

Integrating the Healthcare Enterprise



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# **IHE Radiology Technical Framework Supplement 2007-2008**

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## **Radiation Exposure Monitoring (REM) Integration Profile**

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**Public Comment Draft**

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## 1. Foreword

Integrating the Healthcare Enterprise (IHE) is an initiative designed to stimulate the integration of the information systems that support modern healthcare institutions. Its fundamental objective is to ensure that in the care of patients all required information for medical decisions is both correct and available to healthcare professionals. The IHE initiative is both a process and a forum for encouraging integration efforts. It defines a technical framework for the implementation of established messaging standards to achieve specific clinical goals. It includes a rigorous testing process for the implementation of this framework. And it organizes educational sessions and exhibits at major meetings of medical professionals to demonstrate the benefits of this framework and encourage its adoption by industry and users.

The approach employed in the IHE initiative is not to define new integration standards, but rather to support the use of existing standards, HL7, DICOM, IETF, and others, as appropriate in their respective domains in an integrated manner, defining configuration choices when necessary. IHE maintain formal relationships with several standards bodies including HL7, DICOM and refers recommendations to them when clarifications or extensions to existing standards are necessary.

This initiative has numerous sponsors and supporting organizations in different medical specialty domains and geographical regions. In North America the primary sponsors are the American College of Cardiology (ACC), the Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada has also been formed. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Association of Radiology (EAR) and European Congress of Radiologists (ECR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntengesellschaft (DRG), the EuroPACS Association, Groupement pour la Modernisation du Système d'Information Hospitalier (GMSIH), Société Française de Radiologie (SFR), Società Italiana di Radiologia Medica (SIRM), the European Institute for health Records (EuroRec), and the European Society of Cardiology (ESC). In Japan IHE-J is sponsored by the Ministry of Economy, Trade, and Industry (METI); the Ministry of Health, Labor, and Welfare; and MEDIS-DC; cooperating organizations include the Japan Industries Association of Radiological Systems (JIRA), the Japan Association of Healthcare Information Systems Industry (JAHIS), Japan Radiological Society (JRS), Japan Society of Radiological Technology (JSRT), and the Japan Association of Medical Informatics (JAMI). Other organizations representing healthcare professionals are invited to join in the expansion of the IHE process across disciplinary and geographic boundaries.

The IHE Technical Frameworks for the various domains (IT Infrastructure, Cardiology, Laboratory, Radiology, etc.) defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of medical information to support optimal

85 patient care. It is expanded annually, after a period of public review, and maintained regularly through the identification and correction of errata. The current version for these Technical Frameworks may be found at [http://www.ihe.net/Technical\\_Framework/index.cfm](http://www.ihe.net/Technical_Framework/index.cfm) or <http://www.himss.org/IHE>.

90 The IHE Technical Framework identifies a subset of the functional components of the healthcare enterprise, called IHE Actors, and specifies their interactions in terms of a set of coordinated, standards-based transactions. It describes this body of transactions in progressively greater depth. The volume I provides a high-level view of IHE functionality, showing the transactions organized into functional units called Integration Profiles that highlight their capacity to address specific clinical needs. The subsequent volumes provide detailed technical descriptions of each IHE transaction.

95 <This supplement to the IHE Radiology Technical Framework V8.0 will be submitted for Public Comment around Feb. 27<sup>th</sup>. Comments should be submitted by March 28<sup>th</sup> to [ihe@rsna.org](mailto:ihe@rsna.org) or in the IHE – Radiology Technical Framework Forum at [forums.rsna.org](http://forums.rsna.org)>

<The IHE Radiology Technical Committee will address these comments and publish the Trial Implementation version of this supplement in early summer 2008.>

**Document Date: Feb 28, 2008**

100 **Editor: Kevin O’Donnell**

<Stuff highlighted in blue is a reminder for the editor to cleanup, don’t worry about it too much>

<Stuff highlighted in yellow needs review, discussion and resolution>

105 *These "boxed" instructions for the author to indicate to the Volume Editor how to integrate the relevant section(s) into the overall Technical Framework*

## 2. Introduction

This profile facilitates the collection and distribution of reports detailing patient radiation exposure resulting from imaging procedures.

110 In the vast majority of medical procedures involving radiation, the potential benefit to the patients’ health far outweighs the potential risk, but the trade-off should not be overlooked, and technological mechanisms can facilitate a conscious evaluation if that trade-off.

Tracking radiation dose delivered to patients for medical purposes can facilitate a number of important activities:

- 115 • For facilities exposing patients to radiation, tracking can help monitor such exposure to ensure their policies, procedures and protocols are adequate and being followed appropriately.
- For physicians who are asked to follow guidelines, like constraining patient dose to As Low As Reasonably Achievable (ALARA), tracking can make it easier to see how low their patient dose actually was, and perhaps assemble comparison values to inform estimates of what is reasonably achievable.
- 120 • For patients’ physicians, or patients themselves, tracking can provide a record of radiation administered to the patient.
- For professional societies and regulatory agencies, tracking data can be useful when setting or reviewing radiation dose related guidelines and regulations. Many such groups have expressed a desire to establish standards of practice or dose reference levels based on a quantitative understanding of current practice, however they have found it prohibitively difficult to collect such data.
- 125 • For physicists and physicians, this kind of data can be vital to answering some of the fundamental scientific questions that remain and developing a more detailed understanding of the health impacts of radiation exposure and how it should be measured and managed.
- 130

Interest in monitoring radiation dose is clearly expressed in such documents as the European directive Euratom 97/43 and the American College of Radiology Dose Whitepaper [1].

The profile is directly based on the work done by DICOM and the IEC to develop DICOM Dose Report objects appropriate for dose monitoring.

- 135 By profiling such automated methods, dose information can be collected and monitored without imposing a significant administrative burden on staff otherwise occupied with caring for patients.

<Does any of the above text belong in the final profile? If so, it will need to be moved to the Profile Intro, Use Cases or informative appendix>

140 **2.1. Open Issues and Questions**

2	<p><b>What is the recommended approach for for “legacy” systems?</b></p> <p>Current Text:</p> <ul style="list-style-type: none"><li>— Systems are required to fully support the relevant DICOM Dose Report to qualify as an Acquisition Modality actor.</li><li>— If a modality or 3<sup>rd</sup> party box can properly fill in a DICOM Dose Report by means such as manual entry, skimming or some proprietary interface, it may claim the Acq. Modality actor for this profile. 3<sup>rd</sup> party boxes are required to list both themselves and the actual modality in the Contributing Equipment Sequence (C.12.1.1.5).</li></ul> <p>Proposal:</p> <ul style="list-style-type: none"><li>— If a modality or 3<sup>rd</sup> party box is unable to produce one of the defined Dose SR templates, but is able to provide some Better Than Nothing (BTN) amount of information, to be defined here, it should be allowed to claim the Evidence Creator actor (as a “2<sup>nd</sup> class” producer) for this profile. (E.g. IEC PAS Level 0)</li></ul> <p>Manual Entry – a system creates/stores reports on behalf of a legacy system based on operator entered values. This might work for legacy systems, film systems, or things like CR/DR.</p> <p>Skimming – a system creates/stores reports on behalf of a legacy system based on values skimmed/extracted from DICOM images and/or MPPS messages produced for the procedure. This is sort of an automated form of Manual Entry. In cases where the procedure produces neither images nor MPPS (e.g. a fully film based system, mobile ward systems), one could conceivably skim the HL7 “order scheduled” feed too. The billing system ends up knowing something was performed as well. Note that more than 50% of dose in an interventional study may come from fluoroscopy that produces no recorded</p>
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images to skim.

While encouraging systems to produce full Dose SRs is to be vigorously pursued, there will be some cases where the modality is not getting upgrades to provide it, and it is not practical for a 3<sup>rd</sup> party box to collect ALL the details needed for a fully qualified CT or Projection Dose Template (“You can only expect 30 seconds of typing with one hand worth of data entry from the tech”).

FDA is apparently working on a pathway to help/encourage older fluoro systems to upgrade.

Readers have additional pressure to get this information since Mammo requires dose details to be displayed on the images.

Better Than Nothing (BTN) – there are indications [2] that even something as basic as the number of slices produced or the amount of fluoro time or the number of x-ray studies can be useful information. Technical factors (some of which are available in images, like kVp, mAs) are even better. Should this profile facilitate such a lower level of supplemental reporting by defining a mechanism, or discourage it by requiring sites to design and implement their own integrations for it. It was indicated that site Physicists are regularly trying to piece together a conclusion from sparse information and anything you can get will be useful in some cases.

The BTN discussion is mostly about supporting the hospital Radiation Safety Program and Quality Improvement use cases. The Dose Register use cases can be satisfied with a sample of data and would not suffer as much of studies on older systems went unrecorded. For the Patient History use case, a list of procedures might be sufficient.

IEC introduced a PAS (Publicly Available Spec. – precursor to an IEC Standard) identifying three Levels. Level 3 for systems where Deterministic Injury is Possible, Level 2 for systems where Deterministic Injury is Conceivable, and Level 1 for systems where there is Stochastic Risk Only. System Level is determined by the maximum expected cumulative Air Kerma at the IEC interventional reference point for any normal use of the equipment (Level 1: < 2 Gy, Level 2: > 2 Gy, Level 3: > 7 Gy). Higher level systems would be required to provide more data than lower level systems to comply.

(If IHE has an interest in seeing the PAS finalized into a formal standard, we should request in the next few months for them to make their two year window.)

	<p>So where is the appropriate place to draw the line for what the Dose Information Reporter is expected to know. If someone reviews patient data or departmental practices on the DIR:</p> <ul style="list-style-type: none"><li>— should there be no record that procedures on legacy systems have occurred?</li><li>— should the DIR track that the procedure has occurred?</li><li>— Should the DIR track the patient demographics?</li><li>— should the DIR track the type of procedure?</li><li>— should the DIR track the fluoro time/# of slices</li><li>— should the DIR track limited technical parameters (kVp, mAs, etc.)</li><li>— should the DIR track the procedure mix to see if it is appropriate to the equipment (how many chest x-rays are being done on old non-compliant machines)</li></ul> <p>If we decide on allowing some level(s) how should they be communicated:</p> <ul style="list-style-type: none"><li>— Allow Evidence Creators to use the Store Dose Report transaction to store Dose Reports using other, or self defined templates which allow partial information. The DIR could recognize such objects based on the TID or Title. This also provides a mechanism for Evidence Creators to store Dose Maps or other processed dose information. So any system that has a clever way to identify such unreported studies could fill it in.</li><li>— Allow Evidence Creators to use a new transaction for such information. Same thing, different documentation.</li><li>— Put DIR consoles near legacy and enter the data directly into the DIR without needing transactions. Or record on paper worksheets which are conveyed to the DIR for manual entry.</li></ul>
5	<p><b>How might data from Patient Skin Dosimeters be integrated in the future?</b></p> <p>Current Text:</p> <ul style="list-style-type: none"><li>— Silent.</li></ul> <p>Proposal:</p> <ul style="list-style-type: none"><li>— If the physicists confirm a use case where it would make sense for such information to be provided by a DICOM system, IHE or DICOM could define another SR template for it and a Modality or Evidence Creator could store the data based on manual entry or digital input from the dosimeter.</li><li>— Otherwise, the information could be directly entered at the Dose Information Reporter or some HL7 message could be considered.</li></ul>

	<p>There are four types of patient skin dosimeters:</p> <ol style="list-style-type: none"> <li>1) dosimetry film – which is preferred for its geometric coverage</li> <li>2) arrays of point dosimeters – better than one, but still just a sampled coverage</li> <li>3) realtime electronic point dosimeters – which will generally not end up at the peak dose</li> <li>4) non-realtime point dosimeters – (badges, etc) ditto</li> </ol> <p>Consider recording a text description of the location and the “measurement” result. Would most likely be updated at the DIR since the information is often not available in real time.</p> <p>Literature indicates that although Peak Skin Dose (a desirable measurement) may not occur at a point where a measurement device has been applied to the patient, they do provide useful information, implying that it should be part of the record. [2]</p> <p>The main usage seems to be in interventional cases where there is a risk of skin injury. The information may be used to decide when next procedure can be safely scheduled for the patient. The radiologist may decide to approach the patient from a different direction the second time to avoid “overexposed” areas.</p> <p>(Since a piece of dosimetry film may be scanned into a DICOM image to go into the patient's record, <b>Harry will draft a CP</b> to add to the Dose Report a reference to the image that documents the location/intensity of the radiation applied (for XR). Note that if such an image were secondary capture, it would make it difficult to do desired measurements. Of course, relating the image to the patient coordinate system will be a challenge.)</p>
8	<p><b>What transport protocol should be used to submit reports to the Register?</b></p> <p>Current Text:</p> <ul style="list-style-type: none"> <li>— Specifies “Secure FTP” as the expedient baseline/fallback method.</li> <li>— X.5 Relation Other Profiles points out that if the Register, DIR and Image Manager/Archive systems choose to support XDS/XDM, that can be used to share Dose Reports. (the Image Manager/Archive could be a Source, the DIR or the Image Manager/Archive could register the documents)</li> </ul> <p>Alternative Proposals:</p> <ul style="list-style-type: none"> <li>— Specify XDS/R/M</li> <li>— Specify the DICOM Email “media” and use SMTP</li> <li>— Make it a Named Option</li> <li>— Remove submission from the profile</li> </ul>

- Specify Dose Registers implement a controlled public DICOM server and use C-MOVE with TLS

A baseline method facilitates connectathon testing.

A built-in baseline method should make it easier for registry projects to get off the ground. They can choose to become more sophisticated later and build their own proprietary methods. (See discussion of distributing Dose Consumers with proprietary back-doors in Section 2.4)

Note that XDR has Meta-data in the register transaction as well as in the object which is different. Is that better (somehow useful) or worse (more work with no use)? In the population health use cases, it's not that useful and coordinating a National Affinity Domain might add some overhead as well as extra implementation. In cases where a patient dose history is being compiled across sites, it would be more relevant.

XDR supports multifile bundles, "replacing" documents, etc. And might be useful for working across enterprises. Would need to consider guidance on populating the Patient/Study oriented metadata when sending anonymized data.

FTP (of a DICOM Part 10 of the SR) is relatively simple. Should we talk about how to deal with file directory structures and things like that. Should we require the ability to ZIP a batch of Part 10 objects to make the transfer go MUCH more quickly (eliminates the per-file overhead on a large number of files, and compresses significantly). Should we consider the zipping a PDI structure.

Since "Secure FTP" is being considered, need to decide between

- IETF RFC-4217 Securing FTP with TLS
- FTPS aka FTP/SSL
- SFTP aka SSH FTP

Is any additional profiling of FTP using TLS needed? Note using TLS lets us invoke all the ATNA stuff about bi-directional security etc.

Alternatively, if implementing FTP is a burden or useless, we could leave the transaction out completely and assume that each DIRs vendor will seek out and adapt to the needs of the local dose registers. Or make it a Named Option.

Another alternative would be for Dose Registers to provide a Dose Consumer to each hospital that encapsulates the mechanism for sending Dose Reports to the Register. This puts the workload on the organization that will benefit (the Register), but raises security issues for all the organizations where the "Dose Snooper" is installed.

