptable up to the limit of concurrent checks the Quality Check Performer has specified.

The successful response should contain the SOP Instance UID of the Unified Procedure Step created in this transaction.

3.Y.4.1.3 Expected Actions

Quality Check Performer creates the expected Unified Procedure Step

3.Y RO-Q2: Subscribe to UPS Progress Update

3.Y.1 Scope

In the Subscribe to UPS Progress Update transaction, the Quality Check Requester issues a request to the Quality Check Performer to receive updates on the evaluation.

3.Y.2 Actor Roles

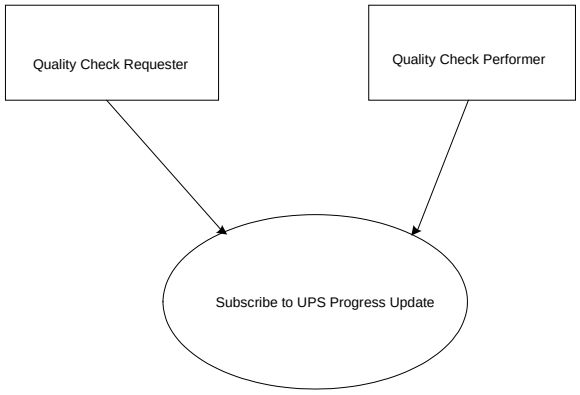


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

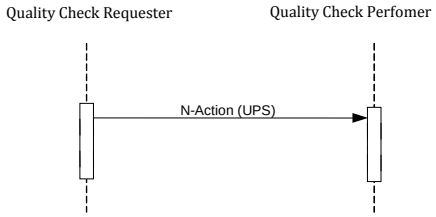
Actor:	Quality Check Requester
Role:	Uses the N-ACTION service request under a UPS Watch SOP class to subscribe to the UPS created in transaction RO-Q1
Actor:	Quality Check Performer
Role:	Processes subscription request

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.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4-2011 Annex CC.2.3

3.Y.4 Interaction Diagram



3.Y.4.1 Subscribe N-ACTION Message

3.Y.4.1.1 Trigger Events

After successful notification from the Quality Check Performer that the UPS has been created, the Quality Check Requester should issue this transaction.

3.Y.4.1.2 Message Semantics

This message should specify the UPS Watch SOP Class as the abstract syntax, but specify the original UPS Push SOP Instance UID of the UPS created in RO-Q1 as the Requested SOP Instance UID in the N-ACTION message.

3.Y.4.1.2.1 Global and Locking Subscriptions

The Quality Check Performer should refuse Global subscription requests. Only non-locking subscriptions should be processed.

3.Y.4.1.3 Expected Actions

Quality Check Performer subscribes the requester to the updates of the Unified Procedure Step.

3.Y RO-Q3: Workitem Input Objects Retrieval for Difference Check

3.Y.1 Scope

In the RO-Q3 Workitem Input Objects Retrieval for Difference Check transaction, the Quality Check Performer requests and receives from the target specified in the UPS in RO-Q1 the RT Plan instance required for performing the evaluation. For the Difference evaluation, this instance of the RT Plan is the Candidate Treatment Plan.

3.Y.2 Actor Roles

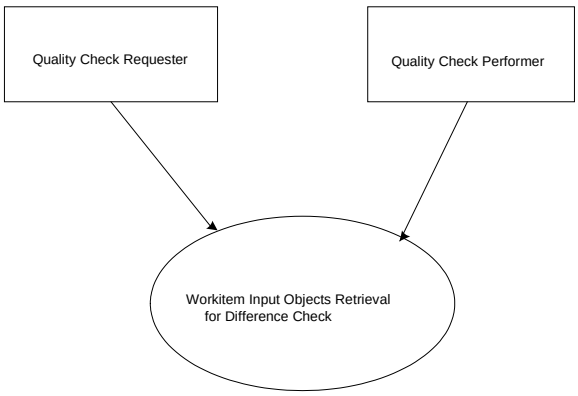


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

Actor:	Quality Check Requester
Role:	Receives request and sends requested DICOM objects to the Quality Check Performer.

Actor:	Quality Check Performer
Role:	Requests and receives requested DICOM objects from the Quality Check Requester

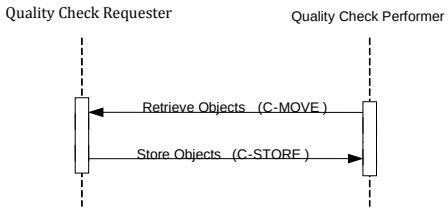
Transaction text specifies behavior for each Role. The behavior of specific Actors may also be specified when it goes beyond that of the general Role.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4: Storage Service Class

DICOM Standard 2011 PS 3.4: Query/Retrieve Service Class

3.Y.4 Interaction Diagram



3.Y.4.1 Workitem Objects Retrieval Message

3.Y.4.1.1 Preconditions

It is expected that for Quality Check Performer actors that implement the Difference Check transaction some previous assessment or approval has been applied to zero or more RT Plans before the transactions in this profile have been started. As a result of these previous checks, a set of QA Assessed Plans will be stored on the Quality Check Performer. The Candidate Treatment Plan moved in this transaction will be compared against a subset of the QA Assessed Plans to determine if a QA Matched Plan exists.

It is also expected that the version of the plan that is assessed by this QA device, and that which is used for treatment will differ. If this is the case, the Quality Check Performer which implements the Difference Check, at the time of the pre-profile assessment, should expect to receive a full treatment plan and also a modified treatment plan that it will actually do the assessment on. It will need to store the results of the assessment along with the modified treatment plan and full treatment plan in order to fully comply with the behavior of this transaction.

The Retrieve (Study Root – MOVE) SOP Class shall be supported. Implementations shall support modes of operation in which a single series (e.g. input CT Series) or specific SOP Instances (e.g. an RT Plan) are retrieved from the Quality Check Requester using the Study Root – MOVE SOP Class. Refer to DICOM 2007 PS 3.4, Annex C, for detailed descriptive semantics.

A Quality Check Performer shall be capable of issuing Study-Root C-MOVE for the RT Plan Object.

