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IHE Radiology Technical Framework Supplement

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Radiation Exposure Monitoring (REM)

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Trial Implementation

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Foreword

25 This is a supplement to the IHE Radiology Technical Framework V9.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This revised supplement is submitted for Trial Implementation as of November 16, 2010 and will be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the
30 Radiology Technical Framework. Comments are invited and may be submitted on the IHE <http://forums.rsna.org/forumdisplay.php?f=12> or by email to radiology@ihe.net.

This supplement describes changes to the existing technical framework documents and where indicated amends text by addition (**bold underline**) or removal (~~**bold strikethrough**~~), as well as addition of large new sections introduced by editor's instructions to "add new text" or similar,
35 which for readability are not bolded or underlined.

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

<i>Replace Section X.X by the following:</i>
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General information about IHE can be found at: www.ihe.net

Information about the IHE Radiology may be found at: <http://www.ihe.net/Domains/index.cfm>

Information about the structure of IHE Technical Frameworks and Supplements can be found at: <http://www.ihe.net/About/process.cfm> and <http://www.ihe.net/profiles/index.cfm>

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

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1 Introduction

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 Healthcare Information and Management Systems Society (HIMSS) and the Radiological Society of North America (RSNA). IHE Canada is sponsored by the Information Technology Association of Canada (ITAC) and Canada Health Infoway. IHE Europe (IHE-EUR) is supported by a large coalition of organizations including the European Society of Radiology (ESR), the Coordination Committee of the Radiological and Electromedical Industries (COCIR), Deutsche Röntgengesellschaft (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 patient care. It is expanded annually, after a period of public review, and maintained regularly

145 through the identification and correction of errata. The current version for these Technical Frameworks may be found at http://www.ihe.net/Technical_Framework/

150 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.

155 *These "boxed" instructions are used by the author to indicate to the Volume Editor how to integrate the relevant section(s) into the overall Technical Framework*

1.1 Profile Abstract

This profile facilitates the collection and distribution of information about estimated patient radiation exposure resulting from imaging procedures.

160 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 of that trade-off.

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

- 165 • For facilities exposing patients to radiation, monitoring such exposures can help ensure their policies, procedures and protocols are adequate and being followed appropriately.
- For imaging physicians, monitoring such exposures can assist them in determining how changes in techniques and protocols impact radiation dose as well as image quality. This will enable them to maintain patient doses As Low As Reasonably Achievable (ALARA).
- 170 • For patients' physicians, overall data provided from monitoring such exposures can help them determine (in consultation with the imaging physician) if the benefit from the diagnostic information provided by an individual examination (or additional examinations) outweigh any small risk that may be associated with the imaging exam.
- For medical physicists, having such post-procedure information available for individual patients may help them make essential patient-specific dose estimates for pregnant patients or
- 175 patients exhibiting skin erythema as a result of long fluoroscopy examinations.
- For professional societies and regulatory agencies, a collection of exposure data can be useful when setting or reviewing radiation dose related guidelines. 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
- 180 difficult to collect such data.
- 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.

185 However, it is important to understand the technical and practical limitations of such dose monitoring and the reasons why the monitored values may not accurately provide the radiation dose administered to the patient:

- The values provided by this tool are not "measurements" but only calculated estimates.
- For computed tomography, "CTDI" is a dose estimate to a standard plastic phantom. Plastic is not human tissue. Therefore, the dose should not be represented as the dose received by
- 190 the patient.

- For planar or projection imaging, the recorded values may be exposure, skin dose or some other value that may not be patient’s body or organ dose.
- It is inappropriate and inaccurate to add up dose estimates received by different parts of the body into a single cumulative value.

195 Despite such limitations, interest in monitoring radiation dose estimates 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 objects appropriate for radiation dose monitoring.

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

1.2 Open Issues and Questions

1.3 Closed Issues

205 This section lists many of the issues which were discussed and resolved during the development of the profile. Feel free to skip this section unless you are interested in the rationale behind these decisions.

0.1	<p>Should the profile address submission of <u>summarized</u> data to dose 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 dose registries.</i></p> <p>RFD might be one approach, but is not yet mature. For now focus on providing Dose registries with the same kind of DICOM Dose objects 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 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 objects 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</p>

	<p>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 objects. Without them it would be hard to link dose objects 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 objects 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 recommend anonymizing the fields.</p>
2	<p>What is the recommended approach for “legacy” systems?</p> <p><i>Answer: The system must produce a valid Dose SR to qualify as an Acquisition Modality</i></p>

	<p><i>actor. If a 3rd party box produces a valid Dose SR on behalf a modality, both systems must be listed in the Contributing Equipment Sequence.</i></p> <p>A meeting will be scheduled to decide if any of the requirements in the current Templates (particularly the Projection X-Ray Template) should be relaxed. Doing so might make it easier for systems currently reporting dose using MPPS mechanisms to comply.</p> <p>The profile does not require the Dose Information Reporter to be able to process non-standard templates such as those that might be created from skimming dose values from image headers. Neither does the profile require the Dose Information Reporter to make dose estimates based on procedure descriptions.</p>
3	<p>What is the recommended approach for CR & 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</p>

	<p>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 favor of the PACS implementing the Image Manager/Archive is that the dose object would be “part of the study” rather than stored separately. Also, modalities 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 labor between actors is expected to be something like:</p> <p>Image Manager/Archive (usually the PACS):</p> <ul style="list-style-type: none"> - accept Dose objects - manage/store/backup Dose objects - reconcile (PIR) Dose objects (together with Study data) when patient info changes - provide Q/R of Dose objects <p>Dose Information Reporter (Enterprise?)</p> <ul style="list-style-type: none"> - display dose object details - compose daily/weekly/monthly reports (outliers, policy compliance, etc) - submit information to a dose registry (based on hospital obligations/policy) <ul style="list-style-type: none"> - currently sending raw data, someday might be sending summary data - deidentify/pseudonymize data if necessary prior to dose registry submission - populate report exception list (to track down missing dose objects for known procedures performed) - populate dose exception list (to review/alert doses that exceed site policies) <p>Dose Information Consumers (3rd Party Box? Feature of other system?)</p> <ul style="list-style-type: none"> - perform realtime dose mapping - perform realtime alerting
5	<p>How might data from Patient Skin Dosimeters be integrated in the future?</p> <p><i>Answer: DICOM is adding a field to the template to allow a reference to a scanned image of a dosimetry film (placed under the patient) which documents the location/intensity of the</i></p>

	<p><i>radiation applied (for XR). The current profile will remain otherwise silent.</i></p> <p>A current need was not identified for a measurement field in the template and since not currently universal, it would have to be optional, and so could easily be added later.</p> <p>Peak Skin Dose is a useful measurement. If a future need demands it, such information could be added as optional to the current templates, or it could be a new template, or even handled in HL7 if that is appropriate to the systems involved.</p> <p>Four types of patient skin dosimeters were identified:</p> <ol style="list-style-type: none"> 1) dosimetry film – which is preferred for its geometric coverage 2) arrays of point dosimeters – better than one, but still just a sampled coverage 3) realtime electronic point dosimeters – which is usually not at the point of peak dose 4) non-realtime point dosimeters – (badges, etc) ditto <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>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>
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. Appropriate fields will be added to the template by a DICOM CP. 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"> — Might need to add an attribute to the Template to put it in. The X-Ray Dose SR has “Calibration Responsible Party”.

	<ul style="list-style-type: none"> — Requesting Physician (0032,1032) could easily be copied from worklist. This would be an argument for making REM dependant on SWF. — Euratom specifically discusses clinical responsibility in Article 2. — May also want to feedback to the ordering physician so they can factor it into patient management [Steve] <p>Which staff <u>administered</u> (had technical control over) the event?</p> <ul style="list-style-type: none"> — Might need to add an attribute to the Template to put it in — There may be multiple people listed — Consider informative text for who this would be for different types of study (CT – Tech, XA – Radiologist, etc.) — The Dose SR records the “observer” but this is who generated the dose object (which is often the equipment), not who performed the procedure. — The SR Document General Module has Participant Sequence but that is currently Source (equipment), Enterer, or Attestor. — 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. <p>Which staff was <u>potentially exposed</u> by the event?</p> <ul style="list-style-type: none"> — The EURATOM Directive include consideration of exposure of staff. — 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. — 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. — Staff dose is monitored on a different regimen/schedule etc.
7	<p>Does anything specific need to be done for Mammography?</p> <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"> — Average Glandular Dose (dGy) — Entrance Exposure at Reference Point (mGy) — Anatomic Laterality [Optional] — Compression Thickness [Optional] — Half Value Layer (measure of x-ray beam quality) [Optional] — Breast Composition (4 BiRads terms from fat to extremely dense) [Optional] <p>And remove:</p> <ul style="list-style-type: none"> — Dose Area Product <p>Nikos Gkanatsios is considering issues around breast density and CAD and will propose additions to the DICOM Dose CP if necessary.</p> <p>If it is determined that a CAD system should supplement or modify Dose objects provided by the modality, the CAD system could be a Dose Information Consumer to get the modality information, and an Evidence Creator to submit additional Dose object details.</p>
8	<p>What transport protocol should be used to submit reports to the Registry?</p> <p><i>Answer : Secure FTP over TLS should be specified to ensure dose registry projects have an expedient baseline/fallback method. Informative pointers to alternative methods may also be provided.</i></p> <p>Without a baseline, dose registry projects would first have to define a transport, then find a way of implementing/handling it in all the Dose Information Reporting systems. Also, transport is necessary to have a testable transaction.</p> <p>Section X.5 Relation Other Profiles can point out that combining REM with other profiles may offer additional methods. The Dose Registry Deployment Appendix may describe additional deployment options.</p>
9	<p>How do we expect dose guidelines to eventually work in the Profile?</p> <p><i>Answer: Briefly, guidelines might be encoded as SR documents which are retrieved from a Dose registry by the DIR, but nothing is decided now.</i></p> <p>Guidelines will likely take the form of Reference Doses which are values that typical</p>

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 percent of studies currently meet).

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.

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.

Guidelines are provided for specific procedures, usually about 20 procedures, and maybe up to 50 for all modalities.

There has been some attempt to categorize interventional procedures by “complexity” since complex procedures can be expected to have higher doses.