11	<p><b>What information about Procedure Type and justification is needed when evaluating a Dose Report?</b></p> <p>Current Text:</p> <p>Based on the derived requirements from DICOM for Dose SR:</p> <p>SR Document General Module has:</p> <ul style="list-style-type: none"><li>— [Type 2] Req. Proc. ID, Description &amp; Code Sequence</li><li>— [Type 3] Reason for Requested Procedure (Text &amp; Code Seq.)</li><li>— [Type 2] Performed Procedure Code Seq. (0040,A372) (list modality procedures or “Create Dose Report”?)</li><li>— [Type 2] Accession # (to cross reference in the RIS)</li><li>— [Type 1C] Referenced Instance Seq</li></ul> <p>General Study Module has:</p> <ul style="list-style-type: none"><li>— [Type 3] Study Description</li><li>— [Type 3] Procedure Code Seq. (0008,1032) (Performed)</li></ul> <p>Patient Study Module has:</p> <ul style="list-style-type: none"><li>— [Type 3] Admitting Diagnosis Description &amp; Code Sequence</li><li>— [Type 3] Patient Age, Size, Weight</li></ul> <p>General Series Module (which is not in the Dose Report IOD) has:</p> <ul style="list-style-type: none"><li>— [Type 3] Protocol Name</li><li>— [Type 3] Series Description</li><li>— [Type 3] Body Part Examined</li><li>— [Type 3] Operator Name, ID</li></ul> <p>SR Document Series Module has:</p> <ul style="list-style-type: none"><li>— [Type 2] Referenced Performed Procedure Step Seq. (PPS during which this document was created which should presumably be the SOP Class UID and Instance UID of the imaging PPS)</li></ul> <p>CT Dose Report content tree has:</p> <ul style="list-style-type: none"><li>— Anatomy Imaged</li><li>— Acq. Protocol (name)</li></ul>
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<p>— some Acq. Parameters</p> <p>Proposal:</p> <ul style="list-style-type: none"><li>— Clarify how modality should fill some of these (e.g. that the Dose Report is to be considered part of the imaging procedure, not a separate procedure in itself) and consider making some required in the Dose Report.</li><li>— Consider issues around a Procedure Lexicon (RadLex?). Variation in reported procedure names/descriptions/codes can complicate population analysis. Lack of detail also a problem CPT=“stent placement” but was it one stent or three?</li></ul> <p>Euratom stresses (Article 3) that all individual medical exposures shall be justified in advance, taking into account the specific objectives of the exposure and the characteristics of the individual involved.</p> <p>It is important to record the indication (clinical question being answered) identified by the Radiologist as justification for the radiation exposure. A lot of policies will include reviewing the indication and dose as a pair. “Reason for Exam” might be too informal or the contents not under control of the Radiologist and thus might not be appropriate or sufficient. (Helmut Koenig - Point of discussion in Germany)</p> <p>Note that WG-20 is dealing with this same issue as well related to their goal of putting dose related details into the standard German Radiology Report as coded in CDA.</p> <p>It should be noted that there are several evaluations here (Steve Balter):</p> <ul style="list-style-type: none"><li>— QA of the ordering process: Reviewing whether the procedure ordered/scheduled was appropriate for the indications (appropriateness criteria)</li><li>— QA of the operational process: Reviewing whether any differences between the procedure scheduled and the procedure performed were justified by the situation/equipment/patient and appropriately approved.</li><li>— QA of the technical process: Reviewing whether the dose was appropriate for the procedure performed.</li></ul> <p>The Dose Report should definitely address QA of the technical process. The other two are open issues. If those details are not included in the dose report, what linkages can be used to combine the relevant dose details and context information (indications/findings/procedure performed).</p> <p>We could avoid the issue and give more work to the DIR by having it try and extract information to support QA of the ordering process by querying/parsing Radiology Reports.</p>
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	<p>If there are details that don't get put into the dose report by the Modality, should the DIR get those details from the RIS (in a new transaction)? Or should the DIR retrieve and parse that information out of the images and/or MPPS?</p>
<p>19</p>	<p>Would a physician (ordering or radiologist) have any need/value in any type of dose information for the current patient being made available to at some point in their workflow?</p> <p>Current Text:</p> <ul style="list-style-type: none"> <li>— Silent.</li> </ul> <p>Would information such as recently accumulated dose for the patient, current facility guidelines and the expected dose of available procedures potentially have an impact on physician decisions. If so, are there points where it would be useful to present such details to the physician. Should this profile facilitate such presentation?</p> <p>Note that anything that touches on the practice of medicine is very controversial. Pursuit of such features should only occur with clear direction from ACR, AAPM.</p> <p>This could be left as a feature for Dose Information Reporters to provide or not. They could allow physicians to manually access such information from terminals.</p> <p>(Balter) Patient dose history rarely affects the decision whether or not to perform a procedure. Dose history can inform decisions about timing (they may delay a procedure to allow skin to heal), or technique (they may approach from a different direction to avoid dosed skin).</p> <p>The dose history is often inferred from the imaging procedure history. They would be interested if a previous procedure that is typically high dose, was not in this instance.</p> <p>Imaging history is also important to avoid unnecessary repetition of prior scans (e.g. cases of two shifts of ER ordering duplicate CT scans).</p> <p>(Coombs) Providing information to the physician post-exposure should be fine. Don't see a need for pre-exposure presentation.</p>
<p>24</p>	<p>Is there anything we can/should do to facilitate Patient Risk estimation?</p> <p>It is difficult to derive Patient Risk directly from Dose values. Patient Risk estimation really needs organ mapping. A Dose Consumer/Evidence Creator might be able to retrieve the dose report and the images from a study, do the necessary organ segmentation and come up with some estimates. So as long as we have the actor w Q/R access to reports and images,</p>

	<p>it's feasible?</p> <p>Do we need a way to store the resulting risk estimate? Would it be a Dose Report with a different template?</p> <p>Does this overlap with the work John Boone is doing for AAPM?</p>
27	<p><b>Are there additional complexities related to Dose Modulation that might need addressing?</b></p> <p>Proposal:</p> <ul style="list-style-type: none"><li>— Call this out during Public Comment</li><li>— Identify those with concerns and push them to promptly submit CPs to DICOM</li><li>— This is primarily a DICOM issue. Vendors have mostly looked at it and want to get started for now with what we have.</li></ul> <p>It was pointed out by one of the CT vendors that for some dual kV systems it's not just the mA that gets modulated. There may need to be CPs to the DICOM dose reports.</p> <p>Also, John Boone (AAPM) may be arranging some investigation work through NEMA on ways of “normalizing” for different vendors dose modulation.</p>
29	<p><b>Should we specify some dose information display requirements?</b></p> <p>On the one hand, IHE tries to specify the data transfer and leave presentation formats to the marketplace. Vendors can work with their customers to “figure it out”.</p> <p>Modalities might display a couple simple values. Data mining/process control will likely be inside the DIR.</p> <p>On the other hand, it is hard for vendors/product managers in some cases to know what to show. More importantly, it is hard for users to “glance at the radiation display” when it looks different on every product.</p> <p>Current SR Renderers are unfriendly to clinical users. Can we help? For Stress Test in IHE Card they provided some display guidance. We could provide some informative material and one example of a good presentation strategy.</p> <p>Would it be appropriate to require that in a display of a Rad Dose object where there are multiple events, to require that be in a tabular form rather than a tree listing? Or to put it in functional terms, to require that multiple exposure events be easily distinguished?</p>
31	<p><b>Should a timeframe for storage of Dose Reports be somehow required?</b></p>

	<p>Current Text:</p> <ul style="list-style-type: none"> <li>— The Trigger Event for Storage recommends “as soon as possible” and includes text requiring the SCU to document it’s timeframe capability in it’s DICOM Conformance Statement.</li> </ul> <p>On the one hand, some applications like realtime Dose Mapping won’t work unless the modality sends very quickly. Also some local dose safety policies might conceivably require that certain alerts be raised before the patient leaves. Note that the Dose Consumer and Dose Information Reporter may care about realtime receipt, but the Image Manager/Archive generally won’t care.</p> <p>On the other hand, some situations make “immediate” storage impossible (CR Readers, mobile disconnected modalities), so a rigid requirement can’t apply all the time. Of course things like Dose Mapping probably wouldn’t be used for such systems.</p>
32	<p><b>How should Dose Reports for Phantoms/Calibration Scans be distinguished from Dose Reports for real patients?</b></p> <p>Current Text:</p> <ul style="list-style-type: none"> <li>— Silent.</li> </ul> <p>Proposal:</p> <ul style="list-style-type: none"> <li>— Probably a DICOM CP, but for what?</li> <li>— Add Quality Control Image (0028,0300) to the Dose SR IOD? Which Module?</li> <li>— Add Something to the SR Template? Ought to be filterable at query?</li> <li>— Mandate contents of Patient Name/ID for Phantom/Calibrations</li> </ul> <p>Dose Reports for Phantoms/Calibrations are likely useful and should probably exist.</p> <p>Dose Reports for Phantoms/Calibrations need to be handled differently than those for patients (e.g. don’t submit to registries, shouldn’t affect hospital metrics, no patient risk, etc.)</p> <p>Quality Control Image (0028,0300) is a Type 3 attribute in the General Image Module which indicates whether or not this image is a quality control or phantom image (YES/NO).</p> <p>The DIR should not have to retrieve images to get that attribute.</p> <p>Note that the operator knows they’re scanning a phantom, but the modality might not.</p>
33	<p><b>Are the matching and return keys in the Query transaction sufficient for the use cases?</b></p>

<p>Proposal:</p> <ul style="list-style-type: none"><li>— Raise the Code Value and Coding Scheme to R+ in the Concept Name Code Sequence to allow matching against document title (as was done for Key Image Note). This will allow DICOM to add or change additional Radiation Dose SR document titles without requiring IHE to later try and “promote” these from O to R+.</li><li>— Also, reject the CP to remove the requirement to support instance level query matching on SOP Class UID.</li><li>— Review the following to see if additional text is needed</li></ul> <p>It is important to have adequate filtering capability (either on the SCP with matching keys or on the SCU via return keys) because although the dose objects are not huge, they are plentiful and retrieving a few hundred just to find the 10 that you want could take a while due to the latency in each transfer.</p> <p>In addition to the Doc Title, above, the other filtering tools include:</p> <ul style="list-style-type: none"><li>— SOP Class UID (a required instance level matching &amp; return key on SCP in the 4-14 table) allows specifically selecting Dose Reports (but doesn’t differentiate type)</li><li>— Template ID (required instance level return key here) allows distinguishing CT Dose Reports, Projection Dose Reports and “other Dose Reports” (but doesn’t differentiate between MX, XA, etc)</li><li>— Modalities in Study (required study level match &amp; return in 4-14) allows distinguishing the specific modality used for acquisition (since the Series modality is always SR it is obscured there)</li></ul> <p>Potential gaps may include helping DIR systems monitor local polices, prepare reports or make submissions to registers based on Patient Age, Sex, Weight, and Procedure Type which have emerged as key axes of analysis for Dose.</p> <ul style="list-style-type: none"><li>— Patient Birth Date is Type 2 to fill and a required return key in 4-14 (although it might get blanked during de-identification)</li><li>— Patient Age is Type 3 to fill and an optional return key in 4-14</li><li>— Patient Sex is Type 2 to fill and a required return key in 4-14</li><li>— Patient Weight is Type 3 to fill and an optional return key in 4-14</li><li>— Patient Size (i.e. height) is Type 3 to fill and an optional return key in 4-14</li><li>— “Procedure Type” is discussed in Issue #11</li></ul> <p>Local policies and reports might also want to select based on room (Location), and (in the case of Mammography) Screening vs. Diagnostic, Unilateral vs. Bilateral.</p>
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	<p>Is there anything we can/should do to make sure these various attributes are well populated so queries will have something to work with?</p>
34	<p>Do we need normative or informative text relating to verification of displayed dose?</p> <p>Current Text:</p> <ul style="list-style-type: none"> <li>— Silent.</li> </ul> <p>Steve reports that the requirements on accuracy of display are:</p> <ul style="list-style-type: none"> <li>— IEC <math>\pm</math> 50% (RPDose &amp;KAP)</li> <li>— FDA <math>\pm</math> 35% (RPDose)</li> </ul> <p>FDA is requiring built-in dosimeters in new fluoro systems. These are generally validated at the factory and usually have reproducibility to within a few % and accuracy within the <math>\pm</math> 35% requirement. They are seldom validated by installers and at quite a few sites never calibrated.</p> <p>When verified as part of QA they should be able to maintain <math>\pm</math> 20%</p>
35	<p>How do we make sure the DIR is a “real application” not just supporting the interface?</p> <p>Are there any prescriptive guidelines on how to set up a Radiation Safety Program that might provide requirements for a valid DIR?</p> <p>On the other hand, we could leave it to caveat emptor.</p>

## 2.2. Closed Issues

0.1	<p>Should the profile address submission of <u>summarized</u> data to registries?</p> <p><i>Answer: No. The contents and format of such submissions have not yet been considered or defined by the owners of such registries.</i></p> <p>RFD might be one approach, but is not yet mature. For now focus on providing Registries with the same kind of DICOM Dose Reports that the Dose Information Reporter gets.</p> <p>Such summaries might be able to better provide information, such as the total number of procedures performed or the frequency of procedures per patient, which are not easily</p>
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	<p>derived from the proposed submission of a sample of de-identified individual reports.</p>
0.2	<p>Is there any need for translating the dose reports into an HL7 format?</p> <p><i>Answer: No needs could be identified at this time, but the possibility of sending data into HL7 was acknowledged. It will not be addressed now.</i></p> <p>Once the use case is presented, an appropriate DICOM/HL7 “border system” can be identified to handle translation, likely into CDA. Such work should involve DICOM WG-20</p>
0.3	<p>Should we include dose from Radiotherapy procedures in the profile?</p> <p><i>Answer: Not yet. Focus on imaging initially. RT can be added later.</i></p> <p>They have plan/record objects, but need to analyze how they would be integrated with imaging dose into a Dose Record.</p>
0.4	<p>Should we include dose from SPECT/PET procedures in the profile?</p> <p><i>Answer: Not yet. The dose SR work in DICOM does not exist for these modalities. When it does, they could be added.</i></p> <p>Some investigation will need to be done to determine how radiation professionals would like to handle the different types of radiation involved. Also note there will be differences between turning on/off an x-ray tube and injecting a radioactive material. Further, NM has other (non-DICOM) systems for managing their radiopharmaceuticals and dose records</p>
1	<p>Should IHE make equipment identification details mandatory?</p> <p><i>Answer: Yes. A DICOM CP will be submitted to add the Enhanced Equipment Module (C.7.5.2) to the Radiation Dose IOD. (Manufacturer, model and serial number attributes would then be Type 1).</i></p> <p>The equipment model and serial number are Type 3 (optional) attributes in the DICOM Dose Report objects. Without them it would be hard to link dose reports to related equipment management/maintenance processes.</p> <p>Some physicists want to identify which systems are “running hotter” and figure out why (equipment config, operator practices, etc).</p> <p>On the other hand, if dose reports are sent to a national database it raises the issue of inter-vendor comparisons and can be used to generate “market share”. Probably ought to</p>