A Quality Check Performer may receive an RT Plan in the Input Information Sequence for which it determines that it cannot perform the Difference Check. (Situations where this can occur are discussed below in "3.3.5.5 Object Requirements for Evaluation")

In such cases:

- If the Procedure Step is not yet "IN PROGRESS", the Quality Check Performer should move the Procedure Step to "IN PROGRESS" and then to "CANCELED" and update any subscribers.
- If the Procedure Step is already "IN PROGRESS", the Quality Check Performer shall move the Procedure step to "CANCELED" and update any subscribers

3.Y.4.1.2 Trigger Events

The Quality Check Performer, in order to perform a Quality Check, requests the RT Plan referenced in the Input Information Sequence (0040,4021) from the Quality Check Requester.

3.Y.4.1.3 Message Semantics

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

A C-MOVE Request from the DICOM Study Root Query/Retrieve Information Model – MOVE SOP Class shall be sent from the Quality Check Performer to the Quality Check Requester.

3.Y.4.1.3.1 Object Requirements for Evaluation

Table 3.Y.4.1.3.1 - RT General Plan Module Requirements for Difference Quality Check Requester

Attribute Name	Tag	DICOM Type	Transaction Req.	Attribute Description
Referenced RT Plan Sequence	(300C,0002)	3	R+*	Related instances of RT Plan. One or more items are permitted in this sequence.

>Referenced SOP Class UID	(0008,1150)	1	R*	Uniquely identifies the referenced SOP Class.
>Referenced SOP Instance UID	(0008,1155)	1	R*	Uniquely identifies the referenced SOP Instance
RT Plan Relationship	(300A,0055)	1	R+*	Relationship of referenced plan with respect to current plan. Defined Terms: PRIOR = plan delivered prior to current treatment ALTERNATIVE = alternative plan prepared for current treatment PREDECESSOR = plan used in derivation of current plan QAPV_EQUIVALENT = referenced plan is purported to be dosemetrically equivalent to the current plan VERIFIED_PLAN = plan which is verified using the current plan. This value shall only be used if Plan Intent (300A,000A) is present and has a value of VERIFICATION CONCURRENT = plan that forms part of a set of two or more RT Plan instances representing a single conceptual 'plan', applied in parallel in one treatment phase

The incoming Candidate Treatment Plan should be compared to the plans that were previously assessed by the Quality Check Performer, called the QA Assessed Plans. This comparison is expected to be done to verify that an earlier, out of profile scope, quality check is still valid.

The rules for matching a Candidate Treatment Plan have been formulated with the understanding that the following events are common clinical practice. These practices may not comply with the exact requirements of the DICOM specification, but products in the space should expect to encounter them, and the structure of the profile accounts for this.

- Patient name or ID being changed/coerced in a plan without generating a new SOP instance UID for the plan ("Bob"->"Robert")

- Non-treatment beams being added or removed from a plan after export from the TPS.
- Delivery parameters being changed outside of the TPS (which typically results in the plan no longer being dosimetrically equivalent)

Every time that a plan is changed and the corresponding new SOP Instance UID is created for the modified plan, one of two things should happen:

- If the change does not affect any dosimetric parameters, then the new plan should have a Referenced RT Plan Sequence added that points to the SOP Instance UID of the previous plan. The RT Plan Relationship value should be QAPV_EQUIVALENT to denote that these two plans should be assumed equivalent for the purposes of the safety checks in this profile.
- If the change does affect dosimetric parameters, then the new plan should have all Referenced RT Plan Sequences with RT Plan Relationship value set to QAPV_EQUIVALENT removed, as the two plans are no longer equivalent for the purposes of the profile.

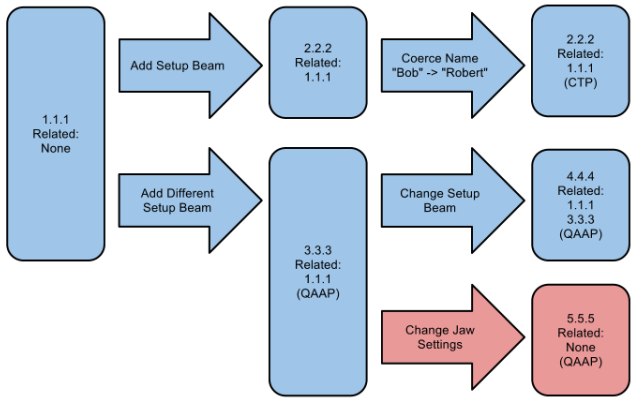
When the Quality Check Performer receives a Candidate Treatment Plan, every QA Assessed Plan that can be linked to the Candidate Treatment Plan must be collected and compared for dosimetric equivalence. A QA Assessed Plan can be linked to a Candidate Treatment Plan by the SOP Instances matching directly, the SOP Instance of one appearing in the QAPV_EQUIVALENT list of the other, or by having a SOP Instance common to both QAPV_EQUIVALENT lists.

If there are zero linked plans in the set of QA Assessed Plans, then the Quality Check Performer must cancel the request.

If any of the linked QA Assessed Plans are not dosimetrically equivalent to the Candidate Treatment Plan, that QA Assessed Plan becomes the QA Matched Plan and the structured report must indicate Critical Issue Found, due to the possibility that the Candidate Treatment Plan has been changed in a way that is dangerous to the patient. Otherwise, the plans are considered equivalent, and the QA Matched Plan is chosen by checking:

- If any of the linked plans have Critical Issue Found set to YES, then the most recent of those is chosen to be QA Matched Plan, and the structured report must indicate a veto.
- Otherwise, the most recent linked plan is the QA Matched Plan, and the structured report is constructed accordingly.

Figure 3.Y.3 QAPV_EQUIVALENT Processing



For the purposes of this example, the plans with SOP Instance UID 3.3.3 ,4.4.4, and 5.5.5 have been previously assessed by the Quality Check Performer. These plans are related via QAPV Equivalence as indicated in the image above.