An FDA group has been doing surveys of dose around the US “Nationwide Evaluation of X-Ray Trends” for 30 years.

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.

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.

If formats were available, it seems likely groups setting up Dose 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.

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.

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.

It is conceivable that the IHE Quality Domain may be involved in defining support for guideline formats and transport in the broad sense.

Also, the ITI “Data Re-use Whitepaper” may have some good advice on Guidelines.

	<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"> — 2008 DOSE DATAMED Report 2: GUIDANCE ON ESTIMATING POPULATION DOSES FROM MEDICAL RADIOLOGY (as required by Article 12 of the EC Medical Exposure Directive) — EUREF Tables (similar to MQSA) have additional categorization, such as based on breast density, in the guidelines. [Euref.org] <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>
11	<p>What information about Procedure Type and justification is needed when evaluating a Dose Report?</p> <p><i>Answer: Procedure Type is significant. Clarification of how to support it should be included, recognizing that some normalization/mapping by the DIR will likely be unavoidable. Indication/Reason for the procedure are also theoretically useful. (Modality, Anatomy, Age, and perhaps Weight, are also important evaluation parameters and are discussed in Issue #33.)</i></p> <p>Clarify the appropriate way to use/fill relevant values.</p> <p>No support was expressed for increasing to Type 1 any of the attributes related to the procedure performed, the body part, or the protocol. Neither will a baseline set of codes be required due to the lack of an accepted standard set.</p> <p>For Procedure and Anatomy identification, the DIR will likely need to do a lookup table to map the variety of procedure/anatomy codes to a smaller set for performing analysis and reporting. Since we won’t be able to do anything significant to remove the need for that table, we should avoid procedure coding changes that would add a significant burden on the modality.</p> <p>Clarify that in the:</p> <p style="padding-left: 40px;">Patient Study Module:</p> <ul style="list-style-type: none"> — Admitting Diagnosis Description (0008,1080) & Code Sequence (0008,1084) [both Type 3] is not required, but modalities are asked to copy

	<p>the value, if present, from the Modality Worklist entry.</p> <p>General Study Module:</p> <ul style="list-style-type: none"> — Study Description (0008,1030) [Type 3] (stay silent) — Procedure Code Seq. (Performed?) (0008,1032) [Type 3] <p>SR Document Series Module:</p> <ul style="list-style-type: none"> — Referenced Performed Procedure Step Seq. (0008,1111) [Type 2], if filled, shall list the SOP Class UID and Instance UID of the image acquisition PPS. — Series Description (0008,103E) [Type 3], if present, shall have a value of “Radiation Dose Information”. <p>SR Document General Module:</p> <ul style="list-style-type: none"> — Req. Proc. Description (0032,1060) [Type 2], if filled, shall be copied from the MWL (same as for the images) — Req. Proc. Code Sequence (0032,1064) [Type 2], (contrary to images?, if provided in MWL, shall be copied to the SR.) — Reason for Requested Procedure (0040,1002) & Code Seq.(0040,100A) [both Type 3] if present, shall be copied from the MWL — Performed Procedure Code Seq. (0040,A372) [Type 2], if filled, shall contain the acquisition procedures performed by the modality, not something like “Create Dose Report”. The Dose object is to be considered part of the imaging procedure, not a separate procedure in itself. <p>CT Dose object content tree:</p> <ul style="list-style-type: none"> — Target Region (required) — Acq. Protocol (name) (optional) <p>XR Dose object content tree:</p> <ul style="list-style-type: none"> — Target Region (optional) (CP-874 may make it required) — Anatomical Structure (optional)
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 & 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 monitoring dose 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 Dose Registry could be fed by multiple DIRs (although the monitoring/reporting logic is more likely to be in a DIR than a dose 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 objects be included (seems unlikely).</p>
<p>18</p>	<p>Should we specify any Patient De-identification capabilities at any point in the chain? <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 dose 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 dose registries should generally be anonymized. Dose registries are considered here to be typically population health systems which do not require patient identification. Dose registries are not personal dose records (those should be handled separately if needed, perhaps with an XDS infrastructure).</p> <p>Currently dose 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. Dose registry implementers are not currently interested in 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>
<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? <i>Answer: No.</i></p> <p>Based on feedback from experts, 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>Providing information to the physician post-exposure is fine. Don't see a need for pre-exposure presentation.</p> <p>No need was expressed to make it a requirement of the profile, however nothing prevents Dose Information Reporters from providing such functions in response to customer requests or regulations.</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 Information 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? <i>Answer: No. Leave that to FDA and/or vendors.</i> This is an application feature not an integration issue.</p>
24	<p>Is there anything we can/should do to facilitate Patient Risk estimation? <i>Answer: No. Stay silent.</i></p> <p>It is difficult to derive Patient Risk directly from Dose values. Patient Risk estimation may need organ mapping among other things. For nuclear medicine studies, organ doses vary by factors of 3-5 based on variations in normal and abnormal physiology</p> <p>Conceivably, a Dose Information Consumer could retrieve the dose objects and the images from a study, do the necessary organ segmentation and come up with some estimates if an acceptable algorithm were discovered. There is no current request for a way to store such resulting risk estimates (although a Dose object with a different template might make sense).</p>
25	<p>See Issue #8</p>
26	<p>Do we need a “copy table” like we have for MWL->Image->MPPS? <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> Consider Group case issues and de-identification as well.</p>
27	<p>Are there additional complexities related to Dose Modulation that might need addressing? <i>Answer: None were identified during Public Comment. Proceed.</i></p> <p>Vendors have reviewed the templates and want to get started for now with what we have. If vendors identify concerns, they can be addressed through DICOM CPs. Since this profile references the DICOM templates, any fields added there (which will have to be optional/conditional) will be inherited by the profile.</p>
28	<p>Should we make use of Quality Domain Profiles for registry submission? <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>
29	<p>Should we specify some dose information display requirements? <i>Answer: No. Insufficient interest/input.</i></p> <p>IHE tries to specify the data transfer and leave presentation formats to the marketplace. Good display formats are hard to specify, even as an example, without clear guidance from the physicists.</p> <p>Since SR Renderers can be unfriendly to clinical users, vendors should work with their customers to “figure it out”. For example, multiple radiation events are probably better displayed as a table than as a tree.</p>
30	<p>Are the actor names clear/appropriate? <i>Answer: Decided on Image Manager/Archive, Dose Information Reporter, Dose Registry, Dose Information Consumer</i></p> <p>Grant that it is Estimated Dose and we are measuring Dose Indexes.</p>
31	<p>Should a timeframe for storage of Dose objects be somehow required? <i>Answer: Yes. Must compose/send at the end of each procedure step.</i></p> <p>Procedure steps have reasonably well defined end-points and are a reasonable granularity.</p> <p>Irradiation Events have well defined end-points, but are likely too fine-grained for transmission, and irradiation events are available inside summary objects, so due to insufficient support/definition for “realtime” use cases, composing/sending at the end of irradiation events is permitted, but not required.</p> <p>Studies have poorly defined end-points, and study level data can be composed from procedure step level data anyway, so composing/sending at the end of studies is permitted, but not required.</p>
32	<p>How should Dose objects for Phantoms/Calibration Scans be distinguished from Dose objects for real patients?</p>

	<p><i>Answer: A DICOM CP is in progress which will address this. (Likely by adding an attribute such as Quality Control Image (0028,0300) to the Dose SR IOD.)</i></p> <p>Dose objects for Phantom/Calibration scans are likely useful and should probably exist.</p> <p>Dose objects for Phantoms/Calibrations need to be handled differently by the DIR than those for patients (e.g., don't submit to dose 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 although the operator will know when a scan is a phantom/calibration, the modality may have to depend on being told if it is going to fill an attribute correctly.</p>
33	<p>Are the matching and return keys in the Query transaction sufficient for the use cases?</p> <p><i>Answer: Yes. The key return keys and guidance (see below) should allow the SCU to obtain a manageable list of instances for retrieval.</i></p> <p>Likely use cases will require selecting/sorting dose objects based on Template (for compatibility reasons) and on Irradiating Modality, Procedure Type, Patient Age, Sex, and Weight which seem to have emerged as the key axes of analysis for Dose. Irradiation Date will be a key filter for “batching” QA and submission processes.</p> <p>Some reasonable server side filtering (i.e., matching keys) is desirable for performance reasons. Although the dose objects are not large, 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> <ul style="list-style-type: none"> — SOP Class UID (a required instance level matching & return key on the SCP in the 4-14 table) allows selection of only Dose Objects (indiscriminate of the modality). An IHE CP had been proposed to remove the requirement for this matching key, but that CP was rejected. — Modalities in Study (required study level match & return in 4-14) mostly allows selection of the irradiating modality (some ambiguity if more than one irradiating modality). The series level Modality attribute is always SR for dose reports so the irradiating modality is obscured there. — Study Date (required study level match & return) range matching and Performed Procedure Step Start Date (required series level match & return) range matching support periodic analysis/reporting use cases like QA

	<ul style="list-style-type: none"> — Patient Name/ID/Accession (required study level match & return) support most use cases involving specific patients/incidents. — Making Code Value and Coding Scheme in the Concept Name Code Sequence required matching keys to allow matching against document title (as was done for Key Image Note) was considered unnecessary since we have the Template ID <p>In addition to server-side filtering, some useful return keys can allow the client to further reduce the number of objects which must be transferred.</p> <ul style="list-style-type: none"> — Template ID (required instance level return key here) allows distinguishing CT Dose objects, Projection Dose objects and “other Dose objects” (but doesn’t differentiate between MX, XA, etc) — Patient Birthdate (required study level return key) may be helpful for some dose registry submission or QA reporting tasks that focus on particular age brackets. (Patient Age is only Type 3 and an optional return key) — Patient Sex (required study level return key) may be helpful for some policy monitoring tasks relating to women of childbearing age. — “Procedure Type” is discussed in Issue #11 — Patient Weight is an optional return key in 4-14 (and Type 3 to fill). It is unlikely to be used as a filter, but would likely be used in the future for processing, so modalities will be encouraged, (but not required) to fill it, either from input or MWL — Patient Size (i.e., height) is Type 3 to fill and an optional return key in 4-14 <p>Ultimately, some client-side object content processing is also likely and unavoidable.</p> <ul style="list-style-type: none"> — The (soon to be added) Quality Control Flag is certainly not supported by PACS queries today so the SCU will have to do content filtering after retrieval. — Staff Shift can be derived from the datetime of the irradiation — Room/Location is probably most reliably obtained for report grouping purposes by using a lookup table from the machine identification (which is required information). <p>Some analysis use cases will likely want to sort/compile dose based on room (Location), Screening vs. Diagnostic, Unilateral vs. Bilateral, but hopefully will want to retrieve all dose objects and sort based on that information, rather than trying to retrieve screening only, bilateral only, etc. which is not currently supported.</p>
34	Do we need normative or informative text relating to verification of displayed dose?