	<p>recommend anonymizing the fields.</p>
3	<p>What is the recommended approach for CR &amp; DX systems (usually three separate devices: X-Ray emitting gantry, image generating Reader, management Console)?</p> <p><i>Answer: Informative text will point out that if any of the devices can correctly populate a Dose SR they can participate as an Acquisition Modality.</i></p> <p>The gantries are often analog to the point of not having any digital port/connector.</p> <p>The reader/console are a better bet since many store DICOM images and may do DICOM modality worklist but it will need to find some way to get dose details. There currently isn't any standard to get dose details from a "Digital" Gantry to the Reader. Some proprietary methods (e.g. RS-232 based link) are thought to exist. Manual entry is a valid, but perhaps tedious, alternative.</p> <p>Note that DX may record detector geometry, while CR generally won't know that either.</p> <p>A joint NAR/DIN and AAPM project is working on an IEC Standard for the dose seen by the detector (each company currently has their own calibration scale/method). This could result in another Dose template in the future.</p>
4	<p>Should the Image Manager/Archive and Dose Information Reporter be kept separate or merged?</p> <p><i>Answer: Keep separate. That allows more implementation flexibility.</i></p> <p>The separate Image Manager/Archive and Dose Information Reporter design allows separation of the responsibility for reliable storage of the DICOM objects, from the responsibility for dose related reporting, policies and business logic.</p> <p>Implementing the Image Manager/Archive actor would be a logical thing for a PACS since these objects are handled in much the same way as the study data it already manages.</p> <p>Implementing the Dose Information Reporter actor would be a logical thing for a RIS since the dose related details may be similar to the reporting, policies and business logic it already handles.</p> <p>A RIS that wants to implement the various storage, storage commitment, query/retrieve, backup and reconciliation capabilities could do so and claim the Image Manager/Archive actor. A third party "dose archive" that stores dose information separately could do the same.</p> <p>Some arguments in favour of the PACS implementing the Image Manager/Archive is that the dose report would be "part of the study" rather than stored separately. Also, modalities</p>

	<p>would generally have to support fewer storage paths. Perhaps most importantly, the collection of dose information could start today.</p> <p>A PACS that wants to implement the reporting, policies and other business logic desired by customers could do so and claim the Dose Information Reporter actor. A third party dose system could do the same (It would probably want to get an MPPS feed if possible).</p> <p>The broad division of labour between actors is expected to be something like:</p> <p>Image Manager/Archive (usually the PACS):</p> <ul style="list-style-type: none"> <li>- accept Dose objects</li> <li>- manage/store/backup Dose objects</li> <li>- reconcile (PIR) Dose objects (together with Study data) when patient info changes</li> <li>- provide Q/R of Dose objects</li> </ul> <p>Dose Information Reporter (Enterprise?)</p> <ul style="list-style-type: none"> <li>- display dose report details</li> <li>- compose daily/weekly/monthly reports (outliers, policy compliance, etc)</li> <li>- submit information to a registry (based on hospital obligations/policy)             <ul style="list-style-type: none"> <li>- currently sending raw data, someday might be sending summary data</li> </ul> </li> <li>- deidentify/pseudonymize data if necessary prior to registry submission</li> <li>- populate report exception list (to track down missing dose reports for known procedures performed)</li> <li>- populate dose exception list (to review/alert doses that exceed site policies)</li> </ul> <p>Dose Consumers (3<sup>rd</sup> Party Box? Feature of other system?)</p> <ul style="list-style-type: none"> <li>- perform realtime dose mapping</li> <li>- perform realtime alerting</li> </ul>
6	<p>Should we record the staff involved in the Irradiation Event? Who ordered? Who administered? Who was exposed?</p> <p><i>Answer: We should support recording who had clinical responsibility for the irradiation and who had operational responsibility. Staff exposure is handled by a different process and is out of scope here.</i></p> <p>Submit DICOM CP to modify the Dose Templates to have ACQ CONTEXT and have fields for something like Supervising Physician (who had clinical responsibility for justifying the administration of radiation), and something like Administering Staff (who had technical control over the administration).</p> <p>This would be useful for sites to identify when policies are not being followed and staff needs reminding.</p>

	<p>Which staff <u>ordered</u> (had clinical responsibility for) the event?</p> <ul style="list-style-type: none"> <li>— Might need to add an attribute to the Template to put it in. The X-Ray Dose SR has “Calibration Responsible Party”.</li> <li>— Requesting Physician (0032,1032) could easily be copied from worklist. This would be an argument for making REM dependant on SWF.</li> <li>— Euratom specifically discusses clinical responsibility in Article 2.</li> <li>— May also want to feedback to the ordering physician so they can factor it into patient management [Steve]</li> </ul> <p>Which staff <u>administered</u> (had technical control over) the event?</p> <ul style="list-style-type: none"> <li>— Might need to add an attribute to the Template to put it in</li> <li>— There may be multiple people listed</li> <li>— Consider informative text for who this would be for different types of study (CT – Tech, XA – Radiologist, etc.)</li> <li>— The Dose SR records the “observer” but this is who generated the dose report (which is often the equipment), not who performed the procedure.</li> <li>— The SR Document General Module has Participant Sequence but that is currently Source (equipment), Enterer, or Attestor.</li> <li>— Might be good to add an attribute for who administered an Irradiation Event, but it would have to be optional since it would be hard to get it filled properly (most modalities do a poor job of tracking exactly which tech is currently operating the system). Note that the Study Time in the IOD and (CT only) the Start of X-Ray Irradiation (DATETIME) could allow identification of the work shift involved.</li> </ul> <p>Which staff was <u>potentially exposed</u> by the event?</p> <ul style="list-style-type: none"> <li>— The EURATOM Directive include consideration of exposure of staff.</li> <li>— The tech would be the mostly likely one potentially exposed, but as said above, this is unlikely to be well filled, and other staff are even less likely to be known by the modality.</li> <li>— On the other hand, if the use case calls for it, the above is just reason to make the attributes optional, not an argument to prevent sending them by not having such attributes.</li> <li>— Staff dose is monitored on a different regimine/schedule etc.</li> </ul>
7	Does anything specific need to be done for Mammography?

	<p><i>Answer: It seems to be handled by DICOM CP 687.</i></p> <p>WG-15 and Penny Butler (ACR, physicist) introduced DICOM CP 687 which is now Final Text and part of the 2008 Standard.</p> <p>The CP did things like add the following to the Mammo version of the X-Ray Dose SR:</p> <ul style="list-style-type: none"><li>— Average Glandular Dose (dGy)</li><li>— Entrance Exposure at Reference Point (mGy)</li><li>— Anatomic Laterality [Optional]</li><li>— Compression Thickness [Optional]</li><li>— Half Value Layer (measure of x-ray beam quality) [Optional]</li><li>— Breast Composition (4 BiRads terms from fat to extremely dense) [Optional]</li></ul> <p>And remove:</p> <ul style="list-style-type: none"><li>— Dose Area Product</li></ul> <p><b>Nikos Gkanatsios will consider issues around breast density and CAD.</b> (Does breast density need to be captured more accurately than the Breast Composition terms? Is there CAD information that should be added to the Modality information? ) How would a CAD system know when the modality used an accurate value for density and thus the CAD supplemental estimate is unnecessary? Use a flag?</p> <p>If it is determined that a CAD system should supplement or modify Dose Reports provided by the modality, the CAD system could be a Dose Consumer to get the modality information, and an Evidence Creator to submit additional Dose Report details.</p> <p>There appears to be interest in Mammography Dose in Europe. European Dose is currently collected in the RIS. <b>Guillaume Peter will solicit participation from Germany to review CP687 and this profile draft.</b></p>
9	<p>How do we expect dose guidelines to eventually work in the Profile?</p> <p><i>Answer: Briefly they might be SR documents retrieved from a Registry by the DIR), but nothing is decided now.</i></p> <p>(Based on input from Steve)</p> <p>Guidelines will likely take the form of Reference Doses which are values that typical studies should not exceed. Reference Doses are often derived from collecting estimated dose from many sites and using the 75th percentile as the reference dose (i.e. the value 75</p>

<p>percent of studies currently meet).</p> <p>Occasionally guidelines may also include a lower bound which represents a value that typically results in an “unacceptable” loss of image quality. Due to evolving technology these are less commonly used.</p> <p>Guidelines are typically provided for several broad patient age categories. Many do not consider weight but that could conceivably be a factor in the future since it affects technique and thus dose. Different guidelines for different sexes or races are generally not provided.</p> <p>Guidelines are provided for specific procedures, usually about 20 procedures, and maybe up to 50 for all modalities.</p> <p>There has been some attempt to categorize interventional procedures by “complexity” since complex procedures can be expected to have higher doses.</p> <p>An FDA group has been doing surveys of dose around the US “Nationwide Evaluation of X-Ray Trends” for 30 years.</p> <p>Formats and strict definitions of guideline contents do not currently exist so they will not be addressed in the initial release of the profile. They could be added as an option in the future, or be handled by a separate profile.</p> <p>Guidelines might list target DLP values for a given procedure/sex/age/weight. They would likely not change frequently. Hospital policies might decide to set their own local targets to be more strict than the guidelines. There might be some similarity between the format/contents of guidelines and/or policies, and the format/contents of a summary report of a site’s practices, or a comparison report benchmarking against similar sites.</p> <p>If formats were available, it seems likely groups setting up Registries would also be likely to set up Guideline Servers. Since hospitals would need to manage their policies/compliance and since it would be easier to configure, it seems more likely sites would pull guidelines rather than have servers push them.</p> <p>The guidelines/policies would likely be downloaded/entered into the DIR, since they would appear in the reports it generates. The Modality would likely not be involved since technique/protocols are handled separately and the plan is already set in what comes from the RIS.</p> <p>Not clear whether the RIS would need direct access to guidelines. As with ATNA, guideline compliance is more likely to involve post-facto review rather than pre-procedure decision support or prescriptive control.</p> <p>It is conceivable that the IHE Quality Domain may be involved in defining support for guideline formats and transport in the broad sense.</p> <p>Also, the ITI “Data Re-use Whitepaper” may have some good advice on Guidelines.</p>
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	<p>A number of papers have been published about the determination and contents of Dose Guidelines. In particular:</p> <ul style="list-style-type: none"> <li>— 2008 DOSE DATAMED Report 2: GUIDANCE ON ESTIMATING POPULATION DOSES FROM MEDICAL RADIOLOGY (as required by Article 12 of the EC Medical Exposure Directive)</li> <li>— EUREF Tables (similar to MQSA) have additional categorization, such as based on breast density, in the guidelines. [Euref.org]</li> </ul> <p>Guideline Distribution today is most commonly “paper based”.</p>
10	<p>Are we overlooking any specific radiation related policy, QA and certification/accreditation activities we should be facilitating?</p> <p><i>Answer: No. The tools look good.</i></p>
12	<p>Are our use cases sufficiently complete?</p> <p><i>Answer: Yes. Reviewed with a variety of “Dose Users”.</i></p>
13	<p>What do we need to do to address differences in Radiation Safety Programs from Country to country? State to state?</p> <p><i>Answer: Looks like we’re OK. Input was solicited from U.S., Canada, France, Germany, Spain, UK &amp; Japan. No critical differences were found.</i></p> <p>European convergence is being driven by IEC/EurAtom regulations.</p> <p>U.S. patient treatment is regulated at the state level and each has a health code. However, the Conference of Radiation Control Program Directors (leaders of the state radiation safety groups) meet and try to harmonize regulations. Drafts of the Suggested State Regulations (SSR) are available crcpd.org. Different states legislate different revisions of the draft, but overall there is convergence.</p>
14	<p>What should we say about how this profile relates to a site Radiation Safety Program?</p> <p><i>Answer: In the use cases and informative text, mention Radiation Safety Officer, annual review of site radiation safety program, etc. Explain that this profile provides some mechanisms to facilitate, but does not constitute a program in itself.</i></p>

15	<p>Does the profile make it feasible to coordinate dose tracking across multiple departments and multiple institutions?</p> <p><i>Answer: Yes. Point out one DIR can Q/R multiple Image Manager/Archives.</i></p> <p>Alternatively a shared Registry could be fed by multiple DIRs (although the tracking/reporting logic is more likely to be in a DIR than a registry).</p> <p>Note that you could have tiers of DIRs if you feel like it.</p>
16	<p>Does the profile need to reference the PIX profile?</p> <p><i>Answer: Sure. Add a section to Interactions with Other Profiles</i></p> <p>It might be useful to consider in order to support compiling dose records across several facilities (since it is not unusual for patients to be imaged in more than one department/facility)</p>
17	<p>Does anything need to be done for PDI?</p> <p><i>Answer: Nothing specific. Add a section to Interactions with Other Profiles</i></p> <p>There is no reason Dose objects can't be included on a CD. Probably don't need to do anything unless we want to mandate dose reports be included (seems unlikely).</p>
18	<p>Should we specify any Patient De-identification capabilities at any point in the chain?</p> <p><i>Answer: Yes. Require the Dose Information Reporter to have this capability.</i></p> <p>Privacy has been identified as an issue. Without de-identification, the registry use case starts to fall apart. Since the DIR does the submission and is already involved in local policy, it seems like the logical location.</p> <p>Data from the modalities should be identified as far as the Dose Information Reporter since local policies may require patient specific followup in certain circumstances.</p> <p>Data sent to the registries should generally be anonymized. Registries are considered here to be typically population health systems which do not require patient identification. Registries are not personal dose records (those should be handled separately if needed, perhaps with an XDS infrastructure).</p> <p>Currently registry implementers indicate they are focused on quality of procedure performance for which anonymized data is fine. Pseudonymization would allow longitudinal analysis of dose which in turn would allow longitudinal population dose and/or evaluation of quality of ordering. Registry implementers are not currently interested in</p>

	<p>either of these topics so pseudonymization is not required now. It is not clear if it can be strictly ruled out for the future as well.</p> <p>Note that ACR has established the alternative of signing a HIPAA BAA with sites which would allow ACR to do the anonymization. Europe doesn't have this option, but doesn't see a need right now.</p>
20	<p>Should we add a Display actor to show the patient dose history?</p> <p><i>Answer: No. Such features can be provided by a Dose Consumer or a terminal on the DIR.</i></p>
21	<p>Do we need to consider any metrics for the image quality that resulted from the procedure?</p> <p><i>Answer: No. It's not clear what the right metrics would be. If anyone wants to play with it, they can put them in the SR as extensions.</i></p> <p>Dose/quality tradeoff analysis might be interesting, but is getting out of scope.</p> <p>The general feeling is that we don't need to directly explore the dose-quality tradeoff since physician feedback will prevent image quality from going too low so the Profile can focus on collection/feedback of dose information and professional societies and local policies will focus on setting dose caps/guidelines.</p>
22	<p>Should the profile require modalities to show "predicted dose" to help with protocol selection?</p> <p><i>Answer: No. Out of Scope. Leave that to FDA and/or vendors.</i></p> <p>The feeling is that Techs and Rads have a pretty good idea for conventional protocols.</p> <p>While some might not have as good an idea for new protocols that use new equipment capabilities such as dual source or dose modulation, and it might be nice for them to see the dose impact as they tweak profiles, e.g. that slight increase in kV the radiologist requested will up the dose by 4%, this is an application feature not an integration issue.</p>
23	<p>Should the profile require modalities to show "delivered dose" on screen?</p> <p><i>Answer: No. Leave that to FDA and/or vendors.</i></p> <p>This is an application feature not an integration issue.</p>
26	<p>Do we need a "copy table" like we have for MWL-&gt;Image-&gt;MPPS?</p>

	<p><i>Answer: Yes. It would be useful since we are filling an SR from an MWL. Add such a table as a Vol. 3 Appendix.</i></p> <p>Consider Group case issues and de-identification as well.</p>
28	<p>Should we make use of Quality Domain Profiles for registry submission?</p> <p><i>Answer: They don't exist yet, so proceed with current baseline.</i></p> <p>We can contact the Quality Domain and review their submission framework when it comes available and add a note in the Other Profiles section if appropriate.</p>
30	<p>Are the actor names clear/appropriate?</p> <p><i>Answer: Decided on Image Manager/Archive, Dose Information Reporter, Dose Register, Dose Information Consumer</i></p> <p>Grant that it is Estimated Dose and we are measuring Dose Indexes.</p>

**TODOs**

- 145 • Submit an IHE CP to add Intermittently Connected Option for the Store/MPPS/Commit transaction (especially the latter). SWF and REM can then make use of it.
- Submit a DICOM CP to modify the Dose Templates to have ACQ CONTEXT and have fields for something like Supervising Physician (who had clinical responsibility for justifying the administration of radiation), and something like Administering Staff (who had technical control over the administration).
- 150 • Submit a DICOM CP (Nikos will collaborate) to fix a few Mammo related elements: Exposure is in Air Kerma Kar, Dose is in mGy, so Entrance Exposure should be Entrance Dose; Wording of Row 7 description needs improvement; Confirm that accumulation is being done per breast; Laterality should be required if Mammo. May be problem that the 4
- 155 terms defined for Breast Composition don't map well to the "70/30 split" type values commonly in use.
- Consider sending someone to Houston in July for the AAPM meeting to promote the profile – Contact John Boone and ask what he needs done.