The Candidate Treatment Plan is one of the two plans with SOP Instance UID 2.2.2, which has 1.1.1 in the QAPV Equivalent list, also as indicated above.

The Candidate Treatment Plan is linked to both 3.3.3 and 4.4.4 due to all three plans having 1.1.1 in their QAPV Equivalent lists.

If any dosimetric differences exist between 2.2.2 and 3.3.3, or between 2.2.2 and 4.4.4, then the Candidate Treatment Plan will be vetoed by returning a structured report with Critical Issue Found set to YES.

The rules for how a product curates the set of QA Assessed Plans is out of scope of this profile. It is expected that the Quality Check Performer will have a set of QA Assessed Plans with more than one member (for example, one or more plan per patient currently undergoing treatment), but that is not required by the profile. It is also expected, but not required, that the set of QA Assessed Plans will include plans that have negative quality assessments, so that the Quality Check Performer can inform the Quality Check Requester that the plan should be vetoed, rather than returning a Cancel due to lack of information.

The Quality Check Performer needs to be able to clearly communicate to the users what plans are present in the set of QA Assessed Plans, as well as if a given plan check is "more recent" than another. The method by which this information is communicated is out of scope for this profile.

For the purposes of plan comparison, how delivery parameters should be compared is not explicitly defined by the profile, and is left to the discretion of each implementation of the QCP actor. In general, it is expected that plans that do not have appreciable differences in their delivery parameters should have equivalent treatment effect upon delivery as each other.

The profile does not require other values to be checked, such as day and time of treatment. Since the emphasis of the profile currently is to catch the most egregious cases, it is felt that this is not ideal, but passable. The Candidate Treatment Plan will be compared against a previously checked and passed plan, whether it is the one appropriate to today's treatment or not. This does not preclude this check from being part of a specific implementation.

The class of plans that a Quality Check Performer will be able to evaluate shall be specified in the DICOM Conformance statement in terms of the beam types and options within the ARTI profile.

The Quality Check Performer is expected to document any exceptions to the supported ARTI Beam Models that would result in a CANCELATION of the requested assessment. In general, it should be possible to infer which plans a Quality Check Performer can assess from its DICOM Conformance Statement.

3.Y.4.1.4 Expected Actions

The Quality Check Requester receives the C-MOVE request, establishes a DICOM association with the Quality Check Performer actor, and transfers the requested object.

The Quality Check Performer is then expected to use the requested objects in the performing of the desired evaluation.

3.Y RO-Q4:Workitem Input Objects Retrieval for Dose Check

3.Y.1 Scope

In the Workitem Input Objects Retrieval for Dose Check transaction, the Quality Check Performer requests and receives from the Quality Check Requester the RT Plan specified in the UPS in RO-Q1 required for performing the evaluation. The Plan instance must

have been supplied in the Input Information Sequence of the initial UPS N-CREATE request.

3.Y.2 Actor Roles

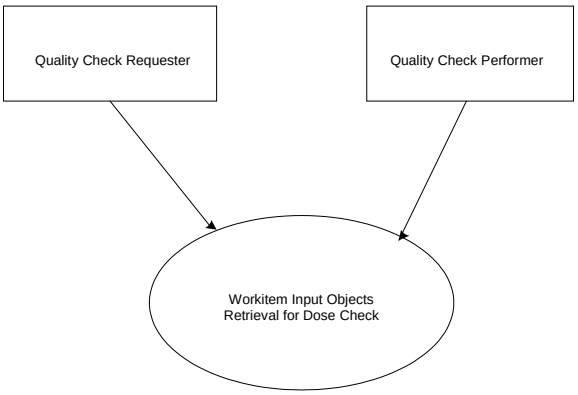


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Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

Actor:	Quality Check Requester
Role:	Receives C-MOVE request and sends requested DICOM objects to the Quality Check Performer
Actor:	Quality Check Performer
Role:	Requests and receives requested DICOM objects from the Quality Check Requester.

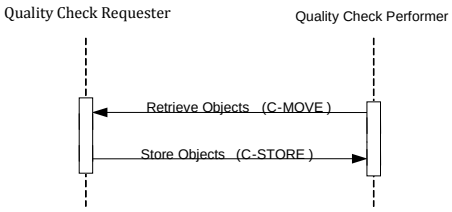
Transaction text specifies behavior for each Role. The behavior of specific Actors may also be
920 specified when it goes beyond that of the general Role.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4:Storage Service Class

DICOM Standard 2011 PS 3.4: Query/Retrieve Service Class

3.Y.4 Interaction Diagram



3.Y.4.1 Retrieve Workitem Objects Message

This is a UPS Push worklist message sent to the Quality Check Performer.

3.Y.4.1.1 Preconditions

The Retrieve (Study Root – MOVE) SOP Class shall be supported. Implementations shall support modes of operation in which a single series (e.g. input CT Series) or specific SOP Instances (e.g. an RT Plan) are retrieved from the Quality Check Requester using the Study Root – MOVE SOP Class. Refer to DICOM 2011 PS 3.4, Annex C, for detailed descriptive semantics.

A Quality Check Performer shall be capable of issuing Study-Root C-MOVE for the RT Plan specified in the Input Information Sequence. Other mechanisms for obtaining the data (such as C-STORE or restoring from a DICOM medium) shall not be relied upon to obtain the data.

A Quality Check Performer may receive SOP Instance UIDs in the Input Information Sequence for which it determines that it cannot perform the Quality Check safely. In such cases:

- If the Procedure Step is not yet “IN PROGRESS”, the Quality Check Performer should move the Procedure Step to “IN PROGRESS” then to “CANCELED” and update any subscribers.
- If the Procedure Step is already “IN PROGRESS”, the Quality Check Performer shall movethe Procedure Step to “CANCELED” and update any subscribers

3.Y.4.1.2 Trigger Events

The Quality Check Performer, in order to perform a Quality Check, requests the RT Plan referenced in the Input Information Sequence (0040,4021) that it needs for the selected work item.

3.Y.4.1.3 Message Semantics

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

A C-MOVE Request from the DICOM Study Root Query/Retrieve Information Model – MOVE SOP Class shall be sent from the Quality Check Performer to the location specified in the UPS Input Information Sequence.