	<p><i>Answer: No.</i></p> <p>Regulations may place such requirements on modalities. That is a product internal feature and out of scope of this profile.</p>
35	<p>How do we make sure the DIR is a “real application” not just supporting the interface?</p> <p><i>Answer: Can’t really. Include a basic requirement for some reporting.</i></p> <p>The DIR is expected to perform analysis and reporting that is useful to the user. The profile facilitates the DIR getting access to the raw data, but does not presume to mandate “the best way to analyze the data”. Analysis features and report formats are product features left to the vendor and user to work out.</p> <p>Profile will include a broad statement that the DIR must be capable of presenting some form of report to the user based on the received dose information.</p>
36	<p>What should the required “Granularity” of dose objects be?</p> <p><i>Answer: Procedure Step (see Issue #31).</i></p> <p>A Dose object should be composed and sent prior to MPPS Completed/Discontinued.</p>

GLOSSARY

210 Add the following to section Glossary:

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

215 events. See RAD TF-3: 4.62.4.1.1 in Store Dose Information for a more detailed description.

Dose Object: A persistent DICOM object (See DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD) for recording details related to Irradiation Events. DICOM has defined Dose Objects for CT and Projection X-ray procedures.

220 **Dose Registry:** A system that collects dose information from multiple sites, generally to perform analysis of Population Dose and Dose Indicators.

Acronyms and Abbreviations

ACR: American College of Radiology

DAP: Dose Area Product

DLP: Dose Length Product

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

ICRU: International Commission on Radiological Units

IEC: International Electrotechnical Commission

PHI: Protected Healthcare Information

PSD: Peak Skin Dose

230 **QA:** Quality Assurance

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

235 [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.

240 [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.

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

245

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

Volume 1 – Integration Profiles

1.7 History of Annual Changes

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

- 250
- Added the REM Profile which defines how DICOM SR objects for CT and projection X-ray dose objects are created, stored, queried, retrieved, and may be processed and displayed.

2 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>	=

255

Add REM to the Profile Diagram Fig 2-1 as a new box in the “content row”, colored similarly to the other SR-based profiles

Add the following section to the end of 2.1

260 2.1.22 Radiation Exposure Monitoring (REM)

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
 265 DICOM SR objects for CT and projection X-ray dose objects are created, stored, queried, retrieved, de-identified, and may be processed and displayed.

Change the Actor Descriptions in 2.3 as follows:

- 270 **Acquisition Modality** - <Creates and stores Dose SR. No change proposed to existing Actor Description >
- 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.
- 275 **Dose Information Reporter** – Responsible for the aggregation, analysis, reporting and business logic related to irradiation events, which may include meeting facility obligations to de-identify and submit data to various dose registries.
- Dose Registry** – Collates information about irradiation events from a number of facilities, generally to perform analysis.

280

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 Registry and Dose Information Consumer.***

285

Change or add the following transaction descriptions in 2.4:

10. Storage Commitment – Request and receive from an actor 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.

290

~~**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.**~~

295

62. Store Dose Information – Send details of Irradiation Events encoded in DICOM SR using DICOM Store.

63. Submit Dose Information – Send details of Irradiation Events encoded in DICOM SR using secure FTP.

300

64. Query Dose Information – Obtain a list of references to Dose objects matching a given filter.

65. Retrieve Dose Information – Obtain specific Dose objects containing descriptions of Irradiation Events.

305

In Table 2.4-1:

*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 Information [RAD 62], Submit Dose Information [RAD 63], Query Dose Information [RAD 64], Retrieve Dose Information [Rad 65].***

310

Add the following section:

22 Radiation Exposure Monitoring (REM) Integration Profile

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

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

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

The Profile addresses dose reporting for imaging procedures performed on CT and projection X-ray systems, including mammography. It does not currently address procedures such as nuclear medicine (PET or SPECT), radiotherapy, or implanted seeds.

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

Background

335 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 of that trade-off.

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

- 340
- For facilities exposing patients to radiation, monitoring such exposures can help ensure their policies, procedures and protocols are adequate and being followed appropriately.
 - For imaging physicians, monitoring such exposures can assist them in determining how changes in techniques and protocols impact radiation dose as well as image quality. This will enable them to maintain patient doses As Low As Reasonably Achievable (ALARA).
- 345
- For patients' physicians, overall data provided from monitoring such exposures can help them determine (in consultation with the imaging physician) if the benefit from the diagnostic information provided by an individual examination (or additional examinations) outweigh any small risk that may be associated with the imaging exam.

- 350 • For medical physicists, having such post-procedure information available for individual patients may help them make essential patient-specific dose estimates for pregnant patients or patients exhibiting skin erythema as a result of long fluoroscopy examinations.
- 355 • For professional societies and regulatory agencies, a collection of exposure 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.
- 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.

360 However, it is important to understand the technical and practical limitations of such dose monitoring and the reasons why the monitored values may not accurately provide the radiation dose administered to the patient:

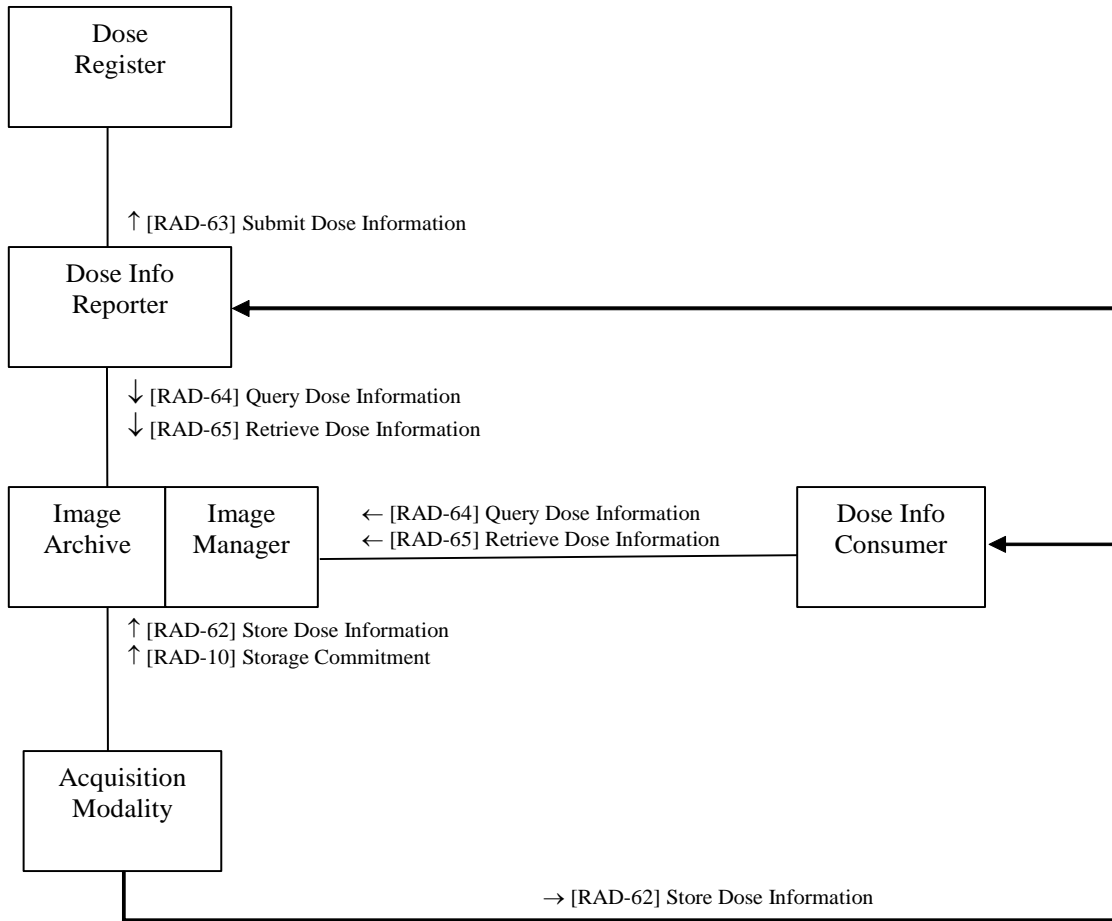
- The values provided by this tool are not “measurements” but only calculated estimates.
- 365 • For computed tomography, “CTDI” is a dose estimate to a standard plastic phantom. Plastic is not human tissue. Therefore, CTDI should not be represented as the dose received by the patient.
- For planar or projection imaging, the recorded values may be exposure, skin dose or some other value that may not be patient’s body or organ dose.
- 370 • It is inappropriate and inaccurate to add up dose estimates received by different parts of the body into a single cumulative value.

Despite such limitations, interest in monitoring radiation dose estimates is clearly expressed in such documents as the European directive Euratom 97/43 and the American College of Radiology Dose Whitepaper [1]. DICOM, with advice from the IEC, AAPM, ACR, NCRP and others, developed DICOM Dose objects appropriate for radiation dose monitoring

375 By profiling automated methods of distribution, dose information can be collected and evaluated without imposing a significant administrative burden on staff otherwise occupied with caring for patients.

