Kvarkki technical specification

version 2.3.4

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Date	Version	Change	Author
3.6.2016	2.1	First published English version	Pekka Rinne
6.6.2016	2.1.1	Supported transfer syntaxes when storing images list is updated	Pekka Rinne
16.12.2016	2.2	Chapters have been specified: Glossary, 4.1.3, 4.4.2, 4.8.1, 4.9.8, 4.13.1, 6, 7.3 (specification of the XUA Assertion signature, SAML table), 9, 9.2, 10, 15.5, 17.1. Figure 13 (IAN) added. Reference to a separate error code document added: Appendix 1.	Pekka Rinne
6.2.2017	2.2.1	Chapter 4.1.3: specified transferring the responsibility of storing. Storage commitment is now mandatory. Chapter 9.2: specified the validation of the studyDescription (0008,1030). Chapter 10: fixed the UID of transfer syntax JPEG Lossless, Non-Hierarchical, (Process 14).	Pekka Rinne
12.6.2017	2.3	Removed the definition and descriptions of a decentralised model from the specification and specified that all XDS requests to Kvarkki utilize XCA Gateway. Chapter 7: XUA requirements updated: e.g. requirements for RAD-69 specifies, emergency search shall now have attribute urn:oasis:names:tc:xspa:1.0:subject:purposeofuse instead of urn:kanta:kvarkki:break-glass. Chapter 4.8.2 and 9.2: specified what modalities are registered into the XDS registry.	Pekka Rinne, Tero Viitala, Tarja Herttuainen (Marko Jalonen)

		Except 4.4.2: added the requirement of mandatory wsa:MessageID with the use of IHE transactions. Chapter 4.4.2: C-MOVE destination configuration specified. Chapter 4.9.4: The support for IHE IOCM concerning Regular use has been added. Appendices 2 & 3 added	
31.10.2017	2.3.1	Added chapter 4.1.4 Time values (UTC) in the XDS-registry Specified chapter 4.10.2 to match grade A certification requirements for Use log Chapter 6 revised concerning temporary patient id's and ADT messages Chapter 7.2 XUA table: - specified the use of registry-specifier attribute in search transactions - role attribute is now optional Appendices 4 & 5 added	Pekka Rinne, Tarja Herttuainen
18.5.2018	2.3.2	Chapter 3.1: added supported HL7 CDA R2 specifications Chapter 4.1.5 added: specified handling of manifest's offline status in the XDS Registry Chapter 4.4.1 and 4.4.2: Specified the requirements for Kanta connection point when communicating from Kvarkki to customer Chapter 4.9.4: specified that customer are not allowed to send IOCM KOS objects to Kvarkki where the rejection reason is 113039, Data Retention Policy Expired Chapter 6: specified handling KOS manifest tags when ADT messages are processed in Kvarkki Chapter 9.2: DICOM validation: specified the handling of mandatory Issuer of Patient ID (0010,0021) and removed the requirement for study description codes with a 'TUTK' attribute. Chapter 12.1.2: specified the use of Title metadata Chapter 12.1.3 added: specified how Kvarkki supports the active custodian information concerning the Finnish regional reform starting from 1.1.2020 References updated	Pekka Rinne
9.11.2018	2.3.3	No technical changes.	Pekka Rinne

		Broken sequence diagrams fixed, Glossary of terms revised throughout the document and the following chapters revised: • Ch. 4.1.3: Storage Commitment is mandatory also when storing KOS objects. • Figure 14: Fixed: Storage Commitment is mandatory • Ch. 4.6: Specified the new identifiers requires with study copies (study, series, instance) • Ch. 4.6.1: Removed references to the encounter ID in DICOM study • Ch. 4.13: Updated the retention control in the Kvarkki DICOM archive • Ch. 12.1.1: Specified that the retrieval of metadata is done with the help of Study Instance UID • Ch. 12.1.2: Removed references to the temporary patient ID. • Figures are now listed in the TOC	
20.12.2018	2.3.4	No technical changes. Specified XUA instructions in chapter 7.2 when Private service provider's Joint connection is used. The following SAML AttributeValues have been specified: • Service provider's organisation ID • Custodian	Pekka Rinne

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1 Introduction

This specification document describes the first implementation phase for the functionality of Kvarkki and its connections to other solutions and specifications in the national healthcare systems. The technical implementation is described with respect to the interfaces and data formats (XDS and DICOM interfaces and technical specifications for the key object selection) as fully as possible and as far as the description of the solution in accordance with the common principles for Kvarkki implementation requires. These implementation principles include the functional principles for the storage of imaging objects and consent and access management.