It is assumed that the RT Plan has been readied for retrieval by a means outside the scope of this profile.

3.Y.4.1.3.1 Object Requirements for Evaluation

The RT Plan that is moved in transaction RO-Q4 has requirements under this profile that are more restrictive than the DICOM standard.

Transaction Requirements that are the same as the DICOM requirements are not listed below, unless it helps in the readability of these tables.

References to Notes or other DICOM sections have been deleted. The DICOM standard should be referenced for supporting information, and for other attribute requirements.

The class of plans that a Quality Check Performer will be able to evaluate shall be specified in the DICOM Conformance statement in terms of the beam types and options within the ARTI profile.

The Quality Check Performer is expected to document any exceptions to the supported ARTI Beam Models that would result in a CANCELATION of the requested assessment. In general, it should be possible to infer which plans a Quality Check Performer can assess from its DICOM Conformance Statement.

All extant DICOM specifications in the RT Plan should also be supplied to the Quality Check Perfomer. The Quality Check Performer should get an RT Plan that is at least as fully detailed as what the Quality Check Requester requires to do treatment, and beyond that, there are further more stringent requirements for this case as documented below.

Table 3.4 - RT Prescription Module Requirements for Quality Check Requester

Attribute Name	Tag	DICOM Type	Transaction Req.	Attribute Description
Dose Reference Sequence	(300A,0010)	3	R+*	Introduces sequence of Dose References. One or more items are permitted in this sequence.
>Dose Reference Structure Type	(300A,0014)	1	R+*	Structure type of Dose Reference. ~~Only a Structure Type of COORDINATES is supported in this profile. COORDINATES = point specified by Dose Reference Point Coordinates~~

				~~(300A,0018).~~
>Dose Reference Point Coordinates	(300A,0018)	1C	R+*	Coordinates (x,y,z) of Reference Point in the patient based coordinate system described in C.7.6.2.1.1 (mm).
>Dose Reference Type	(300A,0020)	1	R*	Type of Dose Reference. Defined Terms: TARGET = treatment target (corresponding to GTV, PTV, or CTV in ICRU50) ORGAN_AT_RISK = Organ at Risk (as defined in ICRU50)
>Constraint Weight	(300A,0021)	3	O*	Relative importance of satisfying constraint, where high values represent more important constraints.
>Delivery Warning Dose	(300A,0022)	3	O*	The dose (in Gy) which when reached or exceeded should cause some action to be taken. (This is not to be confused with one of the Critical Values defined on the Quality Check Performer. This attribute is a setting often found on the TPS or TMS.)
>Delivery Maximum Dose	(300A,0023)	3	R+*	The maximum dose (in Gy) which can be delivered to the dose reference. (Definition unique to this profile: This value can be used if the Dose Reference Type is ORGAN AT RISK.)
>Target Minimum Dose	(300A,0025)	3	R+*	Minimum permitted dose (in Gy) to Dose Reference if Dose Reference Type (300A,0020) is TARGET.
>Target Prescription Dose	(300A,0026)	3	R+*	Prescribed dose (in Gy) to Dose Reference if Dose Reference Type (300A,0020) is TARGET.
>Target Maximum Dose	(300A,0027)	3	R+*	Maximum permitted dose (in Gy) to Dose Reference if Dose Reference Type (300A,0020) is TARGET.

Table 3.5 - RT Fraction Scheme Module Requirements for Quality Check Requester

Attribute Name	Tag	DICOM Type	Transaction Req.	Attribute Description
Fraction Group Sequence	(300A,0070)	1	R*	Introduces sequence of Fraction Groups in current Fraction Scheme. One or more items shall be included in this sequence.
>Fraction Group Number	(300A,0071)	1	R*	Identification number of the Fraction Group. The value of Fraction Group Number (300A,0071) shall be unique within the RT Plan in which it is created.
>Referenced Dose Sequence	(300C,0080)	3	O*	Related instances of RT Dose (for grids, isodose curves and named/unnamed point doses). One or more items are permitted in this sequence. See Note 1.
	>>Include 'SOP Instance Reference Macro' Table 10-11			
>Referenced Dose Reference Sequence	(300C,0050)	3	O*	Introduces sequence of Dose References for the current Fraction Group.
>>Referenced Dose	(300C,0051)	1	R*	Uniquely identifies Dose Reference specified by Dose

Reference Number				Reference Number (300A,0012) within Dose Reference Sequence (300A,0010) in RT Prescription Module.
>>Constraint Weight	(300A,0021)	3	O+*	Relative importance of satisfying constraint, where high values represent more important constraints. Redundant with Prescription Dose. Should be excluded under this Profile if possible.
>>Delivery Warning Dose	(300A,0022)	3	O+*	The dose (in Gy) which when reached or exceeded should cause some action to be taken. Redundant with Prescription Dose. Should be excluded under this Profile if possible.
>>Delivery Maximum Dose	(300A,0023)	3	O+*	The maximum dose (in Gy) which can be delivered to the dose reference. Redundant with Prescription Dose. Should be excluded under this Profile if possible.
>>Target Minimum Dose	(300A,0025)	3	O+*	Minimum permitted dose (in Gy) to Dose Reference if Dose Reference Type (300A,0020) of referenced Dose Reference is TARGET. Redundant with Prescription Dose. Should be excluded under this Profile if possible.
>>Target Prescription Dose	(300A,0026)	3	O+*	Prescribed dose (in Gy) to Dose Reference if Dose Reference Type (300A,0020) of referenced Dose Reference is TARGET. Redundant with Prescription Dose. Should be excluded under this Profile if possible
>>Target Maximum Dose	(300A,0027)	3	O+*	Maximum permitted dose (in Gy) to Dose Reference if Dose Reference Type (300A,0020) of referenced Dose Reference is TARGET. Redundant with Prescription Dose. Should be excluded under this Profile if possible.
>Number of Fractions Planned	(300A,0078)	2	R+*	Total number of treatments (Fractions) prescribed for current Fraction Group. Required to allow safety assessment of treatment course.
>Referenced Beam Sequence	(300C,0004)	1C	R*	Introduces sequence of treatment beams in current Fraction Group. One or more items shall be included in this sequence. Required if Number of Beams (300A,0080) is greater than zero.
>>Beam Dose Specification Point	(300A,0082)	3	O*	Coordinates (x,y,z) of point at which Beam Dose is specified in the patient based coordinate system described in C.7.6.2.1.1 (mm).
>>Beam Dose	(300A,0084)	3	R+*	Dose (in Gy) at Beam Dose Specification Point (300A,0082) due to current Beam.
>>Beam Meterset	(300A,0086)	3	R+*	Machine setting to be delivered for current Beam, specified in Monitor Units (MU) or minutes as defined by Primary Dosimeter Unit (300A,00B3) (in RT Beams Module) for referenced Beam.