22.1 Actors/ Transactions

380 Figure 22.1-1 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.



385

Figure 22.1-1 Radiation Exposure Monitoring - Actor Diagram

390 Table 22.1-1 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 RAD TF-1:22.2.

Table 22.1-1 Radiation Exposure Monitoring – Actors and Transactions

Actors	Transactions	Optionality	Section in Volume 2/3
Acquisition Modality	Store Dose Information	R	4.62
	Storage Commitment	R	4.10

Actors	Transactions	Optionality	Section in Volume 2/3
Image Manager/Archive	Store Dose Information	R	4.62
	Storage Commitment	R	4.10
	Query Dose Information	R	4.64
	Retrieve Dose Information	R	4.65
Dose Information Reporter	Query Dose Information	R	4.64
	Retrieve Dose Information	R	4.65
	Submit Dose Information	R	4.63
	Store Dose Information	R	4.62
Dose Information Consumer	Query Dose Information	R	4.64
	Retrieve Dose Information	R	4.65
	Store Dose Information	R	4.62
Dose Registry	Submit Dose Information	R	4.63

395 An Acquisition Modality actor in this profile might not necessarily generate the irradiation itself. An Acquisition Modality actor may generate Dose objects on behalf of an irradiating modality system based on irradiation details obtained by manual input and/or some proprietary method, as long as it can do so completely and correctly.

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

22.2 Radiation Exposure Monitoring Integration Profile Options

405 Options that may be selected for this Integration Profile are listed in the table 22.2-1 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.

Table 22.2-1 Radiation Exposure Monitoring – Actors and Options

Actor	Options	Vol .Section
Acquisition Modality	<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 Registry	<i>No options defined</i>	--

410 **22.3 Radiation Exposure Monitoring Process Flow**

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 estimated dose a patient (or particular organs) received for a certain exam
- determine if the estimated dose for a given procedure, system or physician regularly exceeds some reference level, policy trigger or is otherwise an "outlier" requiring further 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 or indication
- compare exam-specific "dose summaries" against other sites/regions, against local policy targets or against standards of practice

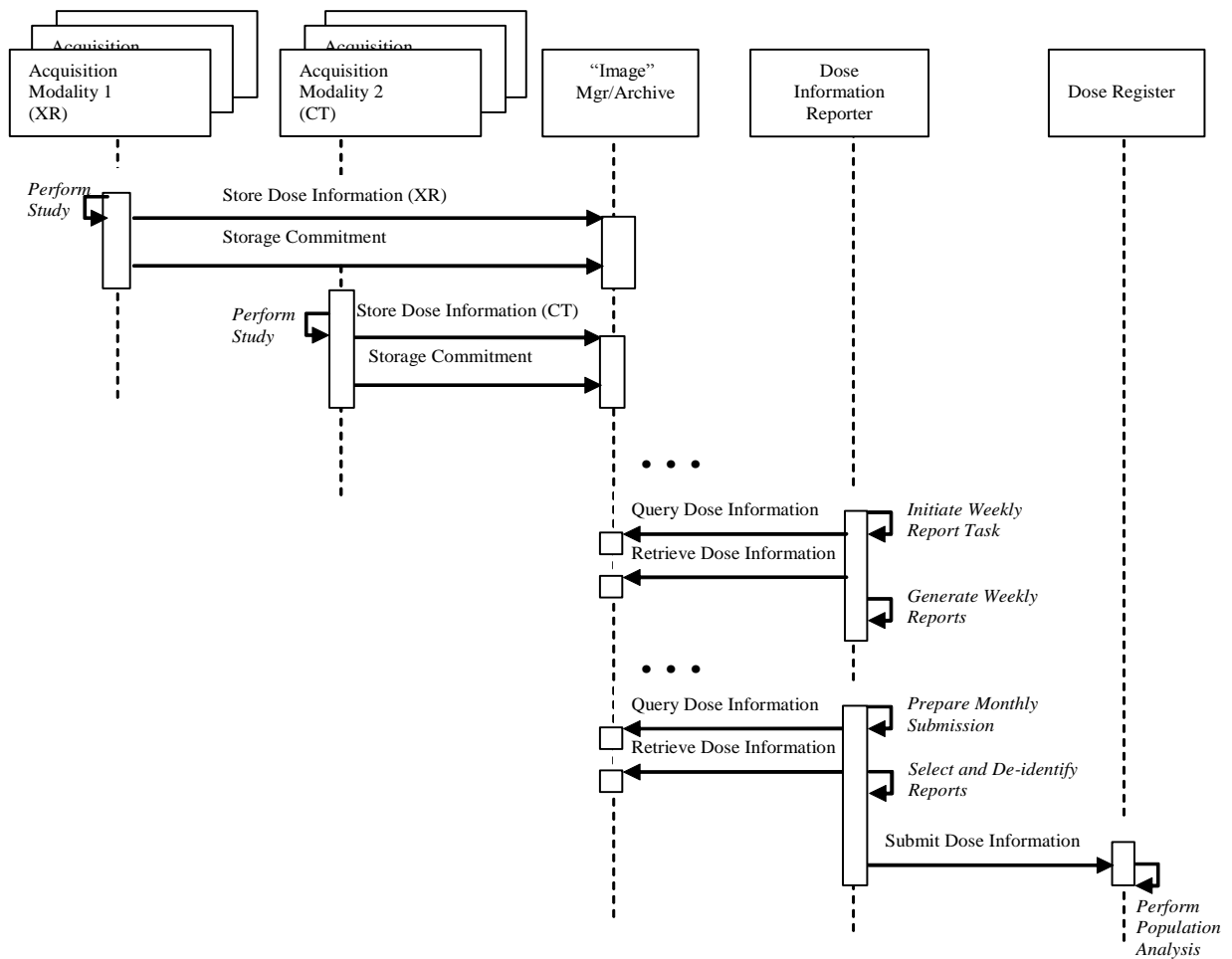
420 Note: To summarize dose for a specific exam type or pathology, the Dose Information Reporter needs to know such details for each dose object. IHE has required that such information be provided in the dose objects as coded values so they will be machine readable. If consistent codes are present in the dose objects, they can simply be sorted or mapped by a lookup table (See RAD TF-1 Appendix I.1.1 Code Set Management). Alternatively a Dose Information Reporter might be grouped with a DSS/Order Filler so such details could be obtained for each
425 Accession #. In either case, a critical task for sites wishing to do such analysis is to choose a set of codes for exam types and pathologies and to distribute and use them consistently across their systems.

22.3.1 General Case

Typically, irradiation events occur on X-ray based imaging modalities, which record them in Dose objects that are part of the same study as the images and stored to the Image
430 Manager/Archive.

In many organizations, a Dose Information Reporter will collect Dose objects covering a particular period (e.g., today, this week or last month), analyze them, compare to site policy and generate summary reports.

435 All, or a sampled subset of the Dose objects might be submitted to a National Registry to facilitate composing population statistics and other research. Such Dose objects will generally undergo a configurable de-identification process prior to submission.



440

Figure 22.3-1 Radiation Exposure Monitoring – General Case

22.3.2 Real-World Use Cases

To provide additional context for the General Case process flow, the following use cases describe real-world applications of the dose information.

Use Case: Department QA (Process Control)

445

Data will generally be continuously collected and evaluated on all procedures. Process control and data analysis would focus on local variations attributable to x-ray equipment, operators, procedures and ordering physicians. For example:

450

As part of the departmental quality improvement program, the hospital’s medical physicist accesses the Dose Information Reporter to carry out his bi-monthly assessment of radiation dose. For a selected set of procedures, the dose-area product of each x-ray 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.

455 It becomes clear that for a certain interventional 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 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 the acquisition
460 sub-total. The number of acquired images (higher than the departmental average) also corroborates this.

The medical physicist 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
465 radiologists agree that the acquisition, although moderately useful, probably does not bring any information that would not be picked up in the rest of the exam, and it is agreed it should not be done. The medical physicist reviews the situation a month later, and is reassured that the results show all radiologists now have similar dose-area product for that procedure.

Hospitals generally have policies relating to patient radiation dose, often benchmarking
470 performance estimates 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 sites monitor whether policies are being followed, and measure progress toward improvement targets. While image quality generally sets the low side limit on dose (too low and the images are unacceptable to the radiologists), QA programs can be an effective way
475 to counter dose creep, establish upper trigger levels and encourage lower values.

Use Case: Patient Impact Evaluation

A few days after a CT exam is carried out for a young female patient, the referring physician identifies the patient as pregnant (which was not known at the time of the scan). The referring physician requests an evaluation of the risk to the fetus from the radiologist who read the exam.
480 The radiologist requests a hospital medical physicist to provide an estimate of the radiation dose received by the uterus in the course of the CT exam.

The medical physicist retrieves the images and dose data for 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
485 of the patient contained in the dose and image objects to estimate the total dose to the uterus.

How the information is recorded and distributed will vary, but in this particular hospital, the dose estimate is then provided to the clinical coordinator of the department, who enters it in the RIS, appending a statement to the report (which had already been signed off), and demoting the status of the study to "pending signature". Before signing off the report, the radiologist completes the
490 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 later.

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

Use Case: Population Dose and Dose Indicators

495 Organizations wishing to assess Population Dose and Dose Indicators will often set up a Dose Registry. A sampling of dose estimates with reasonable accuracy are collected from a number of clinical sites, often for specific targeted procedures. It is not necessary that every procedure performed be collected; a representative sample of procedures is sufficient. That being said, it may be easier for a dose registry to discard a portion of the procedures submitted than to try and
500 get each submitting site to follow the same regimen for selecting procedures to submit.

Note that conversion of estimated dose values to patient or population risk involves complex scientific questions. Streamlining the collection of additional, more detailed data can only help.

For further discussion, See RAD TF-1: Appendix I – Deployment of Dose Registries.

Use Case: Dose Reference Levels

505 Quantitative Dose Guidelines are often distributed in the form of Dose Reference Levels for typical procedures for groups of patients of different characteristics (e.g., a target dose level to stay below for adult head studies).

Such guidelines are often the logical result of analyzing Population Dose or other data mining performed by a professional society or regulatory body.

510 **Use Case: Site Benchmarking**

Imaging facilities may find it useful to compare their dose profile by modality, exam type, and pathology to other facilities of the same type, facilities in the same region, and to the nation as a whole. A national radiation dose registry might provide facilities submitting data with reports comparing them to regional and national benchmarks.

515 **Use Case: Population Epidemiology**

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
520 archived in a manner that makes it both physically readable and dosimetrically intelligible years, or decades, after it is written.

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 benefit from being able to collect dose
525 data to balance against the resulting detection rates for a proper trade-off analysis. Co-submission of image and Dose objects could facilitate this.

Use Case: Procedure Operational Awareness (Quasi-realtime)

530 Some regulations already require that $K_{a,r}$ be displayed on fluoroscopy systems 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 (keeping in mind that $K_{a,r}$ is not the same as cumulative skin dose). Such direct display can be handled by the modality and has no need of the transactions provided by this profile

Use Case: Clinical Management

535 Dose estimates and dose estimate maps can facilitate planning for 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 patients' medical record.