160 **3. GLOSSARY**

*Add the following to section Glossary:*

**Automatic Dose Rate Control (ADRC):** A fluoroscopy feature that maintains the same dose rate despite changing amounts of tissue between the x-ray source and detector.

165 **Deterministic Effect:** A radiation effect characterized by a threshold dose. The effect is not observed unless the threshold dose is exceeded. The threshold dose is subject to biologic variation. Once the threshold dose is exceeded in an individual, the severity of injury increases with increasing dose. Examples of deterministic effects include skin injury, hair loss and cataracts.

170 **Dose Area Product (DAP):** An index of projection X-ray dose expressed in Gy·m<sup>2</sup> and based on a characteristic of the x-ray beam (air kerma in Gy) and the cross-sectional area irradiated by the beam.

**Dose Length Product (DLP):** An index of CT dose expressed in mGy·cm and based on a characteristic of a single slice (CTDI<sub>vol</sub>) and the number of slices (i.e. length) scanned.

For Spiral scanning,  $DLP = CTDI_{vol} \times \text{Scanning Length}$

175 For Sequenced scanning,  $DLP = CTDI_{vol} \times \text{Nominal Total Collimation Width} \times \text{Cumulative Exposure Time} / \text{Exposure Time per Rotation}$

For Stationary and Free scanning,  $DLP = CTDI_{vol} \times \text{Nominal Total Collimation Width}$

**Dose Report:** A persistent DICOM object recording details related to Irradiation Events.

180 **Estimated Effective Dose:** An index of patient dose expressed in mSv adjusted to take into account differing tissue sensitivities to radiation. Since competing definitions of Estimated Effective Dose exist, creators of Dose Reports that provide this value identify the definition used by referencing in the object itself a base publication, such as ICRP Publication 60, that defines Estimated Effective Dose

185 **Irradiation Event:** An irradiation event is one continuous occurrence of irradiation being applied to a patient. A pulsed fluoro X-Ray acquisition, or a multi-slice helical CT scan are examples of single events; while a CT scanogram and the helical scan, or two different presses of the fluoro pedal, or simultaneous irradiation from two X-ray tubes are examples of separate events. See RAD TF-3: 4.Y1.4.1.1 in Store Dose Report for a more detailed description.

190 **Peak Skin Dose (PSD):** An index of patient dose expressed in Gy representing the highest dose at any portion of a patient's skin during a procedure.

**Stochastic Effect:** A radiation effect whose probability of occurrence increases with increasing dose, but whose severity is independent of total dose. Radiation-induced cancer is an example.

**DICOM Terms**

195 **Acronyms and Abbreviations**

**ACR:** American College of Radiology

**ADRC:** Automatic Dose Rate Control

**CRCPD:** Conference of Radiation Control Program Directors (USA)

**DAP:** Dose Area Product

200 **DLP:** Dose Length Product

**FDA:** Food and Drug Administration (USA)

**ICRP:** International Commission on Radiological Protection

**ICRU:** International Commission on Radiological Units

**IEC:** International Electrotechnical Commission

205 **IRP:** Interventional Reference Point

**PSD:** Peak Skin Dose

**References**

[1] American College of Radiology White Paper on Radiation Dose in Medicine, E. Stephen Amis, et al, Journal of American College of Radiology, 2007, Vol 4, pp 272-284

210 [2] Quality Improvement Guidelines for Recording Patient Radiation Dose in the Medical Record, Donald Miller, Stephen Balter, et al, Journal of Vascular Interventional Radiology, 2004, Vol 15, pp 423-429

[3] ICRU. Report 74: Patient Dosimetry for X-Rays Used in Medical Imaging. JICRU 5; 2005.

215 [4] IEC. IEC 60601. (2000). Medical electrical equipment - Part 2-43: Particular requirements for the safety of X-ray equipment for interventional procedures. Geneva; 2000.

[5] IEC. PAS 61910-1 Radiation Dose Documentation Part 1: Equipment for radiography and radioscopy. Geneva; 2007.

220 [6] FDA. Federal performance standard for diagnostic x-ray systems and their major components-- FDA. Final rule. Fed Regist 70: 33998 - 34042; 2005.

[7] Capturing Patient Doses from Fluoroscopically Based Diagnostic and Interventional Systems, Stephen Balter, NCRP Annual Meeting-07; 2008

[\[Reference crcpd.org SSR?\]](http://reference.crcpd.org)

# Volume I – Integration Profiles

225 **4. Changes to Sections 1 – 1.X**

*<Include a subsection for each section/ subsection changed>*

**4.1. 1.7 History of Annual Changes**

*<Brief description of what to add to Volume I, section 1.7 which gives a brief overview of “what’s new” in the given year of the Technical Framework.>*

230 Add the following bullet to the end of the bullet list in section 1.7

- Added the REM Profile which does blah, blah, blah.....

**5. Integration Profiles**

*Add this row to Table 2-1:*

**Table 2-1. Integration Profiles Dependencies**

Integration Profile	Depends on	Dependency Type	Comments
<u>Radiation Exposure Monitoring</u>	<i>None</i>	<i>None</i>	=

235

*Add the following section to the end of 2.1*

**2.1.X Radiation Exposure Monitoring (REM)**

240 The Radiation Exposure Monitoring Integration Profile specifies communications between systems generating reports of irradiation events (generally acquisition modalities and workstations) and systems which receive, store, or process those reports (generally local dose information management systems and/or national/regional dose registries). It defines how DICOM SR objects for CT and projection X-ray dose reports are created, stored, queried, retrieved, processed and displayed.

245 *Change the Actor Descriptions in 2.3 as follows:*

**Acquisition Modality** - *<Creates and stores Dose SR. No change proposed to existing Actor Description>*

**Evidence Creator** - *<Creates and stores “other dose data” – See Open Issue 2. No change proposed to existing Actor Description>*

- 250 **Image Manager/Archive** - *<Accepts/Commits dose data and supports Q/R. No change proposed to existing Actor Descriptions >*
- Dose Information Consumer** – Responsible for supplemental handling of irradiation events, generally on an individual basis, e.g. display, analysis, or further processing.
- 255 **Dose Information Reporter** – Responsible for the aggregation, reporting and business logic related to irradiation events, which may include meeting facility obligations to submit data to various registries.
- Dose Register** – Collates information about irradiation events from a number of facilities, generally to perform analysis.

260 *In Table 2.2-1:*

*Add a column with the heading “**REM**” at the end of the table.*

*Add “X” in this columns’ cells for these actors: **Acquisition Modality, Evidence Creator, Image Manager/Archive, Dose Information Reporter, Dose Register and Dose Information Consumer.***

265

*Change or add the following transaction descriptions in 2.3:*

- 270 **10. Storage Commitment – Request and receive from an actor system which has stored DICOM objects (such as images or Evidence Documents) confirmation of receipt and ownership for the specified objects, generally to allow the requesting actor to safely delete those objects.**
- ~~A requestor (Acquisition Modality or Evidence Creator) requests that the Image Manager confirm ownership for the specified DICOM objects (images, GSPS objects, Key Image Notes, Evidence Documents, or any combination thereof) that the requestor stored in the Image Archive, thus allowing the sender to delete those objects now owned by the Image Manager.~~
- 275 X-1. Store Dose Report – Send a report of a Irradiation Event encoded in DICOM SR using DICOM Store. E.g. an Acquisition Modality sends a report to an Image Manager/Archive.
- 280 X-2. Submit Dose Report – Send a report of a Irradiation Event encoded in DICOM SR using FTP E.g. a Dose Information Reporter sends a report to a Dose Register.
- X-3. Query Dose Report – Obtain a list of references to reports of Irradiation Events matching a given filter. E.g. a Dose Consumer queries a Dose Information Reporter.
- X-4. Retrieve Dose Report – Obtain reports of Irradiation Events. E.g. a Dose Consumer retrieves reports from a Dose Information Reporter.

285

*In Table 2.3-1:*

*Add a column with the heading “**REM**” at the end of the table. Add “X” in this columns’ cells for these transactions: **Storage Commitment [RAD-10], Store Dose Report [RAD Y1], Submit Dose Report [RAD Y2], Query Dose Report [RAD Y3], Retrieve Dose Report [Rad Y4].***

## 290 **2.4 Product Implementations**

*Add the following to section 2.4:*

[Is this helpful or should it be removed for Trial Implementation? Should it be moved into the specific Profile chapter? Should it go into an informative Annex?]

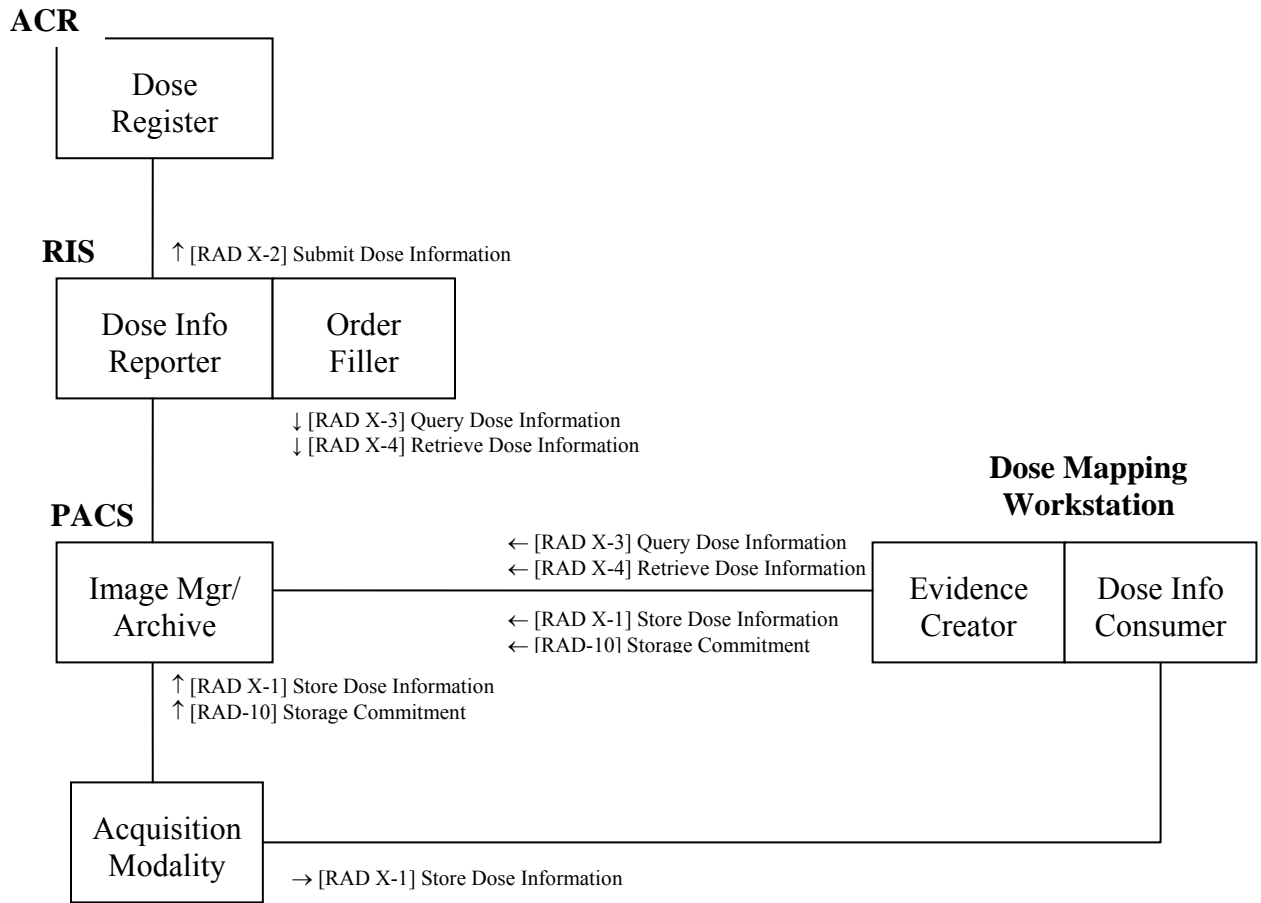
### **2.4.1 Example REM Profile Deployments**

295 These are intended to give the reader a better idea about a few ways the Radiation Exposure Monitoring Profile might be deployed. It is not intended to be normative, or to show all possible deployments.

#### **2.4.1.1 Hospital Case**

Imagine:

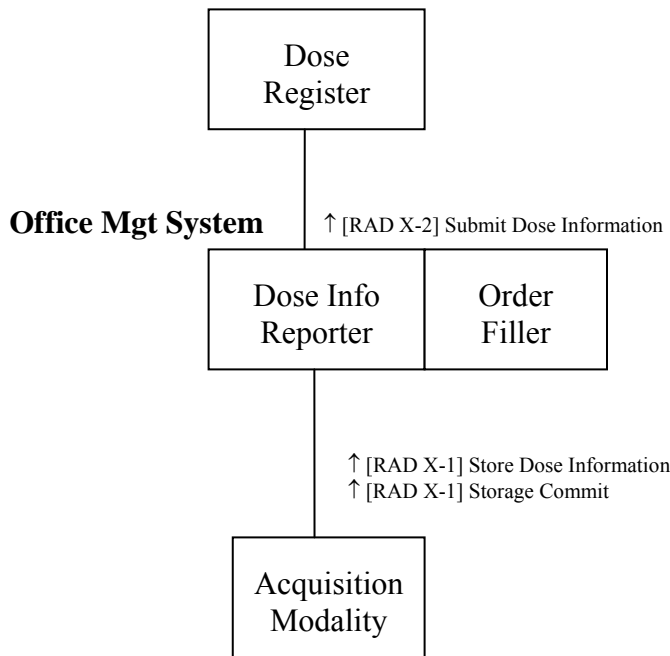
- 300
- the PACS implements the Image Manager/Archive actor and also PIR, SWF, PDI and XDS-I
  - the RIS implements the DIR actor and also SWF, PIR
  - a Dose Mapping Workstation implements the Dose Info Consumer and Evidence Creator
  - a Legacy Modality might be brought in via an Evidence Creator workstation
  - perhaps a Cardiology PACS implements a separate Image Manager/Archive for the
- 305 the cardiology modalities and the DIR (in the Radiology RIS) queries both Archives and manages dose for the hospital in one place.



### 2.4.1.2 Imaging Clinic

310 Imagine (Christoph's example) a PACS-less clinic or an Dose Information Reporter that needs a realtime feed for some reason:

- the Office Mgt System implements the Dose Information Reporter, and takes advantage of it's ability to receive dose reports directly
  - the site decides they do not need long term archiving/reconciliation of the dose objects so no Image Manager/Archive is included
- 315



### 2.4.1.3 Encapsulated Registry Submission

An organization that is setting up a Dose Register might address submission issues and facilitate site participation by distributing an client application to each participating site.