Table 3.6 - RT Beams Module Requirements for Quality Check Requester

Attribute Name	Tag	DICOM Type	Transaction Req.	Attribute Description
Beam Sequence	(300A,00B0)	1	R*	Introduces sequence of treatment beams for current RT Plan. One or more items shall be included in this sequence.
>Primary Fluence Mode Sequence	(3002,0050)	3	R+*	Sequence defining whether the primary fluence of the treatment beam uses a non-standard fluence-shaping. Only a single item is permitted in this sequence. Required for Profile if exists.
>Control Point Sequence	(300A,0111)	1	R*	Introduces sequence of machine configurations describing treatment beam. Two or more items shall be included in this sequence. See C.8.8.14.5 and C.8.8.14.6.
>>Control Point Index	(300A,0112)	1	R*	Index of current Control Point, starting at 0 for first Control Point.
>>Referenced Dose Reference Sequence	(300C,0050)	3	R+*	Introduces a sequence of Dose References for current Beam. One or more items are permitted in this sequence. This sequence should be populated for all beams that will have a dose delivery effect on the dose references listed in the RT Prescription Module
>>>Referenced Dose Reference Number	(300C,0051)	1	R*	Uniquely identifies Dose Reference specified by Dose Reference Number (300A,0012) in Dose Reference Sequence (300A,0010) in RT Prescription Module.
>>>Cumulative Dose Reference Coefficient	(300A,010C)	2	R+*	Coefficient used to calculate cumulative dose contribution from this Beam to the referenced Dose Reference at the current Control Point. See C.8.8.14.7

3.Y.4.1.4 Expected Actions

The Quality Check Requester receives the C-MOVE request, establishes a DICOM association with the Quality Check Performer actor, and uses the appropriate DICOM Object SOP Classes to transfer the requested objects.

The Quality Check Performer is expected to consume the plan and to judge, based on required values in the RT Plan object in comparison with the Critical Values that were previously defined, whether the RT Plan, when delivered, would result in an intolerable radiation exposure. Specifically, the Quality Check Performer should

995 take the RT Prescription specifications, and using the beam description supplied in the RT Beams Module, make a judgment of whether the beam delivery will exceed the prescription in a radical way.

1000 # 3.Y RO-Q5:Update on UPS Progress

3.Y.1 Scope

In the Update on UPS Progress transaction, the Quality Check Performer updates all subscribed actors on any important attribute changes to the UPS.

3.Y.2 Actor Roles

1005

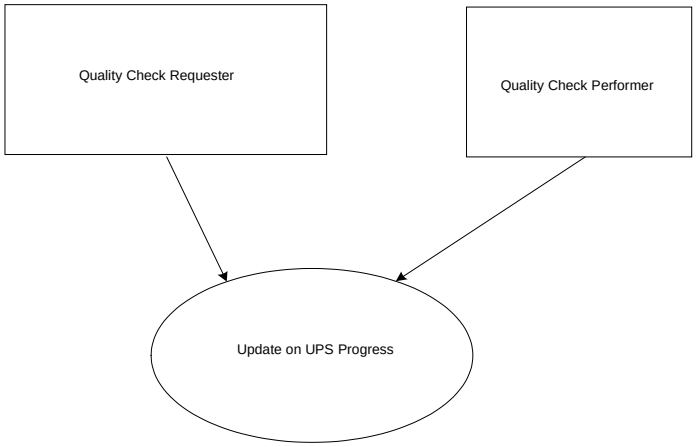


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

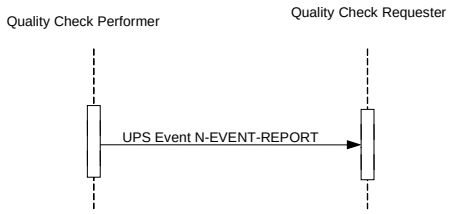
Actor:	Quality Check Performer
Role:	Sends N-EVENT-REPORT to update the Quality Check Requester subscriber when a UPS change occurs.
Actor:	Quality Check Requester
Role:	Receives N-EVENT-REPORT on updates to subscribed UPS.

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.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4-2011 Annex CC.2.4

3.Y.4 Interaction Diagram



3.Y.4.1 Update on UPS Progress

The Quality Check Performer uses the N-EVENT-REPORT of the UPS Event SOP Class to inform the Quality Check Requester of important changes to the UPS. Any state change is appropriate, but there is one required update, documented below.

3.Y.4.1.1 Trigger Events

When important changes occur to the UPS while the Quality Check Performer is running the evaluation, N-EVENT-REPORT messages should be sent.

3.Y.4.1.1.1 Required Actions

The Quality Check Performer MUST send an N-EVENT-REPORT when the UPS is completed or discontinued.

If the evaluation is judged to be undoable, the UPS should be set to CANCELED, and this N-EVENT-REPORT should be sent to the Check Requester.

3.Y.4.1.2 Message Semantics

In either a COMPLETED or CANCELED state change, status report should come with Event Type ID 1. (Table C.C.2.4-1 in PS 3.4-2011). If the UPS is set to CANCELED, the Reason for Cancellation and Procedure Step Discontinuation Reason Code Sequence are required under this profile. Defined Context ID for the Code Sequence is 9300.