Use Case: Longitudinal Patient Dose Record

540 The lifetime radiation dose received by a patient can be stored and retrieved from a longitudinal record, whether it is stored as part of the entire patient history, or as a separate entity. This may in future form a vital source of information for clinical decision-making with respect to the appropriateness and risk of an additional procedure, as well as remediation in the event of an unfortunate outcome. As methods evolve for estimating effective dose to radio-sensitive tissues and quantifying cancer risk, these can be retrospectively applied to stored dose information. This
545 use case is distinct from registry use cases, since the goal is to track the individual, rather than population, dose. It is distinct from the Clinical Management use case, since it spans a longer term, multiple episodes of care and multiple sites.

550 This use case necessarily requires support of acquisition and collation of dose information from multiple acquisition sites, since a patient may be provided healthcare at many sites over their entire life time.

22.3.3 Example REM Profile Deployments

555 These examples are intended to illustrate a few ways the Radiation Exposure Monitoring Profile might be deployed inside a hospital or clinic. It is not intended to be normative, or to show all possible deployments. Further practical examples related to the use of a Registry appear in Appendix I.

22.3.3.1 A Hospital Scenario

The Radiology PACS would perhaps implement the Image Manager/Archive actor in this profile and also the PIR, SWF profiles.

560 The RIS might implement the Dose Information Reporter actor in this profile and be grouped with a DSS/Order Filler supporting the SWF and PIR profiles.

A Dose Mapping Workstation might implement both the Dose Information Consumer (to obtain Dose objects) and the Evidence Creator (to submit new ones).

Perhaps Cardiology has a separate PACS which also implements an Image Manager/Archive for the cardiology modalities. The Dose Information Reporter (in the Radiology RIS) could query
565 both Archives and manage dose for the hospital in one place.

22.3.3.2 An Imaging Clinic Scenario

Many imaging clinics will have a PACS and could follow a similar layout to the Hospital above.

Alternatively, a PACS-less clinic which decides they do not need long term archiving or reconciliation of the Dose objects might not have an Image Manager/Archive.

570 The Office Management System or a standalone workstation could implement the Dose Information Reporter, and takes advantage of its ability to receive Dose objects directly from the local modalities.

22.3.3.3 A Longitudinal Patient Record Scenario

575 Multiple sites, including hospitals and imaging clinics, implement Acquisition Modalities and/or Image Manager/Archives that provide information in response to queries from a local Dose Information Reporter.

580 The local Dose Information Reporter transmits identifiable (as opposed to de-identified) dose information to a remote Dose Register nominated by the patient to act as their lifetime repository of longitudinal dose information. Each local site may use different forms of the patient's name and different domains for patient identifier, and accordingly the Dose Information Reporter should include multiple identifiers for different domains, and/or regional or national identifiers, if known, and the Dose Register may need to be grouped with a PIX Manager or similar mechanism to resolve identities. See also the issues raised in the Multiple Image Manager/Archive (MIMA) profile.

585 If the remote Dose Register is grouped with its own Dose Information Reporter actor, then given the appropriate authorization by the patient, another local site with a Dose Consumer actor may access the information to make clinical decisions.

590 Additionally, if remote Dose Register and/or Dose Information Reporter is also capable of modeling effective dose using organ segmentation information, it may want to receive and store the images reconstructed from the irradiation events described in the dose objects, and hence to be grouped with a remote Image Manager/Archive actor.

22.4 Radiation Exposure Monitoring Profile Security Considerations

Dose Objects have the same security considerations as images.

595 Security and Privacy policies may require the de-identification of some or all of the PHI details prior to the submission or use of Dose Objects (See RAD TF-3: 4.63.4.1.2.1). De-identification behavior may need to vary by destination due to differences in PHI exposure risk and the need to

retain some details, such as approximate patient age or weight, when performing Radiation Dose analysis.

22.5 Relation to Other Profiles

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

22.5.1 Radiology Profiles

22.5.1.1 Portable Data for Imaging (PDI)

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

22.5.1.2 Patient Identification Reconciliation (PIR)

610 An Image Manager/Archive which also implements the Patient Identification Reconciliation Profile is expected to reconcile the Dose objects along with the rest of the DICOM objects in a patients’ study. This is highly desirable.

22.5.1.3 Teaching Files and Clinical Trials Export (TCE)

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

22.5.2 ITI Profiles

22.5.2.1 Patient Identity Cross-referencing (PIX)

620 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.

22.5.2.2 Cross-Enterprise Document Sharing (XD*)

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

22.5.2.3 Consistent Time (CT)

625 Consistent Time is particularly useful if a gantry and reader are trying to compose a Dose object by synchronizing study details based on timestamps.

22.5.2.4 Audit Trail and Node Authentication (ATNA)

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

630

Volume 3 - Transactions

Add sections 4.62, 4.63, 4.64, 4.65

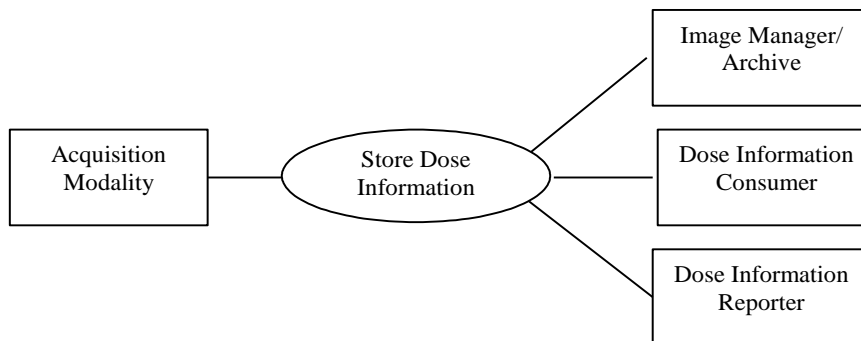
4.62 Store Dose Information

This section corresponds to Transaction RAD-62 of the IHE Technical Framework. Transaction RAD-62 is used by the Acquisition Modality, Image Manager/Archive, Dose Information Reporter and Dose Information Consumer actors.

4.62.1 Scope

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

4.62.2 Use Case Roles



Actor: Acquisition Modality

Role: Generate Dose objects describing irradiation events performed by the Acquisition Modality and store them to one or more receiving actors.

Actor: Image Manager/Archive

Role: Accept and Store Dose objects received from the Acquisition Modality.

Actor: Dose Information Consumer

Role: Accept and process Dose objects received from the Acquisition Modality.

Actor: Dose Information Reporter

Role: Accept and process Dose objects received from the Acquisition Modality.

4.62.3 Referenced Standard

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

DICOM 2008 PS 3.4: Storage Service Class

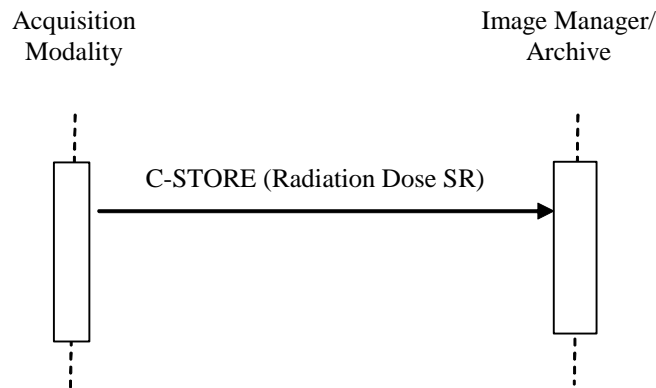
655 DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

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

DICOM 2008 PS 3.16: CT Radiation Dose SR IOD Templates

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

4.62.4 Interaction Diagram



660

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

4.62.4.1 Store Dose Information

665 The Acquisition Modality actor shall implement the X-ray Radiation Dose SR Storage SOP Class in the role of SCU. The Image Manager/Archive actor, Dose Information Reporter actor and Dose Information Consumer actor shall implement the Dose Storage SOP Class in the role of SCP.

Table 4.62-1 Dose 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

670 **4.62.4.1.1 Trigger Events**

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 DICOM 2008 PS 3.16.

675 An Acquisition Modality shall record the relevant details for each irradiation event. These details will be included in Dose objects as described below.

Upon completion or discontinuation of a procedure step where irradiation events occurred, the Acquisition Modality shall compose an appropriate Dose Object containing all the irradiation events for the procedure step and send the Dose object to the configured destinations.

680 **Note:** The Dose Object is a DICOM Instance created in the context of the procedure step, and thus is expected to appear in the list of instances in the corresponding MPPS.

685 In addition to composing Dose objects upon completion or discontinuation of a procedure step, the Acquisition Modality may also compose and send a Dose object upon completion of an irradiation event. If such behavior is supported, the actor shall provide a configuration method to disable it. Such objects could enable applications like dose mapping by a workstation during a procedure. The irradiation events will duplicate events reported in the Dose object for the procedure step, but this can be detected by receiving systems since the same irradiation event UID will appear in both Dose objects.

690 In addition to composing Dose objects upon completion or discontinuation of a procedure step, the Acquisition Modality may also compose and send a Dose Object summarizing an entire study or series. Such objects might be preferred by systems wanting a summary of several procedure steps. If such behavior is supported, the actor shall provide a configuration method to disable it. The irradiation events will duplicate events reported in the Dose object for the procedure step, but this can be detected by receiving systems since the same irradiation event UID will appear in both Dose objects. If the Acquisition Modality does compose such additional Dose objects, it is
695 appropriate to record the prior reports in the Predecessor Documents Sequence (0040,A360).

The Acquisition Modality shall clearly document in its DICOM Conformance Statement its capabilities for grouping irradiation events into Dose objects.

4.62.4.1.1.1 Digitization

700 In the case of a system digitizing a film produced locally for which a Dose object has not been generated, it would be appropriate to create and store a Dose object 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 information in the generated images and/or the MPPS from the film-based modality.

705 Digitizing films for external priors shall be handled differently. The location where the prior was originally created is responsible for recording the original dose. The digitizing system shall be configurable/controllable to digitize external films and not produce a Dose object.