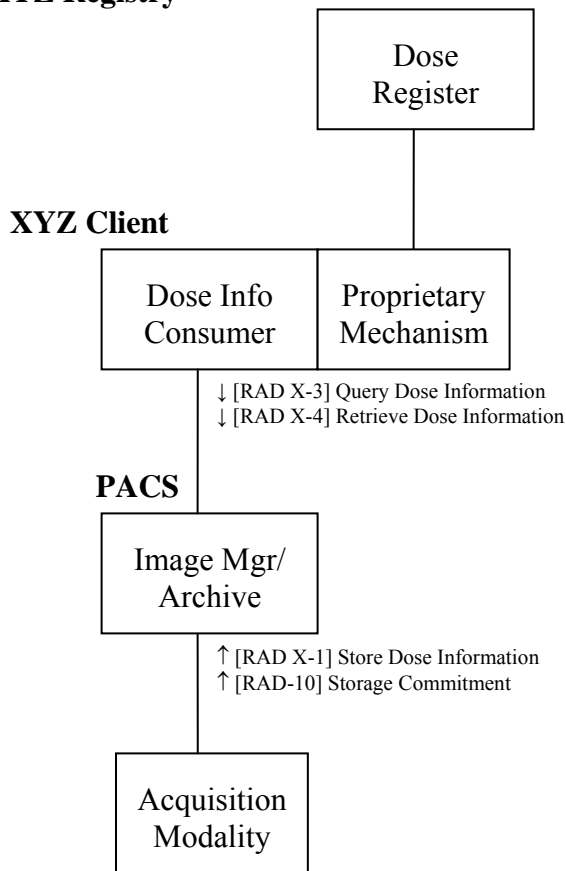
320 The client implements a Dose Information Consumer or Dose Information Reporter to gather dose reports from the Image Archive, and encapsulates a proprietary upload mechanism to get the dose reports up to the registry.

Note that while this approach has the potential to simplify some technical issues, it introduces a number of security issues. Some sites may need to review/approve the client before allowing  
325 foreign software on their network, particularly if it is capable of sending patient data outside the organization.

Imagine:

- the XYZ Registry Client implements the Dose Info Consumer to get dose reports, and some email or web services protocol to send them to the Dose Register

**XYZ Registry**



330

*Add the following section:*

**X Radiation Exposure Monitoring (REM) Integration Profile**

335 This Integration Profile specifies how details of radiation exposure resulting from imaging procedures are exchanged among the imaging systems, local dose information management systems and other systems such as dose registries.

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

340 The Profile focuses on conveying the details of individual irradiation events. A radiation exposure management program at an imaging facility would involve a Radiation Safety Officer and additionally define such things as local policies, local reporting requirements, annual

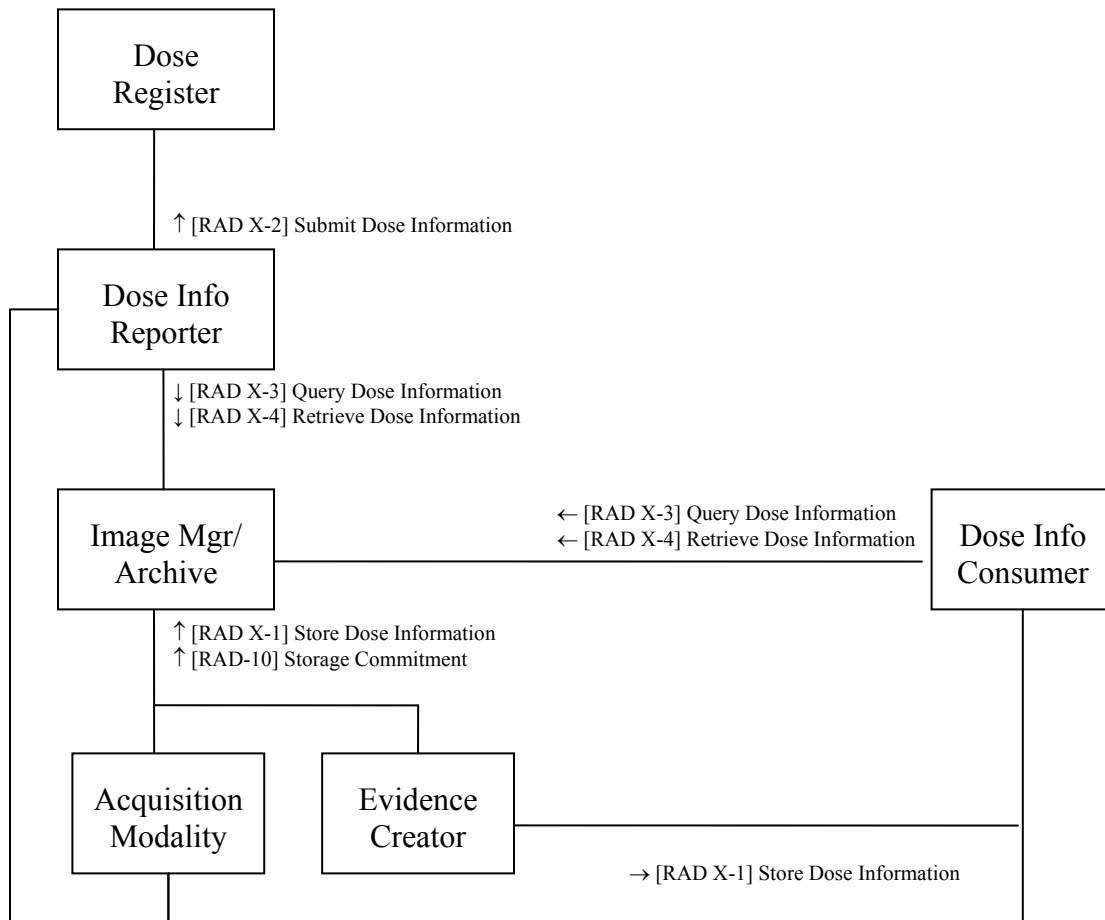
reviews, summary information contents, etc. Although this Profile is intended to facilitate such activities, it does not define such policies, reports or processing, or in itself constitute a radiation exposure management program.

345 The Profile addresses dose reporting for imaging procedures performed on CT and projection x-ray systems, including mammography. It does not currently address nuclear medicine procedures (PET or SPECT), radiotherapy procedures, or implanted seeds. Such information would certainly be useful and could be added to the profile in the future.

350 The data flow in the profile is intended to facilitate recording individual procedure information, collecting data related to specific patients, and performing population analysis.

### **X.1 Actors/ Transactions**

355 Figure X.1-1 shows the actors directly involved in the Radiation Exposure Monitoring Integration Profile and the relevant transactions between them. Other actors that may be indirectly involved due to their participation in other relevant transactions are not necessarily shown.



**Figure X.1-1. Radiation Exposure Monitoring - Actor Diagram**

360 Table X.1-1 lists the transactions for each actor directly involved in the Radiation Exposure Monitoring Profile. In order to claim support of this Integration Profile, an implementation must perform the required transactions (labeled “R”). Transactions labeled “O” are optional. A complete list of options defined by this Integration Profile and that implementations may choose to support is listed in Volume I, Section X.2.

365 **Table X.1-1. Radiation Exposure Monitoring – Actors and Transactions**

Actors	Transactions	Optionality	Volume & Section
Acquisition Modality	Store Dose Information	R	Vol. 3 – 4.Y1
	Storage Commitment	R	Vol. 2 – 4.10

Evidence Creator	Store Dose Information	R	Vol. 3 – 4.Y1
	Storage Commitment	R	Vol. 2 – 4.10
Image Manager/Archive	Store Dose Information	R	Vol. 3 – 4.Y1
	Storage Commitment	R	Vol. 2 – 4.10
	Query Dose Information	R	Vol. 3 – 4.Y3
	Retrieve Dose Information	R	Vol. 3 – 4.Y4
Dose Information Reporter	Query Dose Information	R	Vol. 3 – 4.Y3
	Retrieve Dose Information	R	Vol. 3 – 4.Y4
	Submit Dose Information	R	Vol. 3 – 4.Y2
	Store Dose Information	R	Vol. 3 – 4.Y1
Dose Information Consumer	Query Dose Information	R	Vol. 3 – 4.Y3
	Retrieve Dose Information	R	Vol. 3 – 4.Y4
	Store Dose Information	R	Vol. 3 – 4.Y1
Dose Register	Submit Dose Information	R	Vol. 3 – 4.Y2

A workstation may claim to have implemented the Acquisition Modality actor in this profile if it is able to completely and correctly generate Dose Reports on behalf of the irradiating modality system based on irradiation details obtained by manual input and/or some proprietary method.

370 **X.2 Radiation Exposure Monitoring Integration Profile Options**

Options that may be selected for this Integration Profile are listed in the table X.2-1 along with the Actors to which they apply. Dependencies between options when applicable are specified in notes.

Currently there are no options defined in this profile.

375 **Table X.2-1 Radiation Exposure Monitoring - Actors and Options**

Actor	Options	Vol & Section
Acquisition Modality	<i>No options defined</i>	--
Evidence Creator	<i>No options defined</i>	--
Image Manager/Archive	<i>No options defined</i>	--
Dose Information Reporter	<i>No options defined</i>	--
Dose Information Consumer	<i>No options defined</i>	--
Dose Register	<i>No options defined</i>	--

### X.3 Radiation Exposure Monitoring Process Flow

*<Consider including informative references here to existing exposure management process recommendations, e.g. European directive Euratom 97/43, ACR Dose Whitepaper>*

380 << Maybe speak (in a separate section) to what is appropriate for National Extensions or specific dose projects. >>

<< Mention the need to standardize procedure codes if you want to analyze across them etc.>>

Be VERY sensitive to not imply that this is normative text.

385 This Profile addresses the flow of dose information from the source, through the organization and beyond. It does not mandate, but is intended to facilitate the ability to do things like:

- view the dose a patient (or particular organs) received for a certain exam, hospital stay or course of treatment
- view a patients dose history
- 390 • determine if a given patient dose exceeds some dose standard or is otherwise an "outlier" requiring investigation
- compute the population "dose summary" for a specific exam in a certain hospital or region
- compute the population "dose summary" for a certain pathology
- 395 • compare exam-specific "dose summaries" against other sites/regions, against local policy targets or against standards of practice

#### X.3.1 General Case

In a typical situation, irradiation events occur on x-ray based imaging modalities, which record them in Dose Report objects that are stored to the same study as the images on the Image Manager/Archive. In some organizations, a Dose Information Reporter will collect Dose Reports covering a particular period, analyze them, compare practices to site policy and generate summary reports. All, or a sampled set of the Dose Reports may be submitted to a National Register to facilitate composing population statistics and other research.

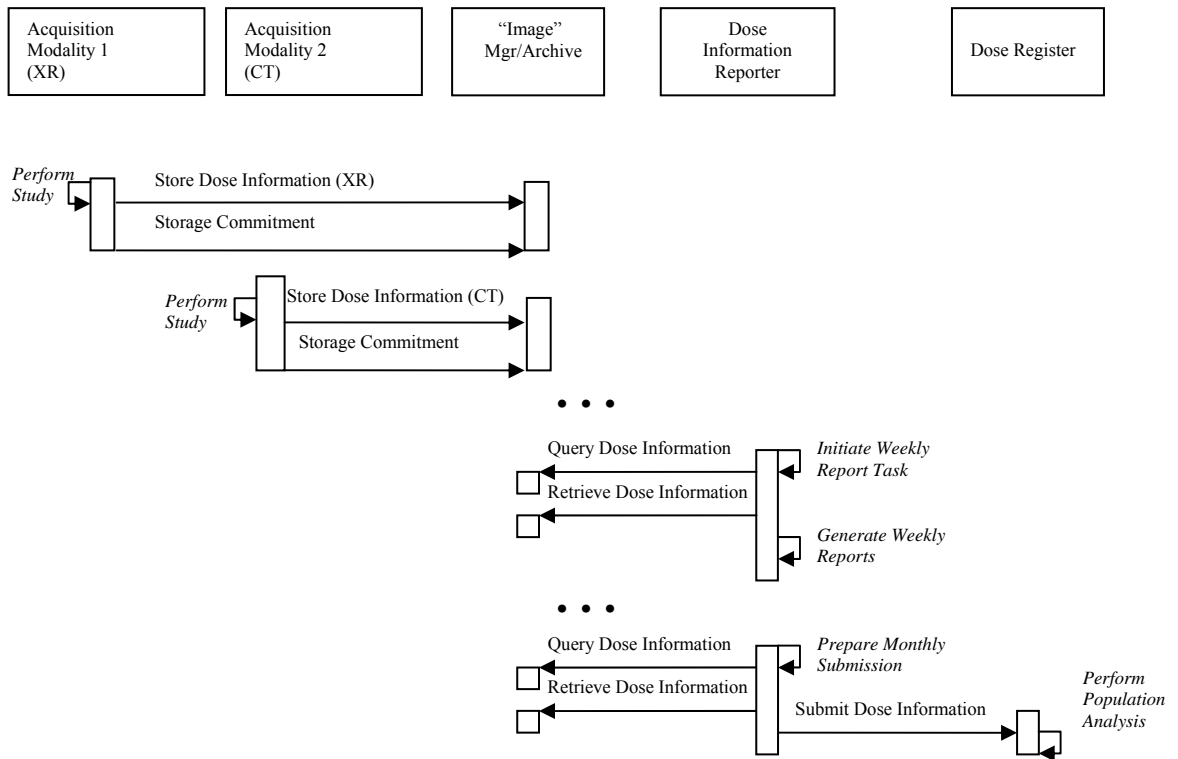


Figure X.3-1. Radiation Exposure Monitoring - General Case

405 **X.3.2 Radiation Exposure Monitoring – Real-World Use Cases**

The following use cases describe real-world application of the dose information. The use cases are roughly ordered from cases closest to the “source”, to cases further away.

**Use Case: Procedure Operational Awareness (Quasi-realtime)**

410 The intent of both the IEC and FDA is to make the fluoroscopic operator aware of dose accumulation during a procedure. Thus,  $K_{a,r}$  is required to be displayed within sight of the primary operator. This permits the operator to factor radiation effects into the continuous clinical benefit-risk analysis occurring during any procedure. (Note that  $K_{ar}$  is not cumulative skin dose)

One approach to this use case is direct display of details by the modality which does not require the use of this profile.

415 Dose Reports could also be stored after each irradiation to enable real-time processing such as the computation of skin dose maps. Such mapping might let a physician shift the beam “off the hot spot”. Film-based mapping has not helped for this since it shows “what happened”, not “what’s happening”.

**Use Case: Clinical Management**

420 Dose mapping facilitates planning for and decision making during subsequent procedures (such as deciding how much time to allow for tissue to heal, or deciding what direction to image from to avoid damaged tissues). Particularly for interventional fluoroscopy, the dose distribution delivered by each procedure should be part of the patient’s medical record.

425 Some guidelines recommend that dose data should be recorded, manually if no better source is available, for 100% of interventional procedures (Miller et al. 2004) and for a statistically appropriate sample of other procedures.

**Use Case: Patient Impact Evaluation**

430 A few days after a CT exam is carried out for a young female patient, that patient is identified as pregnant (this was not identified before the scans because tech didn’t ask, patient misunderstood, patient didn’t know, etc.). The referring physician is at that point aware that the newly discovered pregnancy of the patient is problematic in this context, and requests from the radiologist who had read the exam an evaluation on the risk to the fetus. The radiologist requests a hospital medical physicist to provide her with an estimate of the radiation dose received by the uterus in the course of the CT exam.