~~No specific semantics.~~

3.Y.4.1.3 Expected Actions

When completion is signaled, the Quality Check Requester should perform the RO-Q6 transaction.

3.Y RO-Q6: Output Information Sequence Retrieval

3.Y.1 Scope

In the Output Information Sequence Retrieval transaction, the Quality Check Requester issues a request to the Quality Check Performer to get the Output Information Sequence of the Quality Check UPS.

3.Y.2 Actor Roles

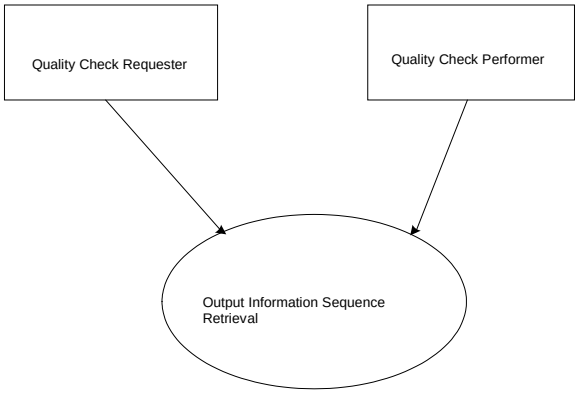


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

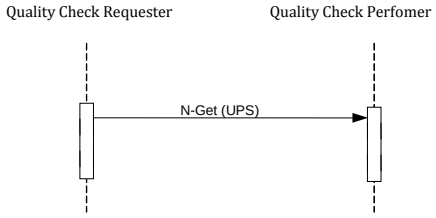
Actor:	Quality Check Requester
Role:	Uses the N-GET service request under a UPS Watch SOP class to retrieve attributes of the UPS created in transaction RO-Q1
Actor:	Quality Check Performer
Role:	Honors the request.

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.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4-2011 Annex CC.2.7

3.Y.4 Interaction Diagram



3.Y.4.1 Output Information Sequence Retrieval

This is a UPS Push worklist message sent to the Quality Check Performer.

3.Y.4.1.1 Preconditions

The location of the Quality Check Report is indicated by the information fetched in RO-Q6. This location is not required to be the AETitle and Address of the Quality Check Performer itself. The Quality Check Performer must insure that the instance of the Quality Check Report is stored and available for retrieval before issuing RO-Q6.

3.Y.4.1.2 Trigger Events

After successful notification from the Quality Check Performer that the UPS has been Completed or Canceled, the Quality Check Requester should issue this transaction. The Quality Check Performer is not required to populate the Output Information Sequence if the Procedure was CANCELED.

3.Y.4.1.3 Message Semantics

This message should specify the UPS Watch SOP Class as the abstract syntax, but specify the original UPS Push SOP Instance UID of the UPS created in RO-Q1 as the Requested SOP Instance UID in the N-GET message.

If the UPS returns Procedure Step State (0074,1000) with value of CANCELED, the Quality Check Requester can inspect the Progress Information Sequence for the Reason for Cancellation (0074,1238) and Procedure Step Discontinuation Reason Code

Sequence (0074,100E) for information on the Cancelation. Defined Context ID for the Code Sequence is 9300. Actions taken after determination of the Cancelation reasons are outside the scope of this profile. The Quality Check Performer is not required to create an instance of the Quality Check Report or to populate the Output Information Sequence of the Unified Procedure Step Performed Procedure Sequence if the step was CANCELED. In the case of a CANCELED step, the Quality Check Performer can choose to populate a Quality Check Report, and in that case, needs to populate the Output Information Sequence with the location of the report.

If the UPS returns Procedure Step State (0074,1000) with a value of COMPLETED, the Quality Check Requester will request the value of the Unified Procedure Step Performed Procedure Sequence, and get the values contained in the Output Information Sequence (0040,4033).

The Quality Check Requester can request attributes as follows:

Attribute Name	Tag	Type (SCU/SCP)	Additional Information
Unified Procedure Step Progress Information Module			
Procedure Step State	(0074,1008)	R+*/1	
Progress Information Sequence	(0074,1000)	R+*/R+*	Will include Cancelation information on return, if UPS was CANCELED.
Unified Procedure Step Performed Procedure Information Module			
Unified Procedure Step Performed Procedure Sequence	(0074,1216)	R+*/R+*	Shall be returned if exists.

All other standard N-Get behavior should be supported, so the above table in no way limits the information that the Quality Check Requester inquire about.

3.Y.4.1.4 Expected Actions

The Quality Check Requester is expected to retrieve the Quality Check Report if it exists.

3.Y RO-Q1: Quality Check Report Retrieval

3.Y.1 Scope

In the Quality Check Report Retrieval transaction, a Quality Check Requester retrieves a structured report using the location obtained in RO-Q6. The report indicates the checks that were performed and the status of each.

3.Y.2 Actor Roles

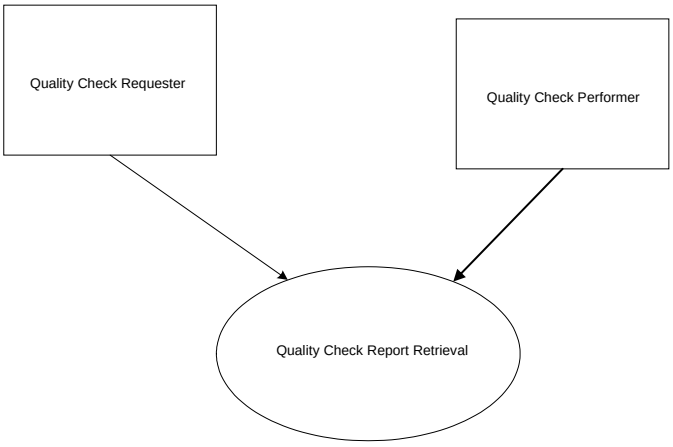


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

Actor:	Quality Check Performer
Role:	Accepts request to move a DICOM Structured Report to the Quality Check Requester**.**
Actor:	Quality Check Requester
Role:	Requests and receives the requested Structured Report

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.