4.62.4.1.2 Message Semantics

710 The Acquisition Modality actor shall use the DICOM C-STORE message to send Dose objects encoded as DICOM SR objects. These objects serve as a record of irradiation performed by the device.

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

The Acquisition Modality is responsible for delivery of Dose objects to the destination in spite of intermittent connections (e.g., due to mobile modalities, network trouble, or the destination being down).

720 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.

725 **Note:** TID 10011, TID 10001 and their sub-templates are under review in DICOM. A notification of the result of that review and the affect on the 2009 Connectathon will be put on the Radiology Technical Framework page on www.ihe.net. If any aspects of this are still unresolved when this profile goes to Final Text, a note will be added in RAD TF-1: Appendix B.2 DICOM Topics.

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

730 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.

The Irradiation Event UID in the template allows receiving systems to recognize duplicate events. For example, the same dose event might appear in both an SR summarizing a procedure and an SR summarizing the whole study.

735 The following attributes are Type 2 and Type 3. Although not required, Acquisition Modalities which do not fill them in will make their Dose objects more difficult to process and analyze. If present with a value in the Dose object, these attributes shall be populated as described in Table 4.62-2:

Table 4.62-2 Dose Context Attributes

Attribute Name	Tag	Requirement
Series Description	(0008,103E)	Shall have a value in the appropriate language for local use that means the equivalent of "Radiation Dose Information", or similar.
Referenced Performed Procedure Step Sequence	(0008,1111)	Shall list the SOP Class UID and Instance UID of the image acquisition PPS. Typically, only a single PPS is associated with a Dose object. Since DICOM only permits a single value in this sequence, in the case where a Dose object summarizes several PPS (e.g., of a whole multi-step study), this attribute shall be left empty.

Attribute Name	Tag	Requirement
Performed Procedure Code Sequence	(0040,A372)	Shall contain the codes for the acquisition procedures performed by the modality (i.e., not a code for “Create Dose Report”). Creation of the Dose object is to be considered part of the imaging procedure, not a separate procedure in itself.
Requested Procedure Description	(0032,1060)	Shall be copied from the relevant acquisition SPS (Modality Worklist entry)
Admitting Diagnoses Description	(0008,1080)	Shall be copied from the relevant acquisition SPS (Modality Worklist entry). This can facilitate checking compliance to indication-based dose policies.
Admitting Diagnoses Code Sequence	(0008,1084)	
Reason for the Requested Procedure	(0040,1002)	
Reason for Requested Procedure Code Sequence	(0040,100A)	
Patient’s Weight	(0010,1030)	Shall be copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry and may be approximate. This may facilitate future dose estimation and analysis.
Patient’s Size	(0010,1020)	I.e., height. Shall be copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry, and may be approximate. This may facilitate future dose estimation and analysis.
Patient’s Age	(0010,1010)	Shall be filled from any valid source (e.g., computed from Patient’s Birthdate and Study Date, copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry) and may be approximate. This may facilitate future dose estimation and analysis.
Patient’s Sex	(0010,0040)	Shall be copied from the relevant acquisition SPS (Modality Worklist entry), if present, else obtained by operator entry.

740 In the event of a Group Case acquisition (see RAD TF-2: 4.6.4.1.2.3) a Dose object shall be generated, reflecting the single acquisition procedure step performed, and should take its attribute values from that image set. The procedure type would reflect the combined acquisition. Allocating subsets of the dose to the pseudo-sub-procedures of the group is not required. If the modality chooses to replicate the dose object under each component accession of the group case it shall set the Identical Documents Sequence appropriately. In either case the DIR can recognize the duplication based on the Irradiation Event UIDs.

745

If the Dose object is not being created by the equipment which actually administered the radiation, the equipment creating the report shall reference itself in the Contributing Equipment Sequence (0018,A001) and reference the irradiating equipment in the four Type 1 attributes in the Enhanced General Equipment Module (DICOM 2008 PS 3.3: C.7.5.3).

750

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

4.62.4.1.2.1 Cross-referencing Dose Objects and Image Objects

755 See RAD TF-2: 4.8.4.1.2.4, which requires Acquisition Modalities to record the Irradiation Event UID (0008,3010) in related image instances.

The Projection X-Ray Dose Template (TID 10003) mandates that UID references be recorded in the Acquired Image element for image instances created from the irradiation event. The CT Dose Template does not include references to images since the instances sent to the Image Manager/Archive are typically generated some time after the irradiation is complete.

760 Note that it is possible for a study to have dose objects but no image objects. For example, due to poor quality images not being stored, or fluoroscopy images not being captured.

4.62.4.1.3 Expected Actions

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

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

Dose Information Reporter actors shall be capable of processing both TID 10001 and TID 10011.

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

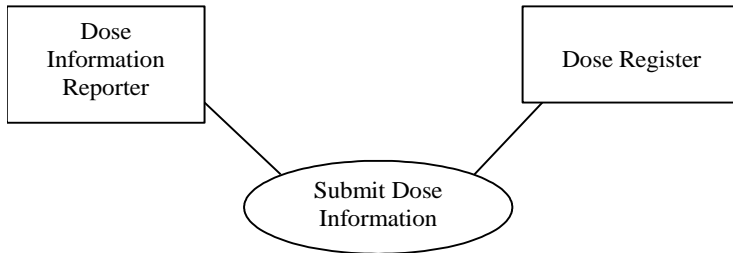
4.63 Submit Dose Information

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

780 4.63.1 Scope

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

4.63.2 Use Case Roles



Actor: Dose Information Reporter

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

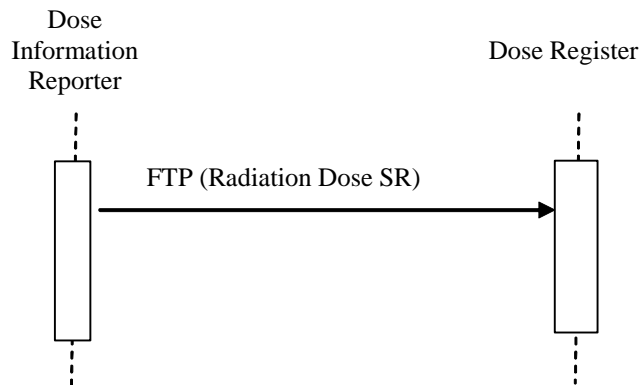
Actor: Dose Registry

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

4.63.3 Referenced Standard

- DICOM 2008 PS 3.3: A.35.8 X-Ray Radiation Dose SR IOD
- 795 DICOM 2008 PS 3.10: Media Storage and File Format
- DICOM 2008 PS 3.16: X-Ray Radiation Dose SR IOD Templates
- DICOM 2008 PS 3.16: CT Radiation Dose SR IOD Templates
- IETF RFC-4217 Securing FTP with TLS

4.63.4 Interaction Diagram



800

4.63.4.1 Submit Dose Information

4.63.4.1.1 Trigger Events

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

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

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

810 4.63.4.1.2 Message Semantics

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

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

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

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

825 When initiating the FTP session, the Dose Information Reporter:

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

835 7. Shall disconnect when TLS fails.

Note: Certificate Management by the Dose Information Reporter and the Dose Registry is outside the scope of this Profile. Dose Registries may find it convenient to make their public certificate available on their web server. Hospitals with Dose Information Reporters might have their public certificate available in a file they could email to the Dose Registry administrator when joining such a project. A detailed discussion of certificate management can be found in the “Management of Machine Authentication Certificates” Whitepaper developed by the NEMA Security and Privacy Committee, available on the NEMA Website at:
840 <http://www.medicalimaging.org/policy/security.cfm>

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

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

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

The Dose objects may be transferred as either:

- individual files, or
- composed into Zip File Media as described in DICOM 2008 PS 3.12 Annex V.

DICOM Zip File Media requires a valid DICOMDIR be present.

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

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

4.63.4.1.2.1 De-identification

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

There is considerable variation in what attributes need to be removed to achieve sufficient de-identification for any particular purpose. See the discussion in RAD TF-2: Appendix R.1 [TCE Supplement Document] and DICOM Supplement 142.

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

870 The Dose Information Reporter may provide a mechanism to allow the user to configure those attributes that will be removed or replaced. At minimum the Dose Information Reporter shall support the ability to configure removal and replacement of all those attributes listed in the Basic Application Level Confidentiality Profile in DICOM PS 3.15 and revised in DICOM Supplement 142. It shall be configurable to use:

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

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

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

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

In some scenarios, it may be appropriate to perform no de-identification, such as when the Dose Registry is doing a longitudinal study for specific patients (and necessary consents and/or privacy agreements have been taken care of). In such cases, if the Patient Identity Removed
890 (0012,0062) attribute is present in the dataset it shall not be changed before submitting the dataset; if the attribute is absent it shall be added with a value of NO.

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

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

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

905 If the same instances are exported multiple times on different occasions, the identifying attributes and UIDs therein shall be replaced with the same values on each occasion. That is, this transaction requires deterministic behavior for replacement of identifying attributes and UIDs. This assures that the receiving Dose Registry can detect duplicate submissions and not accumulate the same dose multiple times. The safest way to assure detection of duplicate

910 submissions from a single or multiple sites is not to replace the UIDs in the first place, but local regulations or policy may not permit this.

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

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

920 The Dose Information Reporter is not required to be able to pseudonymize Dose objects. For a description of pseudonymization, See RAD TF-2: 4.51.4.1.4.3 and RAD TF-2: Appendix R.2 [TCE Supplement Document].