435 The medical physicist retrieves the images of the study in question, and determines with the help of the radiologist which series encompass the uterus. Knowing which series are of interest, the medical physicist is then able to leverage the dose indicators and weight of the patient contained in the image headers to sum up the total dose to the uterus. The dose value is then provided to the clinical coordinator of the department, who enters the dose estimate in the RIS. This causes a statement to be automatically appended to the report (which had already been signed off), and the status of the study is automatically demoted to "pending signature" as is the case when an addendum is added to an existing report. Before signing off the report, the radiologist completes the addendum with her estimate of the risk to the fetus given the dose measurement, and communicates this result by phone to the referring physician, who also receives the written addendum electronically signed by the radiologist a few days latter.

445 Important analysis details include time/date of scans, body area irradiated, exposure values.

**Use Case: Department QA (Process Control)**

This is perhaps the most significant of the use cases.

450 Data will generally be continuously collected and evaluated on all procedures. Process control/data analysis focuses on local variations attributable to x-ray equipment, operators, procedures and ordering physicians. E.g:

As part of the departmental quality improvement program, the radiation safety officer (RSO) of the hospital accesses the RIS to carry out his bi-monthly assessment of radiation dose use. For a selected set of procedures, the dose-area product of each

455 procedure is evaluated for each room. No significant variation of the average is found  
over the last 6 months. Another report compares average dose for different performing  
radiologists over several interventional procedures, and a third report compares  
performing technologists for CT and radiographic exams.

460 It becomes clear that for a certain procedure a newly arrived radiologist tends to generate  
2 to 3 times the dose-area product of his colleagues, whose averages are in a narrow  
cluster well below the value created by the newcomer. While the dose-area product sub-  
total in fluoroscopy is similar among the radiologists (and is consistent with the average  
fluoroscopy time of the report), there is a significant discrepancy in dose-area product for  
465 the acquisition sub-total. The number of acquired images (higher than the departmental  
average) also corroborates this.

The RSO writes a memo to the department chair, who raises the issue at the weekly  
radiologist meeting. Upon discussion, it becomes clear the radiologist uses a  
supplementary acquisition which his colleagues do not. After more discussion, the  
radiologists agree that the acquisition, although moderately useful, probably does not  
470 bring any information which would not be picked up in the rest of the exam, and it is  
agreed it should not be done. The RSO reviews the situation a month later, and is  
reassured that the results show all radiologists now have similar radiation dose for that  
procedure.

Hospitals generally have policies relating to patient radiation dose, often benchmarking  
475 performance against published reference levels. Policies (and reference levels) are often broken  
down by procedure, patient age group, and perhaps weight group, or gender.

Analysis tools can help them monitor whether policies are being followed, and measure progress  
toward it's targets. Such programs can be an effective way to counter dose creep, establish upper  
limits and encourage lower values. Image quality sets the low side limit on dose (too low and  
480 the images are unacceptable to the radiologists).

Note that access to effective values is important when establishing metrics or thresholds. A  
simple fluoro time threshold might be used to trigger a case review if it is exceeded. Some  
studies with high dose might avoid the trigger due to excessive use of cine mode (high dose)  
lowering the fluoro time.

#### 485 **Use Case: Population Risk Estimation**

This and the Dose Reference Levels case are probably the second most significant use cases.

Organizations wishing to perform Population Risk Estimation or similar *data mining* will often  
set up a Dose Registry. Sampled dose data is collected from a number of clinical sites for  
specific procedures with reasonable accuracy. It is not necessary that every procedure performed  
490 be collected; a representative sample of procedures is sufficient. That being said, it may be

easier for a registry to discard a portion of the procedures submitted than to try and get each submitting site to follow the same regimine for selecting procedures to submit.

495 Once a registry has calculated the typical dose of a given procedure, a number of ways are used to estimate the total number of procedures performed in order to extrapolate dose for a total population:

- number of machines installed \* estimated # of procedures per machine
- collect RIS data on procedures performed
- collect reimbursement data for a given population

500 Note that conversion of estimated dose values to patient or population risk involves <complex> scientific questions. Of course, streamlining the collection of additional, more detailed data can only help.

**Use Case: Dose Reference Levels**

The most likely distribution of quantitative Guidelines is in the form of Dose Reference Levels for typical procedures for groups of patients of different characteristics.

505 Such guidelines are often the logical result of Population Data Mining performed by a professional society or regulatory body.

**Use Case: Site Benchmarking**

510 Another potential function of a national radiation dose registry could be to provide the facilities submitting data with periodic reports comparing them against regional and national benchmarks. Using this report, Mr. Smith's hospital can compare its dose profile by modality, exam type, and pathology to facilities of the same type, facilities in the same region, and to the nation as a whole.

**Use Case: Population Epidemiology**

515 To analyze certain population epidemiology questions, e.g. the occupational hazards of being a radiologist, one has patients with a known disease and would like to use the patients radiation history to estimate the likelihood of radiogenic etiology. Requirements include access to a complete radiation history of each such patient. Because of long latent periods, data must be archived in a manner that makes it both physically readable and dosimetrically intelligible years to decades after they are written.

520 **Use Case: Clinical Trials**

The radiation dose can be an important component of a clinical trial. For example, a trial of a proposed low-dose CT lung screening procedure would like to be able to collect dose data to balance against the resulting detection rates for a proper trade-off analysis.

A Radiation Exposure Monitoring Profile could enable a lot of studies.

525 **X.3.3 Radiation Exposure Monitoring – Real-World Projects**

A number of organizations have established projects relevant to Radiation Exposure Monitoring.

**Project: ACR Registry**

ACR is forming a national registry for Radiation Dose. The initial focus is CT. They have not yet thought through the implications for diagnostic or interventional XA.

530 Their goal is minimizing dose to the population and they are interested in Use Cases including: Population Risk Estimation and Benchmarking. They are specifically not interested in the Patient Dose History Use Case (they have no plan to become a national personal dose record).

ACR is interested in collecting for all CT exams performed:

- Patient gender, age – to permit age/sex specific guidelines (different risks)
- 535 • Patient weight – affects dose, affects imaging, used in guidelines
- Patient ID (pseudonymized) – to allow for evaluation of individual dose histories
- Dose Indices: CTDIvol, DLP
- Equipment details [ACR will confirm during public comment]
  - System Name/ID - can be anonymized System 1, System 2, etc.
  - 540 • Detector Rows – Single vs 16 vs 64, etc.
  - # of Sources – see TID 10013
  - Pitch Factor – see TID 10013
  - etc.
- [See table in separate ACR document for full list of desired attributes]

545 Note that Detector Rows = Nominal Total Collimation Width (TID 10013 Row 12) / Nominal Single Collimation Width (TID 10013 Row 11)

This follows the attributes defined in the CT Image Module, which notes that for single collimation “Adjacent physical detector rows may have been combined to form a single effective acquisition row”, and that Total Collimation Width “will be equal the number of effective detector rows multiplied by single collimation width.” So a 64 slice machine operating in “16 slice mode” will have attributes appropriate to 16 effective detector rows.

550 They are considering a service to review the performance of a given hospital against the benchmarks and perhaps provide performance summaries for “comparable” facilities.

555 The ACR benchmark report becomes a “report card” for a site. Benchmarking will, admittedly, be a challenge because the technology continues to move very quickly. Higher levels do not necessarily reflect poor practices at a site, and a variety of factors can impact doses at a site.

**Project: French Ministry of Health Registry**

French regulations mandate the submission of Dose Reference Level data to a federal registry.

560 Every year each specialists must submit dosimetric information (at least 20 patients) for each of at least two examination types (generally the most frequent or most irradiating examinations).

They are interested in Use Cases including: Population Risk Estimation, Dose Reference Levels.

In **Conventional Radiology** the requested dosimetric information is

- entrance surface dose (in mGy) for one exposure, or
- dose area product (DAP in mGy.cm<sup>2</sup>) for one examination or for the overall procedure.

565 — Examinations of interest are:

- Adult: Lung (PA), Lung (profile), Lumbar spine (AP), Lumbar spine (profile), Abdomen, Pelvis, Breast, Skull (AP), Skull (profile)
- Child 0-1 year: Lung (PA), Pelvis (AP)
- Child 5 years: Lung (PA), Lung (profile), Skull (PA or AP), Skull (profile), Pelvis (AP), Abdomen

570

In **Computed Tomography** the requested dosimetric information is

- weighted CT dose index (CTDI<sub>w</sub> in mGy) for each sequence
- dose length product (DLP in mGy.cm) for each sequence or for the overall procedure
- volume CT dose index (CTDI<sub>vol</sub> in mGy) is also accepted

575 — Examinations of interest are:

- Adult: Head, Thorax, Abdomen, Pelvis

In **Nuclear Medicine** (out of scope of the REM Profile this year) the requested dosimetric information is

— injected activity (in MBq)

580 — type of radiopharmaceutical

— Examinations of interest are:

- Bone scintigraphy, Lung scintigraphy, Thyroid scintigraphy, Cardiac SPECT, Cardiac scintigraphy, Kidney scintigraphy, Dynamic kidney scintigraphy, Brain SPECT, Scintigraphy of somatostatin receptors, PET FDG

### 585 **X.3.4 Radiation Exposure Monitoring – Regulatory**

Several groups interested in regulatory issues (IEC, FDA, AAPM, etc) drove definition of the DICOM Dose SR Objects in the first place. Some of the ways they envision the objects being used are presented here.

### U.S. Regulatory

590 ACR is not a regulator of dose. They will collect dose information at a national level, but not directly for regulatory purposes. (Analysis of the collected data might inform guidelines that could find their way into accreditation).

### European Regulatory

595 European regulation is based on European Directive Euratom 1997/43/EC. The application of the directive is mandatory in all EU countries (27 today) since 2000. All European national regulations have to be compatible with the directive. Different countries have varied in their reactions/actions to Euratom.

Euratom specifies a follow up for each patient and statistics at population level.

600 <These national subsections may be refactored to focus on national specifics, deviations and additions, and the common details could be moved up here to the European level.>

### French Regulatory

Today two regulations specify the dosimetric information that a user of ionising radiation must provide in France.

- 605 — One text, published in March 2004, concerns Dose Reference Levels (DRL) (Arrêté du 12 février 2004 relatif aux niveaux de référence diagnostiques en radiologie et en médecine nucléaire – Journal Officiel de la République Française du 16 mars 2004) (Since this seems to be in support of a registry, the details are listed below in the Registry section)
- 610 — Another text, published in September 2006, concerns dosimetric information that must be present in the medical record of the diagnostic examination (Arrêté du 22 septembre 2006 relatif aux informations dosimétriques devant figurer dans un compte rendu d'acte utilisant les rayonnements ionisants - Journal Officiel de la République Française du 29 septembre 2006).

615 For each medical procedure using ionising radiation, the medical record must include information allowing estimation of the dose received by the patient.

<b>Diagnostic or Interventional Radiology</b> (for procedures concerning the head, neck, thorax, abdomen or pelvis)	<ul style="list-style-type: none"><li>— type of examination (radiography or fluoroscopy)</li><li>— dose area product (DAP)</li><li>— If DAP is not known and the patient is either under 16yrs, a woman of childbearing potential getting a pelvis exam, or a pregnant woman getting a justified pelvis and/or abdomen exam, then it must record:</li></ul>
--	---

	<ul style="list-style-type: none"> <li>○ high voltage (kV)</li> <li>○ available details of the following:             <ul style="list-style-type: none"> <li>▪ intensity time product</li> <li>▪ source-skin distance</li> <li>▪ fluoroscopy time</li> <li>▪ intensity for each field size</li> <li>▪ number of exposures in graphy</li> </ul> </li> </ul>
<b>Mammography</b>	<ul style="list-style-type: none"> <li>— mean glandular dose             <ul style="list-style-type: none"> <li>○ If the device doesn't allow direct measurement, consider estimating based on number of exposures * phantom dose measured every six months during mandatory external QA.</li> </ul> </li> </ul>
<b>Computed Tomography</b> (for examinations concerning the head, neck, thorax, abdomen or pelvis)	<ul style="list-style-type: none"> <li>— dose length product (DLP) must be indicated with distinction between sequences concerning head and neck on one side and trunk on the other side</li> <li>— If the DLP is not available, the following information can be provided:             <ul style="list-style-type: none"> <li>○ examination length</li> <li>○ CTDI<sub>w</sub> or CTDI<sub>vol</sub></li> </ul> </li> <li>— For women with childbearing potential or pregnant (justified examination) it is mandatory to indicate:             <ul style="list-style-type: none"> <li>○ CTDI<sub>vol</sub></li> </ul> </li> </ul>
<b>Nuclear Medicine</b>	<ul style="list-style-type: none"> <li>— radiopharmaceutical name</li> <li>— administered activity</li> <li>— route of administration</li> </ul>

**German and Dutch Regulatory**

In Germany and the Netherlands, dose information is not conveyed above the Hospital level. Dose information is required and must be auditable.

- 620 Germany is working on additions to DICOM Basic Diagnostic Imaging Report (SupXXXX in WG-20) to include Radiation Regulation related details such as:
- Pregnancy Status
  - Indications for Procedure
  - Physician Responsible for Indication
  - 625 — Performing Person (who administered)
  - Radioactive Substance Administered
  - Radiation Exposure (text description of "the exposure")
  - Performing Person's Organization Name

### **Spanish Regulatory**

- 630 In Spain, dose information is not conveyed above the Hospital level.
- Dose information is required in order to audit the use of diagnostic equipment (comparing with Dose Reference Levels) and must be auditable by the responsible health authority. Also the responsible health authority and the Nuclear Security Council will guarantee that the distribution of the estimations of resulting individual doses is determined, for the population and the
- 635 significant groups of reference of the population, whose results will be sent to the Ministry of Health and Consumption.

## **X.4 Radiation Exposure Monitoring Profile Security Considerations**

*<Point out that Dose Reports have the same security considerations as images>*

- 640 *<Put some anonymization related stuff here>*

## **X.5 Relation to Other Profiles**

Several synergies and interactions of the Radiation Exposure Monitoring Profile with other profiles are specifically called out here.

### **X.5.1 Radiology Profiles**

- 645 **X.5.1.1 Portable Data for Imaging (PDI)**

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

650 In theory, a re-writable CD could be used to let a patient continually append to a personal dose record (although it would be a good idea to back it up).

#### **X.5.1.2 Patient Identification Reconciliation (PIR)**

It would be highly desirable for an Image Manager/Archive to also implement the Patient Identification Reconciliation Profile, in which case it would be expected to reconcile the Dose Report objects along with the rest of the DICOM objects in a patients study.

#### **655 X.5.1.3 Teaching Files and Clinical Trials Export (TCE)**

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

#### **660 X.5.2 ITI Profiles**

##### **X.5.2.1 Patient Identity Cross-referencing (PIX)**

The PIX Profile could clearly be useful if there is a need to collate patient dose records across multiple Patient ID Domains. It could also be useful if a single Dose Information Reporter is querying multiple Image Manager/Archives in different Patient ID Domains.

##### **665 X.5.2.2 Cross-Enterprise Document Sharing (XDS)**

Some sites might find it useful to use the collection of XDS Profiles to pool dose records across multiple sites. The Image Manager/Archive could be a Source, the DIR or the Image Manager/Archive could be a Repository and register the documents with an XDS Registry Actor.

##### **X.5.2.3 (XDR)**

670 <See XDS>

##### **X.5.2.3 Consistent Time (CT)**

Consistent Time could be particularly useful if a gantry and reader are trying to compose a Dose Report by synchronizing study details based on timestamps.