3.Y.3 Referenced Standards

DICOM 2011 PS 3.4: Storage Service Class

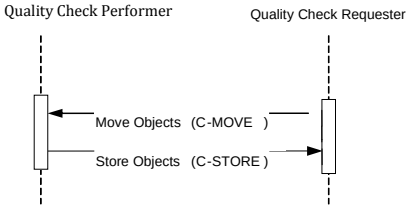
DICOM 2011 PS 3.4: Annex B.5.1.5 and Annex O: C-STORE of Structured Report

DICOM 2011 PS 3.16

DICOM 2011 PS3.3 A.35

DICOM 2011 PS 3.4: Query/Retrieve Service Class

3.Y.4 Interaction Diagram



3.Y.4.1 Quality Check Report Retrieval Message

This is a UPS Push worklist message sent to the Quality Check Performer.

3.Y.4.1.1 Preconditions

The Retrieve (Study Root – MOVE) SOP Class shall be supported by the Quality Check Performer as an SCP. Implementations shall support modes of operation in which a single series (e.g. input CT Series) or specific SOP Instances (e.g. an RT Plan) are retrieved from the Quality Check Performer using the Study Root – MOVE SOP Class. Refer to DICOM 2007 PS 3.4, Annex C, for detailed descriptive semantics. The Quality Check Performer shall support the Query / Retrieve Service on instance level.

A Quality Check Requester shall be capable of issuing a Study-Root C-MOVE to obtain Quality Check Structured Report Object created by the Quality Check Performer

The C-STORE service for Basic Text SR (SOP Class UID 1.2.840.10008.5.1.4.1.1.88.11) will be supported by the Quality Check Requester as an SCP.

3.Y.4.1.2 Trigger Events

The Quality Check Requester has retrieved the Output Information Sequence from the Quality Check Performer in transaction RO-Q6

3.Y.4.1.3 Message Semantics

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

A C-MOVE Request from the DICOM Study Root Query/Retrieve Information Model – MOVE SOP Class shall be sent from the Quality Check Requester to the Quality Check Performer location specified in the Output Information Sequence

It is assumed, when the UPS is reported as "COMPLETED" that the Structured Report has been fully prepared before the Quality Check Performer does the final state update via transaction RO-Q5

A Quality Check Performer that implements the Dose Check should create a structured report with Critical Issues Found set to YES when the Quality Check Performer determines that delivering the Candidate Treatment Plan would pose a threat to the health or well-being of the patient.

A Quality Check Performer that implements the Difference Check should create a structured report with Critical Issues Found set to YES when the Candidate Treatment Plan matches one or more QA Assessed Plan and:

- A single matching QA Assessed Plan was not approved in the earlier quality check.
- There are multiple matching QA Assessed Plans, and at least one of them was failed in the earlier quality check.
- The Candidate Treatment Plan has changed in some way that may affect the dosemetric delivery or safe treatment of the patient.

The Quality Check Requester must behave according to the guidelines in section 2.3.3 "Plan Veto" when a Critical Issue Found is YES.

The SOP class expected to be moved:

Quality Check Performer (SCU) SOP Class	SOP Class UID
Basic Text SR	1.2.840.10008.5.1.4.1.1.88.11

3.Y.4.1.3.1 Structured Report

TID 2300~~XXXX~~
Radiotherapy Treatment Plan Check Request Result

Type: Extensible Order: Significant ~~(TBD)~~

	NL	Relation with Parent	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	EV (XYZ000, DCM, "RT Plan Check Request Result")				
~~1~~2	≥	CONTAINS	CODE	EV (XYZ001~~00000~~, DCM, "Critical Issues Found")	1	M		DCID (230) Yes-No
~~3~~2	≥	CONTAINS	INCLUDE	DTID 1021 Device Participant	1	M		$DeviceProcedureRole = EV(113915, DCM, "Quality Check Performer")]
~~4~~3	≥	CONTAINS	DATETIME	EV (XYZ011~~00001~~, DCM, " Datetime when the Check was completed")	1	M		
~~5~~4	≥	CONTAINS	TEXT	EV (~~100002~~XYZ002, DCM, "Summary of Result")	1	M		
~~5~~6	≥	CONTAINS	UIDREF	EV (~~100003~~XYZ003, DCM, "Candidate Treatment Plan SOP Instance UID")	1	M		The UID of the Candidate Treatment RT Plan that was supplied by the Quality Check Requester.
~~5.5~~7	≥	CONTAINS	~~UIDREF~~COMPOSITE	EV(~~100008~~XYZ004, DCM, "Assessed Plan SOP Instance	1	MC	Required if Quality Check Performer implements a Difference Check.	~~Required if Quality Check Performer implements a Difference Check.~~
~~8~~6		CONTAINS	TEXT	EV (100004, DCM, "Check Results")	1	MC	Required if Critical Issues Found = Yes	~~Required if Critical Issues Found = Yes~~ Number of checks reported on.
~~9~~7	>	CONTAINS	INCLUDE	DTID (2310~~YYYY~~) Radiotherapy Treatment Plan Check Request Result Detail	1-n	MC	Required if Critical Issues Found = Yes	Number of entries should match value in EV(100004, DCM, "Check Results') ~~Required if Critical Issues Found = Yes~~ All Critical Issues found must be included in this sequence.
~~10~~8		CONTAINS	UIDREF	~~EV (100005, DCM, "UPS SOP Instance UID")~~ **EV (121126, DCM, "Performed Procedure Step SOP Instance**	1	M		The UID of the Unified Procedure Step that was created and modified for this check.

	NL	Relation with Parent	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint
				UID")				
11~~9~~		CONTAINS	TEXT	EV(100006, DCM, "Requester AETitle")	1	M		
~~10~~1 2		CONTAINS	TEXT	EV (100007, DCM, "Check Performer Result Key")	1	U		Ideintifier that can be used to retrieve further details on the Quality Check from the Quality Check Performer.