4.63.4.1.3 Expected Actions

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

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

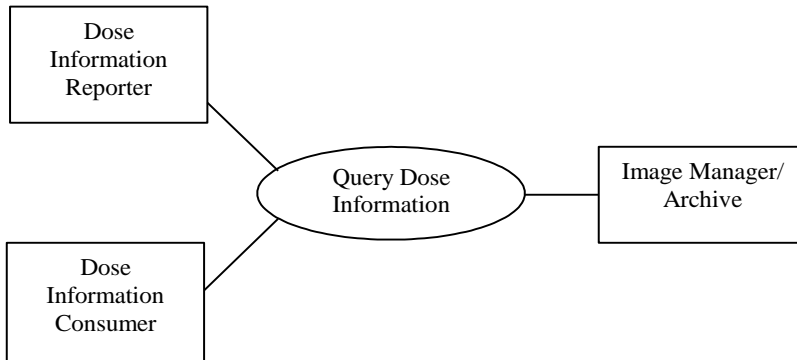
4.64 Query Dose Information

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

4.64.1 Scope

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

4.64.2 Use Case Roles



Actor: Dose Information Reporter

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

Actor: Dose Information Consumer

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

Actor: Image Manager/Archive

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

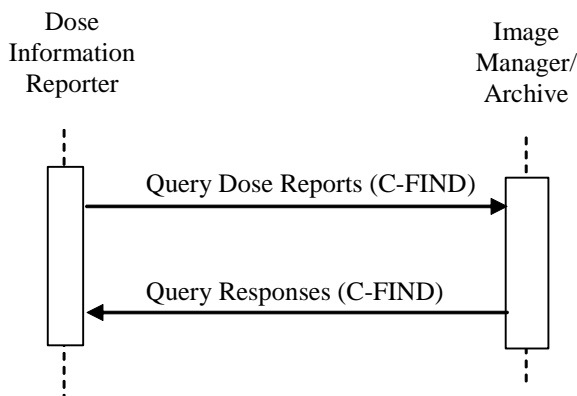
4.64.3 Referenced Standard

DICOM 2008 PS 3.4: Query/Retrieve Service Class

DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

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

955 4.64.4 Interaction Diagram



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

4.64.4.1 Query Dose Information

960 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.

4.64.4.1.1 Trigger Events

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

965 Often this will be triggered by the Dose Information Reporter preparing to produce reports, preparing to perform analyses or preparing to submit data to a dose registry based on local policies. Examples of such triggers might include generating a daily report of procedures exceeding Diagnostic Reference Levels for certain procedure types, producing a summary of dose to a particular patient over the past year, or submitting reports for all procedures performed in the past week to a national dose registry.

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

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

975

4.64.4.1.2 Message Semantics

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

980 The Dose Information Reporter and Dose Information 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.

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

985 The Dose Information Reporter or Dose Information 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).

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

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

995

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

Attribute Name	Tag	Query Keys Matching		Query Keys Return	
		SCU	SCP	SCU	SCP
Dose Report Instance Specific Level					
SOP Class UID	(0008,0016)	O	R+	O	R+
SOP Instance UID	(0008,0018)	O	R	O	R
Content Date	(0008,0023)	O	O	O	R+
Content Time	(0008,0033)	O	O	O	R+
Referenced Request Sequence	(0040,A370)				
>Study Instance UID	(0020,000D)	O	O	R+*	R+
>Accession Number	(0008,0050)	O	O	R+	R+
>Requested Procedure ID	(0040,1000)	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)	O	O	R+*	R+
>Coding Scheme Designator	(0008,0102)	O	O	R+*	R+
>Coding Scheme Version	(0008,0103)	O	O	O	R+
>Code Meaning	(0008,0104)	O	O	R+	R+

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

4.64.4.1.2.1 Filtering Strategies

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

- 1000 Filtering can occur at three points. Matching keys allow filtering on the server side; only instances that pass the filter have metadata returned. Return keys allow filtering on the client side; only instances whose metadata passes the filter are subsequently retrieved. Finally object attributes or content tree elements allow further client side filtering; only retrieved instances that pass the filter are processed further.
- 1005 Client-side filtering of the object attributes and content is the most flexible, but to avoid retrieving an unnecessarily large number of objects, the use of matching and return keys is very helpful.

To filter for Dose objects:

- 1010
- Matching key - SOP Class UID (0008,0016) allows selection of the X-ray Radiation Dose SR Storage SOP Class.

To filter for a specific date range:

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

To filter for specific modalities:

- 1015
- Matching key - Modalities in Study (0008,0061) allows selection of a desired modality (e.g., CT, XA, DR, DX, CR, MX)

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

- 1020
- Return key - Template ID (0040,DB00) allows identification of either CT or Projection X-Ray dose reports. Future dose reports will also be identifiable by new Template ID values, making this a potentially valuable attribute for the Archive to support as a matching key.
 - Object Content Tree - Procedure Reported allows differentiation of Mammography from other types of projection x-ray

1025 To filter for specific procedure types:

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

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

1035 To filter for specific body regions:

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

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

- 1040
- Object Content Tree – Anatomical Structure, if present, may also identify body regions in projection x-ray dose reports.

To filter for patient age category:

- Return key – Patient’s Birth Date (0010,0030) allows identification of patients in an age range.
 - Return key - Patient’s Age (0010,1010) is a Type 3 attribute and an optional return key but may allow identification of some patients in an age range.
- 1045

To filter for patient weight category:

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

To filter for patient sex:

- 1050
- Return key – Patient's Sex (0010,1040) allows identification of patients sex (e.g., for monitoring policies relating to women of childbearing age).

4.64.4.1.3 Expected Actions

1055 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 Information Consumer via C-FIND responses.

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

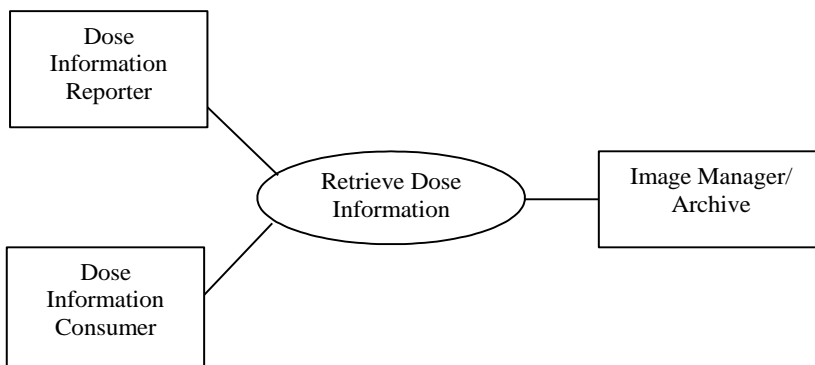
4.65 Retrieve Dose Information

1060 This section corresponds to Transaction RAD-65 of the IHE Technical Framework. Transaction RAD-65 is used by the Dose Information Reporter, Dose Information Consumer and Image Manager/Archive actors.

4.65.1 Scope

1065 A Dose Information Reporter or Dose Information Consumer requests and receives from the Image Manager/Archive specified instances of Dose objects.

4.65.2 Use Case Roles



Actor: Dose Information Reporter

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

1070 **Actor:** Dose Information Consumer

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

Actor: Image Manager/Archive

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

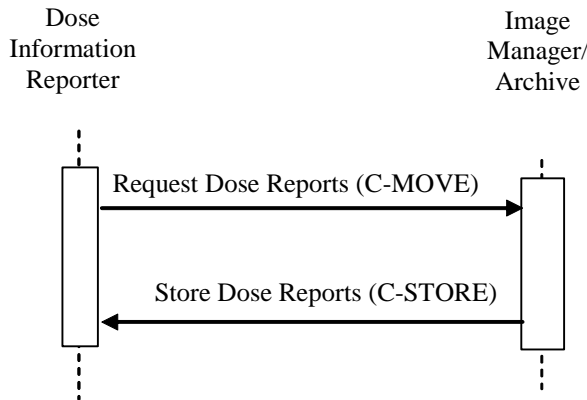
1075 **4.65.3 Referenced Standard**

DICOM 2008 PS 3.4: Query/Retrieve Service Class

DICOM 2008 PS 3.4: Structured Reporting Storage SOP Classes

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

4.65.4 Interaction Diagram



1080

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

4.65.4.1 Retrieve Dose Information

1085 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 Information Consumer actors shall support the SOP Classes shown in Table 4.65-1 below.

1090

Table 4.65-1 Dose 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

4.65.4.1.1 Trigger Events

The Dose Information Reporter or Dose Information Consumer decides it needs a specific Dose object.

1095 **4.65.4.1.2 Message Semantics**

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 Information Consumer is the DICOM C-Move SCU and DICOM Storage SCP and the Image Manager/Archive is the DICOM C-Move SCP and DICOM Storage SCU.

1100 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.

1105 It is the responsibility of the Image Manager/Archive to assure that the patient and procedure information is current in the Dose objects when they are retrieved from the Image Manager/Archive.

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

1110 **4.65.4.1.3 Expected Actions**

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

1115 Dose Information Reporter actors shall be capable of processing both TID 10001 and TID 10011.

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

1120 The same Irradiation Event (as identified by its Irradiation Event UID) may be referenced in multiple Dose objects. For example, the same dose event might appear in both an SR summarizing a procedure and an SR summarizing the whole study.

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

1125 The Dose Information Reporter shall be capable of presenting some form of report to the user based on the retrieved dose information. The format, contents and analysis of such reports is not defined by this profile. Such details should be worked out as part of the product design.

Volume 2 - Transactions

Edit sections 4.8, 4.18, 4.10, and Appendix A as follows

1130

4.8 Modality Images Stored

Insert the following text:

4.8.4.1.2.4 Recording of Dose Information

1135 Acquisition Modality actors claiming the Radiation Exposure Monitoring (REM) Profile shall record the Irradiation Event UID (0008,3010) of the event(s) that resulted in the data from which the image was derived in each image created; if the image or frame is derived from more than one irradiation event, multiple values shall be present (see DICOM CP 1090). The value(s) of the Irradiation Event UID shall match those encoded in the corresponding SR Dose Information instance. If the SR Dose Information instance is not
1140 being created by the equipment that actually administered the radiation, the equipment creating the SR Dose Information shall assure that all images contain the correct Irradiation Event UIDs.

1145 The Irradiation Event UIDs may be used to identify images corresponding to irradiation events for purposes such as identifying irradiated tissues and organs for dose mapping or for advanced effective dose estimations or for comparing the noise characteristics of the images with the dose.

1150 The Irradiation Event UIDs (0008,3010) shall be included in both original and derived images produced by the Acquisition Modality (such as retrospective reconstructions from the same raw data with different slice thickness or reconstruction intervals, multi-planar or 3D reconstructions from the same irradiation event, as well as for processing and for presentation projection images).