675

## Volume 3 - Transactions

*Add sections 4.Y1 , 4.Y2, 4.Y3, 4.Y4*

### 4.Y1 Store Dose Report

680

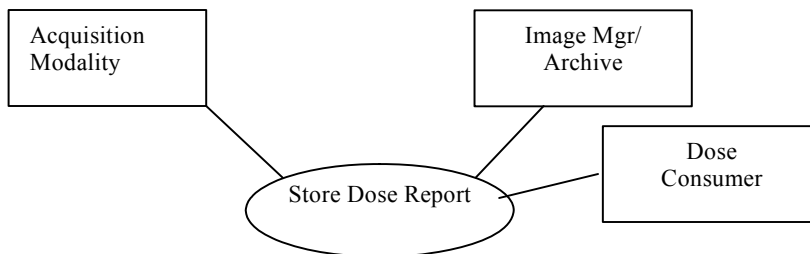
This section corresponds to Transaction RAD-Y1 of the IHE Technical Framework. Transaction RAD-Y1 is used by the Acquisition Modality, Image Manager/Archive and Dose Consumer actors.

#### 4.Y1.1 Scope

685

This section describes DICOM Storage requests of Structured Report objects containing Dose Reports which detail irradiation events. An Acquisition Modality sends Dose Reports to an Image Manager/Archive for storage so they can be later used for tracking or analysis of patient radiation exposure.

#### 4.Y1.2 Use Case Roles



**Actor:** Acquisition Modality

690

**Role:** Generate Dose Reports describing irradiation events performed by the Acquisition Modality.

**Actor:** Image Manager/Archive

**Role:** Accept and store Dose Report objects received from the Acquisition Modality.

**Actor:** Dose Consumer

**Role:** Accept and store Dose Report objects received from the Acquisition Modality.

695

#### 4.Y1.3 Referenced Standard

DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

DICOM 2008 PS 3.4: Storage Service Class

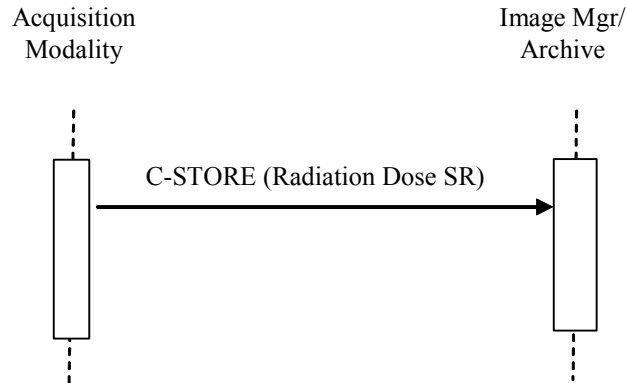
DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

DICOM 2008 PS 3.16: X-Ray Radiation Dose SR IOD Templates

700 DICOM 2008 PS 3.16: CT Radiation Dose SR IOD Templates

DICOM 2008 PS 3.17: Annex AA: Radiation Dose Reporting Use Cases

#### 4.Y1.4 Interaction Diagram



#### 4.Y1.4.1 Store Dose Report

##### 705 4.Y1.4.1.1 Trigger Events

An Acquisition Modality shall generate an appropriate Dose Report upon completion of each irradiation event.

710 An irradiation event is a single continuous exposure of radiation. For a more precise definition including details relating to pulsed acquisition, dose modulation, dual source systems, etc. refer to the relevant sections of DICOM 2008 PS 3.16.

The Acquisition Modality shall send the Dose Report to the configured destinations, usually an Image Manager/Archive, for storage. The Acquisition Modality shall be capable of sending the Dose Report to multiple destinations.

715 The Acquisition Modality shall clearly document in its DICOM Conformance Statement, the time frame in which it is able to store a Dose Report relative to the completion of the irradiation event. Some applications, such as “Realtime” Dose Mapping, depend on Dose Reports being made available in a timely fashion. Acquisition Modalities are strongly recommended to store Dose Reports as soon as possible after the irradiation event.

720 The Acquisition Modality shall be capable of queuing Dose Reports when the Image Manager/Archive or Dose Consumer is unreachable and delivering the reports later when the

connection is re-established. This may be due to network trouble, the Image Manager/Archive being down, or the modality being intermittently connected (as might be the case with a mobile X-Ray system).

**4.Y1.4.1.1.1 Digitization**

725 In the case of a system digitizing a film produced locally for which a dose report has not been generated, it would be appropriate to create and store a dose report along with the digital images. The digitizing system might create the report based on manual entry. An adjacent system might create the report based on the generated images or the MPPS from the film-based modality.

730 In the case of a system digitizing an external prior, the site that created the film in the first place should be responsible for recording the dose, and it is not a current procedure, so it would be inappropriate to generate a dose report since it would be a duplicate irradiation event with a unique ID, and would likely be incomplete.

**4.Y1.4.1.2 Message Semantics**

These objects serve as a record of irradiation performed by the device.

735 The Acquisition Modality actor shall use the DICOM C-STORE message to store Dose Reports encoded as DICOM SR objects.

The Acquisition Modality actor shall implement the Dose Report Storage SOP Class in the role of SCU. The Image Manager/Archive actor and Dose Consumer actor shall implement the Dose Report Storage SOP Class in the role of SCP.

740 **Table 4.Y1-1. Dose Report Storage SOP Classes**

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.88.67	X-Ray Radiation Dose SR

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

745 Acquisition Modality actors which report on irradiation events for Modalities of type CT shall be capable of producing an SR compliant with TID 10011.

Acquisition Modality actors which report on irradiation events for Modalities of type XR, XA, RF, MG, CR, or DX shall be capable of producing an SR compliant with TID 10001.

750 The modality type of the acquisition being reported on shall be recorded in the Dose Report in the Modalities in Study (0008,0061) attribute.

Each irradiation event shall be assigned a UID so that it can be uniquely identified.

Systems that also implement either the Modality Images Stored transaction or the Creator Images Stored transaction should note the requirement to record the Irradiation Event UID (0008,3010) as documented in RAD II 4.8.4.1.2.4.

755 If the Dose Report is not being created by the equipment which actually administered the radiation, both the irradiating equipment and the report creating equipment shall be referenced in the Contributing Equipment Sequence (See C.12.1.1.5).

The Acquisition Modality shall be capable of creating Dose Reports for patient scans and for phantom/calibration scans.

760 [There was some question about whether a Dose Report that contains Summary information is expected to contain all the dose events spanned by the summary, or just the “current” one? I believe it just contains the current one. Including all would mean subsequent events would be steadily larger]

#### 4.Y1.4.1.3 Expected Actions

765 The Image Manager/Archive shall store the received Dose Report objects and make them available for query/retrieval.

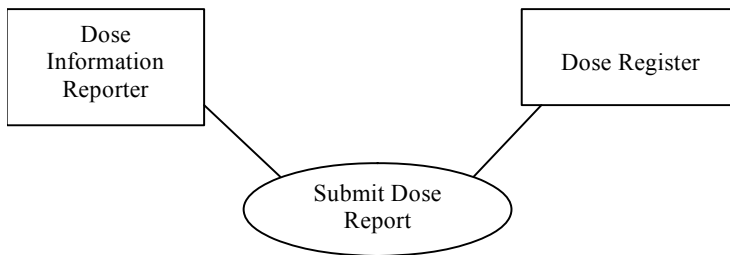
### 4.Y2 Submit Dose Report

770 This section corresponds to Transaction RAD-Y2 of the IHE Technical Framework. Transaction RAD-Y2 is used by the Dose Information Reporter and Dose Register actors.

#### 4.Y2.1 Scope

775 This section describes FTP transfers of DICOM Structured Report objects containing Dose Reports which detail irradiation events. A Dose Information Reporter sends Dose Reports to a Dose Register for subsequent compilation, monitoring and analysis of population radiation exposure and current practices.

#### 4.Y2.2 Use Case Roles



**Actor:** Dose Information Reporter

780 **Role:** Periodically submit (de-identified or pseudonymized) Dose Reports describing irradiation events performed by Acquisition Modalities in its facility.

**Actor:** Dose Register

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

785 **4.Y2.3 Referenced Standard**

DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

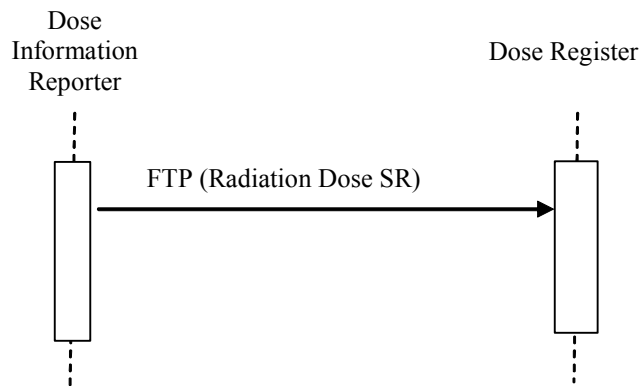
DICOM 2008 PS 3.10: Media Storage and File Format

DICOM 2008 PS 3.16: X-Ray Radiation Dose SR IOD Templates

790 DICOM 2008 PS 3.16: CT Radiation Dose SR IOD Templates

IETF RFC-4217 Securing FTP with TLS

**4.Y2.4 Interaction Diagram**



**4.Y2.4.1 Submit Dose Report**

795 **4.Y2.4.1.1 Trigger Events**

A Dose Information Reporter shall be capable of periodically submitting Dose Reports accumulated since the last submission. The Dose Information Reporter may need to keep track

of which Irradiation Event UIDs have been previously submitted to make sure none are missed or to avoid submitting duplicates.

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

The Dose Information Reporter shall be capable of submitting Dose Reports to multiple configured Dose Registers.

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

810 The Dose Information Reporter shall be capable of queuing Dose Reports when the Registry is unreachable. The Dose Information Reporter shall document in its DICOM Conformance Statement it's method for dealing with failed transfers (e.g. cue for next time, notify operator, etc).

#### **4.Y2.4.1.2 Message Semantics**

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

The Dose Information Reporter shall use (Secure) FTP (File Transfer Protocol) to submit Dose Reports encoded as DICOM SR objects and formatted as DICOM Part 10 media files.

820 The Dose Information Reporter shall send the Dose Reports to the configured destinations, usually a Dose Register, for processing. The Dose Information Reporter shall be capable of sending the Dose Report to multiple destinations.

#### **4.Y2.4.1.2.1 De-identification and Pseudonymization**

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

825 The Dose Information Reporter is not required to be able to pseudonymize Dose Reports (for example, as described in RAD II 4.51.4.1.4.3 and RAD II Appendix R.2).

There is considerable variation in what attributes need to be removed to achieve sufficient de-identification and pseudonymization for any particular purpose. See the discussion in Appendix R.1.

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

The Dose Information Reporter shall provide a mechanism to allow the user to configure those attributes that will be removed or replaced, and at minimum shall support the ability to configure

835 removal and replacement of all those attributes listed in the Basic Application Level Confidentiality Profile in DICOM PS 3.15. This configurability is particularly important since \ details such as patient sex, approximate age and weight, anatomy imaged and type of procedure are typically part of population dose analysis and such analysis would be severely limited without the ability to leave such information in submitted data.

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

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

845 In some scenarios, it may be appropriate to perform no de-identification, such as when the Dose Register is doing a longitudinal study for specific patients (and necessary consent or BAAs have been taken care of). In such cases, if the Patient Identity Removed (0012,0062) attribute is present in the dataset it shall not be changed; if it is absent it shall not be added.

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

850 In some de-identification scenarios, the UIDs need to be replaced. This transaction does not require that UIDs be replaced, but does require that if UIDs are replaced, internal consistency within the exported set of instances be maintained; the implementation shall be configurable to support both. This entails adherence to the following rules:

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

865 If the same instances are exported multiple times on different occasions, the identifying attributes and UIDs therein may or may not be replaced with the same values on each occasion. That is, this transaction does not require deterministic behavior for replacement of identifying attributes and UIDs.

The actions of the de-identification must not create invalid IODs. Specifically:

- Mandatory and conditional attributes may not be removed, but rather must be replaced.

- 870
- Type 1 attributes must be given a value.
  - Type 2 attributes may be encoded zero length, but it is often advisable to encode a value, especially for attributes likely to be used in browsers such as Patient Name, Patient ID, Study ID and Accession Number.

#### 4.Y2.4.1.3 Expected Actions

The Dose Register shall accept the received Dose Report objects.

875

### 4.Y3 Query Dose Reports

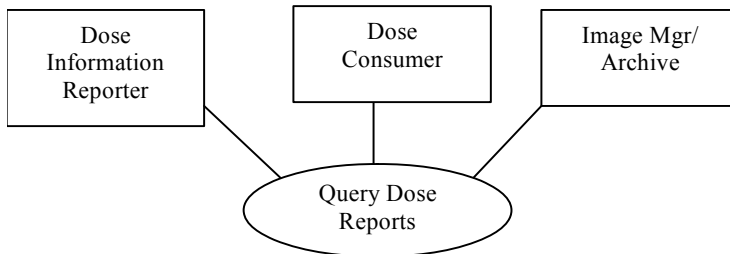
This section corresponds to Transaction Y3 of the IHE Technical Framework. Transaction Y3 is used by the Dose Information Reporter, Dose Consumer and Image Manager/Archive actors.

880

#### 4.Y3.1 Scope

A Dose Information Reporter or Dose Consumer requests and receives from the Image Manager/Archive a list of instances of Dose Reports matching a specified filter.

#### 4.Y3.2 Use Case Roles



885 **Actor:** Dose Information Reporter

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

**Actor:** Dose Consumer

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

**Actor:** Image Manager/Archive

890 **Role:** Respond to queries from Dose Information Reporters and Dose Consumers for Dose Reports matching the specified filter.

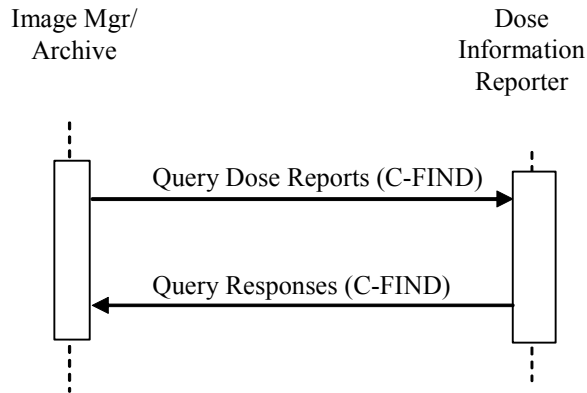
### 4.Y3.3 Referenced Standard

DICOM 2008 PS 3.4: Query/Retrieve Service Class

DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

895 DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

### 4.Y3.4 Interaction Diagram



#### 4.Y3.4.1 Query Dose Reports

900 The Query (Study Root – FIND and optionally Patient Root – FIND) SOP Classes shall be supported. Refer to DICOM 2008 PS 3.4: Query/Retrieve Service Class for detailed descriptive semantics.

##### 4.Y3.4.1.1 Trigger Events

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

905 Often this will be triggered by the Dose Information Reporter preparing to produce reports, perform analyses or submit data to a registry based on local policies. Examples of such triggers might include generating a daily report of procedures exceeding Diagnostic Reference Levels for certain procedure types, producing a summary of dose to a particular patient over the past year, or submitting reports for all procedures performed in the past week to a national registry. Refer to the Use Cases in RAD TF-1: X.3 Radiation Exposure Monitoring Process Flow for more details.

910

The Dose Consumer needs to obtain information about Dose Reports.