1170

TID ~~YYYY~~2310
Radiotherapy Treatment Plan Check Request Result Detail

Type: Extensible Order: Significant ~~(TBD)~~

	NL	Relation with Parent	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint
1			CONTAINER	**EV (XYZ100, DCM, "RT Plan Check Request Result Detail")**	1	M		
2~~1~~		CONTAINS	CODE	EV(XYZ~~100~~101, DCM, "Critical Issue Found")	1	M		DCID (230) Yes-No
3~~2~~		CONTAINS	CODE	EV (XYZ~~100~~106, DCM, "Informational Issue Found")	1	M		DCID (230) Yes-No
~~4~~		CONTAINS	TEXT	EV(XYZ~~100~~102, DCM, "Assessment Code")	1	M		Manufacturer specific code
5		CONTAINS	CODE	EV(XYZ~~100~~103, DCM, "Assessment Reporting Type")	1	M		DCID (Either "Upper Bound, "Lower Bound, "Range","Tag Inconsistency", "Equality", "Existence", "Non-Specific"
6		CONTAINS		EV(XYZ~~100~~104, DCM, "Specific Assessment Sequence")		MC	Required if Assessment Reporting Type equal to any of "Upper Bound, "Lower Bound, "Range","Tag Inconsistency", "Equality", "Existence", "Non-Specific"	~~Required if Assessment Reporting Type equal to any of "Upper Bound, "Lower Bound, "Range","Tag Inconsistency", "Equality", "Existence", "Non-Specific"~~
6.1	>	CONTAINS	TEXT	EV (XYZ~~100~~111, DCM, "Value Units")	1	M		UNITS = DCID(82) "Units

Comment [E1]: Will IHE-RO become a coding scheme designator? Same remark for other concept names with IHE-RO as coding scheme designator.

	NL	Relation with Parent	Value Type	Concept Name	VM	Req Type	Condition	Value Set Constraint
								of Measurement"
6.2	>	CONTAINS	TEXT	EV (XYZ~~100~~112, DCM, "Upper Bound Value")	1	MC	Required if Assessment Reporting Type is "Upper Bound", "Range", "Equality"	~~Required if Assessment Reporting Type is "Upper Bound", "Range", "Equality"~~ Value as decimal string
6.3	>	CONTAINS	TEXT	EV(XYZ~~100~~113, DCM, "Lower Bound Value")			Required if Assessment Reporting Type is "Lower Bound" or "Range"	~~Required if Assessment Reporting Type is "Lower Bound" or "Range"~~Value as decimal string
6.4	>	CONTAINS	TEXT	EV (XYZ~~100~~114, DCM, "Supplied Attribute Name")	1	M		Example: "Specified Primary Meterset"
6.5	>	CONTAINS	TEXT	EV(XYZ~~100~~115, DCM, "Supplied Attribute Tag")	1	M		Example: "(3008,0032)"
6.6	>	CONTAINS	TEXT	EV (XYZ~~100~~116, DCM, "Supplied Attribute Value")	1	M		
7		CONTAINS		EV(XYZ~~100~~105, DCM, "General Assessment Sequence")		MC	Required if Assessment Reporting Type is "Non-specific"	~~Required if Assessment Reporting Type is "Non-specific"~~
7.1	~~>~~>>?	CONTAINS	TEXT	EV(XYZ~~100~~102, DCM, "Check Description")	1	M		Short description of what was checked

3.Y.4.1.3 Expected Actions

If the report indicates a critical issue was found, the Critical Check Requester must veto delivery in a clear manner.

3.Y RO-Q8:Unsubscribe to UPS Progress

3.Y.1 Scope

In the Unsubscribe to UPS Progress transaction, the Quality Check Requester issues a request to the Quality Check Performer to stop receiving updates on the evaluation.

3.Y.2 Actor Roles

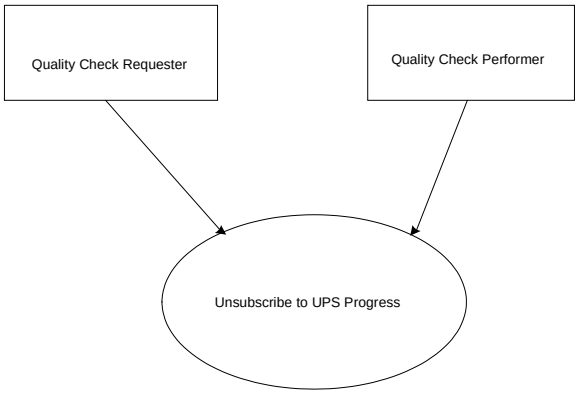


Figure 3.Y.2-1: Use Case Diagram

Table 3.Y.2-1: Actor Roles

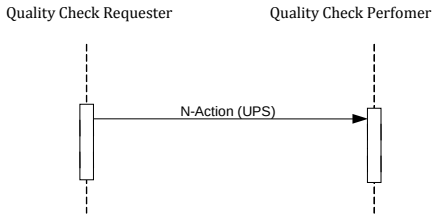
Actor:	Quality Check Requester
Role:	Uses the N-ACTION service request under a UPS Watch SOP class to unsubscribe to the UPS created in transaction RO-Q1
Actor:	Quality Check Performer
Role:	Honors the request.

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.

3.Y.3 Referenced Standards

DICOM Standard 2011 PS 3.4-2011 Annex CC.2.3

3.Y.4 Interaction Diagram



3.Y.4.1 Unsubscribe to UPS Progress Message

3.Y.4.1.1 Trigger Events

After successful notification from the Quality Check Performer that the UPS has been canceled, or the evaluation is complete, the Quality Check Requester should issue this transaction.

3.Y.4.1.2 Message Semantics

This message should specify the UPS Watch SOP Class as the abstract syntax, but specify the original UPS Push SOP Class UID of the UPS created in RO-Q1 as the Requested SOP Instance UID in the N-ACTION message.

The Quality Check Requester should implement this behavior in all cases to be well behaved.

Appendices

Volume 2 Namespace Additions

Add the following terms to the IHE General Introduction Appendix G:

<There will be namespace additions pending a DICOM change proposal to add codes and the structured report items.>

Volume 4 – National Extensions

Add appropriate Country section

4 National Extensions

Not applicable.