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

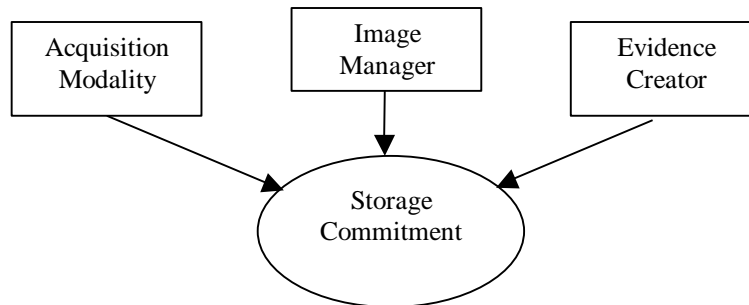
1155 4.10 Storage Commitment

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

4.10.1 Scope

1160 After the Acquisition Modality or Evidence Creator has sent images, Presentation States, Spatial Registration objects, **Dose Objects, Evidence Documents** or Key Image Notes to the Image 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



1165

Actor: Acquisition Modality

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

1170

Actor: Evidence Creator

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

Actor: Image Manager.

1175

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

4.10.4.1.3 Expected Actions

1180 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. The Acquisition Modality is then free to manage its own internal resources accordingly.

1185

RAD TF Volume 3 - Add the following rows to the end of the table 5.1-2 in the Radiology Audit Trail Option:

<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 Information</u> <u>[RAD-62]</u>	<u>Begin-storing-instances</u>	<u>Sender (Acq. Mod)</u>
	<u>Instances-Stored</u>	<u>Receiver (Image Manager/Archive)</u>
<u>Submit Dose Information</u> <u>[RAD-63]</u>	<u>PHI-export</u>	<u>Sender (Dose Information Reporter)</u>
	<u>PHI-import</u>	<u>Receiver (Dose Registry) - when PHI is present (i.e., when the de-identification flag is not set)</u>
	<u>Node-Authentication-failure</u>	<u>Sender (Dose Information Reporter)</u> <u>Receiver (Dose Registry)</u>
<u>Query Dose Information</u> <u>[RAD-64]</u>	<u>Query Information</u>	<u>Image Manager/Archive</u>
<u>Retrieve Dose Information</u> <u>[RAD-65]</u>	<u>Instances-Stored</u>	<u>Sender (Image Manager/Archive)</u>
	<u>Study-used</u>	<u>Receiver (Dose Information Reporter)</u> <u>Dose Information Consumer)</u>

1190 RAD TF Volume 1 - Add the following Appendix I:

Appendix I – Deployment of Dose Registries

1195 The Radiation Exposure Management Profile is intended to facilitate Dose Registry projects. Participating sites that have implemented the REM profile can be depended on to provide data with known contents in a known format and will all support a common transport mechanism. See the Submit Dose Information transaction for details (RAD TF-3: 4.63).

This appendix includes discussions of logistical issues related to the deployment of dose registries. This is not part of the normative text of the REM profile, but the discussions here may be helpful when deploying and using the REM profile.

1200 I.1 Dose Registry Deployment Issues

I.1.1 Code Set Management

1205 Although the REM Profile does manage to provide consistent dose data, for a Dose Registry to analyze dose objects and prepare summary statistics for a specific exam type, anatomy or pathology/indication, it will need to select/group dose objects based on exam type, anatomy or pathology/indication.

If the different sites submitting data used consistent code sets for coding such details, this might be easy, but unfortunately, for technical and organizational reasons, such code set consistency is unlikely. Due to similar issues, consistency *within* an organization may even be challenging.

1210 Dose Registries should be prepared to deal with such non-uniformity. For example, they may need to manage lookup tables to map codes from each submitting organization to a set of standard codes or categories. This may involve reverse engineering the codes from Code Description fields, when available, or it may involve requesting code sets from participating sites.

1215 Dose Registries should also be prepared for a lack of detail e.g., there may be a procedure code for “stent placement” but no indication if it was one stent, three stents, or more.

I.1.2 Configuration of Secure FTP (Submit Dose Information Transaction – RAD-63)

The REM Profile requires Dose Information Reporters support the Submit Dose Information Transaction for the purpose of submitting dose data to Dose Registries.

1220 The Submit Dose Information Transaction specifies the use of FTP over TLS.

When setting up the FTP server the dose registry project should consider useful features such as:

- Setting up individual login accounts for each participating site
- Directing files from clients into specific folders based on their login account id
- Preventing clients from looking at other folders

1225 **I.1.3 Alternative Transport Mechanisms**

The Secure FTP Transport defined in the Submit Dose Transaction is intended to provide a baseline transport mechanism. It is not intended to prohibit Dose Registry projects from using other transport mechanisms.

1230 Having a built-in baseline method available at participating hospitals should make it easier for dose registry projects to get off the ground. However, if a dose registry project feels there is enough benefit, they may choose to define an alternative transport mechanism and find a way to get it implemented at each of their participating hospitals.

Some alternative transport mechanisms to consider include sending the objects via:

- CD using the IHE Portable Data for Imaging (PDI) Profile
- 1235 • Email using the DICOM Email Media Profile and SMTP
- Network using DICOM C-Move over TLS to a controlled public DICOM server
 - Note the need to get each site's firewalls to allow outgoing DICOM connections. Some DICOM servers can be configured to accept connections from any source which would reduce the amount of configuration work at the Registry.
- 1240 • Network using the IHE Cross-Domain Document Sharing for Imaging (XDS-I) Profile
 - Note the need to establish an Affinity Domain covering all contributing sites and to fill in the XDS metadata which may be complicated by de-identification.
- Network using the IHE Cross-Domain Document Reliable Interchange (XDR) Profile
 - 1245 • This might be attractive if XDR features such as multi-file bundles, and "replacing" documents would be useful.
 - Note again the need to fill in the XDS metadata.

I.1.4 Encapsulated Dose Registry Submission

1250 Another approach to addressing submission issues and facilitating site is for the organization that is setting up a dose registry project to develop and distribute a client application to each participating site.

The client includes an implementation of a Dose Information Consumer or Dose Information Reporter which allows it to gather dose objects from the Image Archive. The client would also incorporate a proprietary upload mechanism to get the dose objects up to the dose registry.

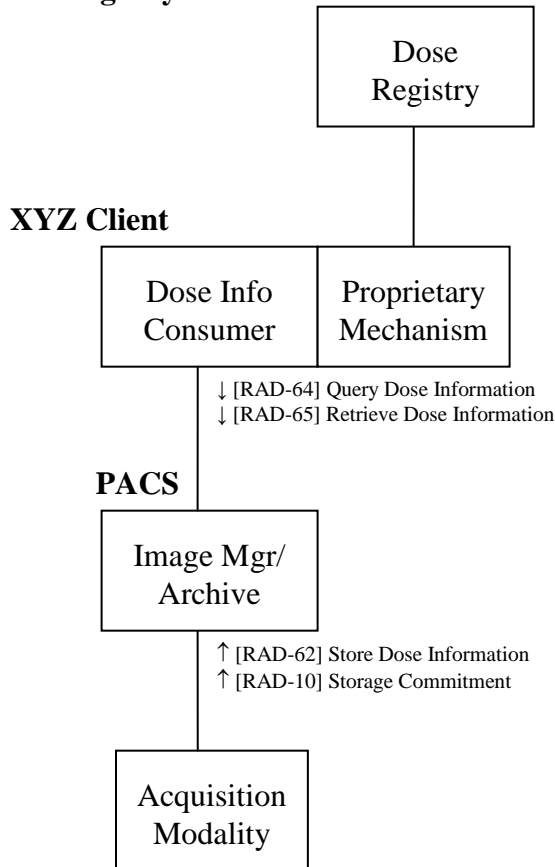
1255 Note that while this approach has the potential to simplify some technical issues, it introduces a number of security issues. Some sites may need to review and approve such a client before

allowing foreign software on their network, particularly if it is capable of sending patient data outside the organization.

Imagine:

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

XYZ Registry



I.2 Real-World Projects

A number of organizations have established or are in the process of establishing Dose Registry projects.

Project: ACR Registry - USA

ACR is forming a national Dose Index Registry (DIR). The initial pilot program will compare CT dose indices across 10-12 facilities to identify areas that may require changes to CT dose protocols. At the completion of the pilot program, the DIR will launch nationwide.

1270 Their ultimate goal is minimizing dose to the patient population and they are interested in Use Cases including: Population Dose and Dose Indicators, Dose Reference Levels and Benchmarking. They are specifically not interested in the Patient Dose History Use Case as they have no plans to become a national personal dose record.

Website: nrdr.acr.org

1275 **Project: French Ministry of Health Registry**

French regulations mandate the submission of Dose Reference Level data to a federal dose registry managed by the Institut de Radioprotection et de Sûreté Nucléaire / Institute for Radiation Protection and Nuclear Safety (IRSN).

1280 Every year each specialist must submit dosimetric information (at least 20 patients) for each of at least two examination types (generally the most frequent and most irradiating examination types).

1285 The ministry is interested in Use Cases including: Population Dose and Dose Indicators, and Dose Reference Levels. Data collection spans Radiography, Fluoroscopy, Mammography, Computed Tomography and Nuclear Medicine. The data is further broken down by patient age category, and body part.

Website: www.irsn.org/en

I.3 Dose Monitoring Regulations

Several groups interested in regulatory issues (IEC, FDA, AAPM, etc) drove original definition of the DICOM Dose SR objects.

1290 The following sections contain some contributed summaries of different regulatory initiatives. These are only intended to provide a sense of the type of activities. Readers should refer to the regulations themselves for accurate information.

European Regulatory

1295 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 statistical analysis at the population level.

Euratom: http://ec.europa.eu/energy/nuclear/radioprotection/legislation_en.htm

1300 Diagnostic Reference Levels (DRLs) in Europe:

http://www.eu-alara.net/index.php?option=com_content&task=view&id=156&Itemid=53

French Regulatory

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

- 1305 • 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).
- 1310 • 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).

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

1315 **German & Dutch Regulatory**

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

Germany is working on additions to the DICOM Basic Diagnostic Imaging Report to include Radiation Regulation related details such as:

- 1320 • Pregnancy Status
- Indications for Procedure
- Physician Responsible for Indication
- Performing Person (who administered)
- Radioactive Substance Administered
- 1325 • Radiation Exposure (text description of "the exposure")
- Performing Person's Organization Name

Spanish Regulatory

In Spain, dose information is not conveyed above the Hospital level.

- 1330 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 significant groups of reference of the population, whose results will be sent to the Ministry of Health and Consumption.
- 1335