Often this will be triggered by the Dose Consumer preparing to display or further process the contents of one or more Dose Reports. Examples of such triggers might include processing the

915 contents of a dose report together with the generated images in order to produce a dose map. Refer to the Use Cases in RAD TF-1: X.3 Radiation Exposure Monitoring Process Flow for more details.

**4.Y3.4.1.2 Message Semantics**

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

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

The Image Manager/Archive, Dose Information Reporter and Dose Consumer actors shall support the SOP Classes shown in Table 4.Y3-1 below.

**Table 4.Y3-1. Dose Report SOP Classes**

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.88.67	X-Ray Radiation Dose SR

925

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

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

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

The Dose Information Reporter (SCU), the Dose Consumer (SCU) and the Image Manager/Archive (SCP) shall also support the Dose Report Instance-specific keys defined in table 4.Y3-2.

940 **Table 4.Y3-2. Dose Report Instance Specific Query Matching and Return Keys**

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
<b>Dose Report Instance Specific Level</b>					
Content Date	(0008,0023)	O	O	O	R+
Content Time	(0008,0033)	O	O	O	R+

		Query Keys Matching		Query Keys Return	
Referenced Request Sequence	(0040,A370)				
>Study Instance UID	(0020,000D)	O	O	R+*	R+
>Accession Number	(0008,0050)	O	O	R+	R+
>Requested Procedure ID	(0040,1000)	O	O	R+	R+
>Requested Procedure Code Sequence	(0032,1064)				
>>Code Value	(0008,0100)	O	O	O	R+
>>Coding Scheme Designator	(0008,0102)	O	O	O	R+
>>Coding Scheme Version	(0008,0103)	O	O	O	R+
>>Code Meaning	(0008,0104)	O	O	O	R+
Content Template Sequence	(0040,A504)				
>Template Identifier	(0040,DB00)	O	O	R+	R+
Concept Name Code Sequence	(0040,A043)				
>Code Value	(0008,0100)	R+	R+	R+*	R+
>Coding Scheme Designator	(0008,0102)	R+	R+	R+*	R+
>Coding Scheme Version	(0008,0103)	O	O	O	R+
>Code Meaning	(0008,0104)	O	O	R+	R+

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

#### 4.Y3.4.1.3 Expected Actions

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

The Dose Information Reporter or Dose Consumer may use the Template Identifier (0040,DB00) to select specific types of Dose Reports for retrieval.

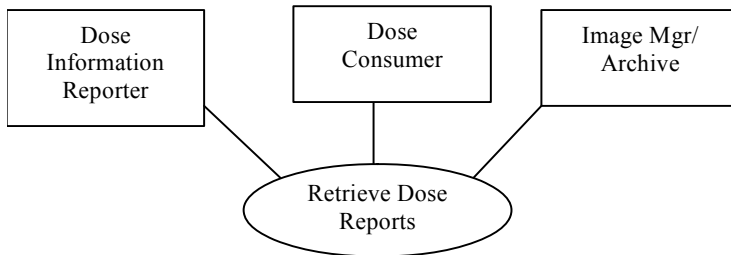
#### 4.Y4 Retrieve Dose Reports

950 This section corresponds to Transaction Y4 of the IHE Technical Framework. Transaction Y4 is used by the Dose Information Reporter, Dose Consumer and Image Manager/Archive actors.

##### 4.Y4.1 Scope

A Dose Information Reporter or Dose Consumer requests and receives from the Image Manager/Archive specified instances of Dose Reports.

#### 4.Y4.2 Use Case Roles



955

**Actor:** Dose Information Reporter

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

**Actor:** Dose Consumer

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

960

**Actor:** Image Manager/Archive

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

#### 4.Y4.3 Referenced Standard

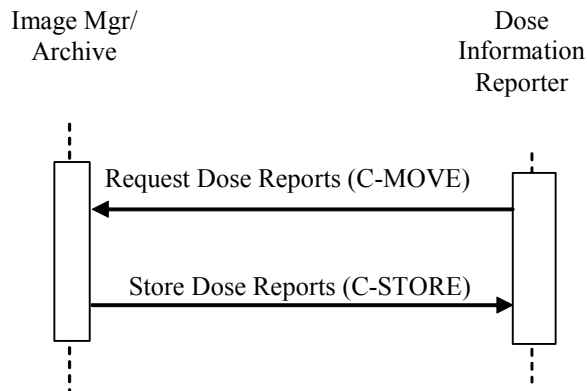
DICOM 2008 PS 3.4: Query/Retrieve Service Class

965

DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD

#### 4.Y4.4 Interaction Diagram



#### 4.Y4.4.1 Retrieve Dose Reports

970 The Retrieve (Study Root – MOVE and optionally Patient Root – MOVE) SOP Classes shall be supported. This requires that C-MOVE also be supported at the Series Level. Refer to the DICOM 2008 PS 3.4 Annex C for detailed descriptive semantics.

The Image Manager/Archive, Dose Information Reporter and Dose Consumer actors shall support the SOP Classes shown in Table 4.Y4-1 below.

975

**Table 4.Y4-1. Dose Report SOP Classes**

SOP Class UID	SOP Class Name
1.2.840.10008.5.1.4.1.1.88.67	X-Ray Radiation Dose SR

##### 4.Y4.4.1.1 Trigger Events

The Dose Information Reporter or Dose Consumer decide they need a specific Dose Report.

##### 4.Y4.4.1.2 Message Semantics

980 The message semantics are defined in the DICOM Query/Retrieve Service Class section of the DICOM 2008 PS 3.4: Query/Retrieve Service Class. The Dose Information Reporter or Dose Consumer is the DICOM Storage SCU and the Image Manager/Archive is the DICOM Storage SCP.

985 Note that the contents of the X-Ray Radiation Dose SR will likely have been based on Baseline Template TID 10001 "Projection X-ray Radiation Dose" or Baseline Template TID 10011 "CT Radiation Dose" but those templates are extensible, and other templates are not prohibited.

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

##### 990 4.Y4.4.1.3 Expected Actions

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

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

When multiple Dose Reports are retrieved, the same Irradiation Event (as identified by it's Irradiation Event UID) may be referenced in multiple Dose Report objects. It is the responsibility of the recipient to look for such duplicate Irradiation Event UIDs and handle them appropriately when processing or generating reports based on the retrieved data.

1000

## 4.8 Modality Images Stored

*Insert the following text:*

### 4.8.4.1.2.4 Recording of Dose Information

1005 Systems also supporting the Radiation Exposure Monitoring Profile as the Acquisition Modality actor shall meet the requirements described in the following text.

This section is referenced in the Creator Images Stored transaction (Section 4.18) so the Evidence Creator actor may also be referred to in the text here.

The Irradiation Event UIDs (0008,3010) directly involved in the creation of the image shall be recorded in the General Image Module of each image created.

1010 Such UIDs may be used to identify images corresponding to irradiation events for purposes such as identifying irradiated tissues and organs for dose mapping or advanced effective dose estimations.

When deriving subsequent images, the contents of Irradiation Event UIDs (0008,3010) shall be copied to the new images.

1015

## 4.18 Creator Images Stored

*Insert the following text:*

### 4.18.4.1.2.5 Recording of Dose Information

1020 Systems also supporting the Radiation Exposure Monitoring Profile as the Acquisition Modality actor shall meet the requirements described in the Modality Images Stored transaction section 4.8.4.1.2.4 Recording of Dose Information.

## 4.10 Storage Commitment

*Replace the existing text in sections 4.10.1, 4.10.2, 4.10.4.1.3 by the following text:*

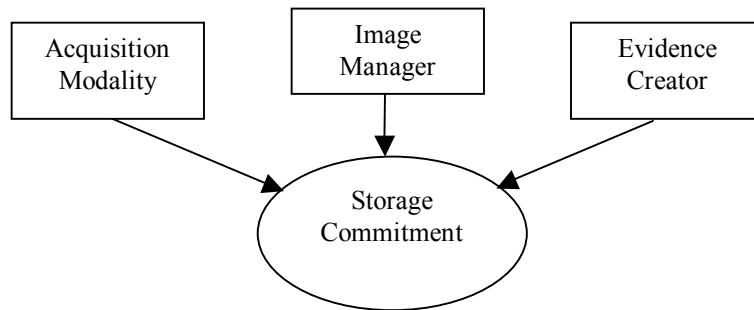
1025

### 4.10.1 Scope

After the Acquisition Modality or Evidence Creator has sent images, Presentation States, Spatial Registration objects, **Dose Reports, Evidence Documents** or Key Image Notes to the Image

1030 Archive, it requests that the Image Manager/Image Archive accept responsibility for them. The objective of this transaction is to provide a formal release of storage responsibility to the Acquisition Modality or Evidence Creator, allowing it to reuse its internal resources allocated to the study.

#### 4.10.2 Use Case Roles



**Actor:** Acquisition Modality

1035 **Role:** Make requests for storage commitment to the Image Manager for the images, Presentation States, Spatial Registration objects, **Dose Reports**, Key Image Notes, and Evidence Documents previously transmitted.

**Actor:** Evidence Creator

1040 **Role:** Make requests for storage commitment to the Image Manager for the images, Presentation States, Spatial Registration objects, **Dose Reports**, Key Image Notes, and Evidence Documents previously transmitted.

**Actor:** Image Manager.

**Role:** Assume responsibility for reliable storage, retrieval, and validity of images, Presentation States, Spatial Registration objects, **Dose Reports**, Key Image Notes, and Evidence Documents.

#### 1045 4.10.4.1.3 Expected Actions

The Image Manager in coordination with the Image Archive accepts responsibility for the safe storage of the transferred **DICOM instances** ~~image data, or Presentation States or Spatial Registration objects~~. (The form of the cooperation is beyond the scope of the IHE Technical Framework.) Ownership of data transfers from the Acquisition Modality to the Image Manager.  
1050 The Acquisition Modality is then free to manage its own internal resources accordingly.

## A.1 Attribute Consistency for Radiation Dose

---

<<Table to be worked on during Public Comment Period>>

Check/Add attributes, make two conditional sections for CT and XR

1055 Group Case: One dose report, multiple values for certain fields? Should we leave some fields empty? If the dose report is in another study, then do the images need to reference the SOP instances of the dose reports? Want to make sure that the system checking for missing dose reports can see that the three ordered accession#s are covered in the one dose report. Maybe some complexity in how it gets mapped to procedures. How should dose be divided if they choose to map parts of the dose to the three composite procedures? (Modality records exactly what it did. If anyone wants to do clever splitting, that's business logic, i.e. for the DIR to do. Keep the record real. Put it in one study, can reference it from each)

1060

Consider anonymization flags/notes in the table as well.

1065

**Table A.1-1: Radiation Exposure - required mapping of corresponding attributes**

DICOM attribute	Modality Worklist	Filling values for:			
	(return attribute values)	Dose Report SR IOD	Image IOD		MPPS IOD
<b>Study Instance UID</b> (0020,000D)	Source	Copy	Copy		Scheduled Step Attributes Sequence (0040,0270)
<b>Referenced Study Sequence</b> (0008,1110)	Source	Copy	Copy		
<b>Accession number</b> (0008,0050)	Source	Copy	Copy See (IHE-A.1.1)		
<b>Requested Procedure ID</b> (0040,1001)	Source	Copy	Request Attributes Sequence (0040,0275)	Copy	
<b>Requested Procedure Description</b> (0032,1060)	Source	Copy		Copy Note: extended attribute	
<b>Scheduled Procedure Step ID</b> (0040,0009)	Source	Copy		Copy	
<b>Scheduled Procedure Step Description</b> (0040,0007)	Source	Source		Copy	
<b>Scheduled Protocol Code Sequence</b> (0040,0008)	Source	Source	Copy	Copy	
<b>Performed Protocol Code Sequence</b> (0040,0260)	n.a.	Equal?	Equal (internally generated). Recommendation: Absent if the value is not known. Is non-em-		Equal (internally generated). Shall be zero length if the value is not known, e.g. Assisted Protocol Setting

DICOM attribute	Modality Worklist	Filling values for:		
	(return attribute values)	Dose Report SR IOD	Image IOD	MPPS IOD
			pty if Assisted Protocol Setting option is supported (see 4.6.4.1.2.4).	not supported.
<b>Study ID</b> (0020,0010)	n.a.	n.a.	Equal (internally generated). Recommendation: use Requested Procedure ID.	Equal (internally generated). Recommendation: use Requested Procedure ID.
<b>Performed Procedure Step ID</b> (0040,0253)	n.a.	n.a.	Equal (internally generated). See (IHE-A.1.2)	Equal (internally generated).
<b>Performed Procedure Step Start Date</b> (0040,0244)	n.a.	n.a.	Equal (internally generated). Recommendation: use the same value for Study Date.	Equal (internally generated).
<b>Performed Procedure Step Start Time</b> (0040,0245)	n.a.	n.a.	Equal (internally generated). Recommendation: use the same value for Study Time.	Equal (internally generated).
<b>Performed Procedure Step Description</b> (0040,0254)	n.a.	n.a.	Equal (internally generated). Recommendation: use the same value for Study Description.	Equal (internally generated).
<b>Requested Procedure Code Sequence</b> (0032,1064)	Value shall be used for Procedure Code Sequence as specified below.	Value shall be used for Procedure Code Sequence as specified below.	n.a.	n.a.
<b>Procedure Code Sequence</b> (0008,1032)	n.a.	n.a.	Copy from: Requested Procedure Code Sequence (0032,1064). Recommendation: absent, if empty in MWL or perfor-med acquisition is different to what was scheduled.	Copy from: Requested Procedure Code Sequence (0032,1064). Recommendation: empty, if empty in MWL or perfor-med acquisition is different to what was scheduled.
<b>Referenced SOP Class UID</b> (0008,1150)	n.a.	n.a.	1.2.840.1008.3.1.2.3.3	Equal (internally generated). See (IHE-A.1.4)

DICOM attribute	Modality Worklist	Filling values for:		
	(return attribute values)	Dose Report SR IOD	Image IOD	MPPS IOD
<b>Referenced SOP Instance UID</b> (0008,1155)	n.a.	n.a.	Equal to SOP Instance of the associated MPPS (IHE-A.1.5).	Equal (internally generated). See (IHE-A.1.5)
<b>Protocol Name</b> (0018,1030)	n.a.	n.a.	Recommendation: equal (internally generated)	Equal (internally generated)

1070

*Add the following rows to the end of the table 5.1-2 in the Radiology Audit Trail Option in Volume 3 of the Radiology Technical Framework:*

<u>IHE Radiology Transaction</u>	<u>ATNA Trigger Event(s)</u>	<u>Actor(s) that shall be able to record audit event</u>
<u>Store Dose Reports [RAD-Y1]</u>	<u>Begin-storing-instances</u>	<u>Sender (Evidence Creator, Acq. Mod) shall audit</u>
	<u>Instances-Stored</u>	<u>Receiver (Image Manager/Archive) shall audit</u>
<u>Submit Dose Reports [RAD-Y2]</u>	<u>Begin-storing-instances</u>	<u>Sender (Dose Information Reporter) shall audit</u>
	<u>Instances-Stored</u>	<u>Receiver (Dose Register) shall audit</u>
<u>Query Dose Reports [X-3]</u>	<u>Query Information</u>	<u>Image Manager/Archive shall audit</u>
<u>Retrieve Dose Reports [X-4]</u>	<u>Instances-Stored</u>	<u>Sender (Image Manager/Archive) shall audit</u>
	<u>Study-used</u>	<u>Receiver (Dose Information Reporter, Dose Information Consumer) shall audit</u>