The specification is strongly based on the content definitions of the Kanta archive, use cases of HIS systems and other functional and technical specifications, and it is not possible to build interoperability with the Kanta archive and the Kvarkki by reading this specification only.

The first publication version of the specification was produced during 2014 and published in January–February 2015 after the first round of comments. The specification has been updated in 2016 and 2017 by Kela to meet the new requirements of the first deployment of Kvarkki.

1.1 Overview of Kanta architecture

This specification document describes the first implementation phase for Kvarkki imaging archiving and sharing infrastructure. It is translated and condensed from the official version written in Finnish with this additional introduction part for the readers not familiar with the Finnish Kanta architecture. The following figure depicts the overall Finnish healthcare national Kanta architecture of which Kvarkki (Radiology DICOM studies) is not yet realized as of the writing of this document.

Kanta architecture is mostly based on HL7 V3 and CDA R2 interfaces and Kvarkki extends the architecture with IHE XDS interfaces and DICOM studies. First the XDS interfaces are used only for imaging related data (radiology referrals, study documents, reports and DICOM studies) but later they may be extended to the whole Kanta dataset – the complete electronic patient record including the patient overview.

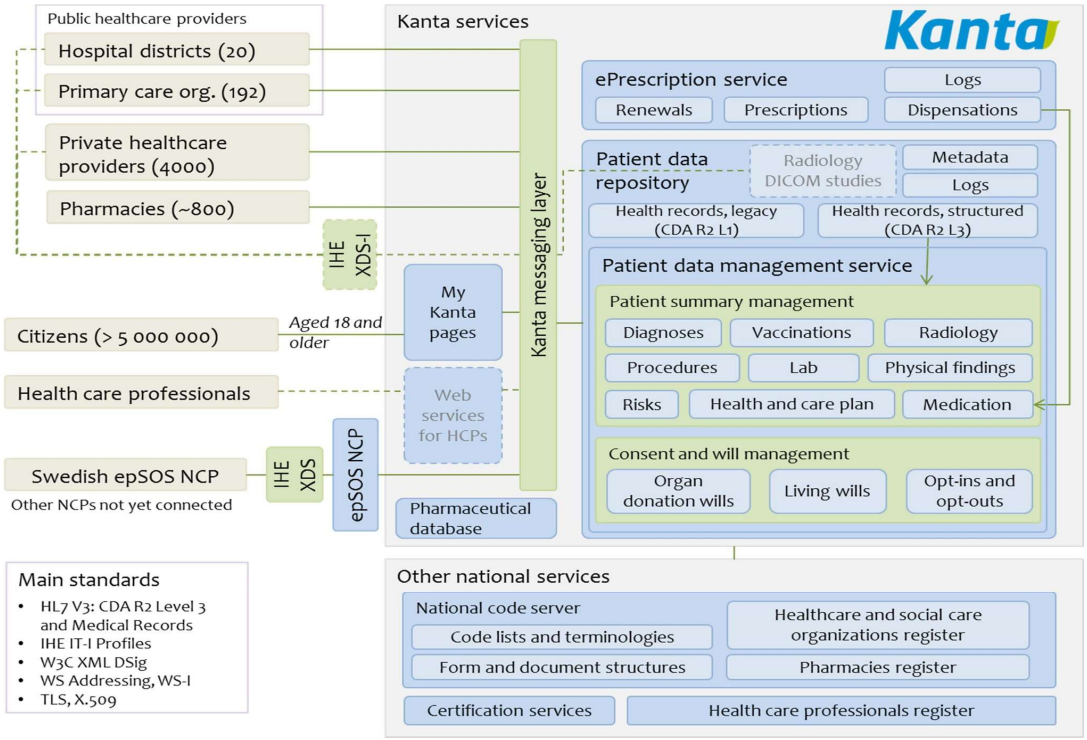

Figure 1 Kanta overall architecture

1.2 Kvarkki architecture and this document

Kvarkki architecture definition describes the Kvarkki architecture with the following figure. As depicted, the architecture relies on XCA interfaces for integrating customers to the centralised (national) affinity domain. The architecture roadmap allows for the healthcare areas to integrate to the centralised model for the storage and management of DICOM studies. For CDA R2 patient records (including the radiology imaging referrals, study documents and reports) the "original document" is always stored in the national Kanta Patient Data Repository aka Kanta archive.

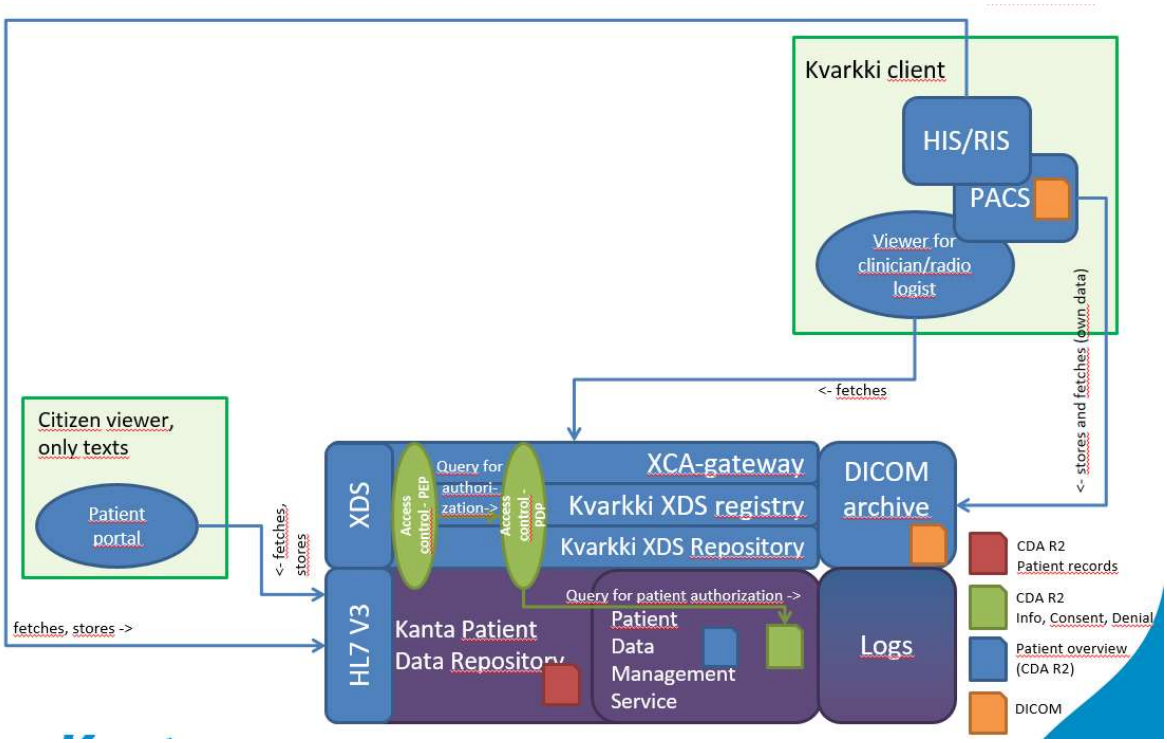

Figure 2 Kvarkki architecture model and co-existence with Kanta

This specification describes the first implementation phase for Kvarkki functionalities and the integration to other national Kanta services. Technical implementation provides blueprint for employing the interfaces and information entities (XDS and DICOM interfaces as used in Finnish architecture) as comprehensively as currently possible in order to be able to implement the required services. Additional requirements include eg. managing the retention periods and consent management policies. This specification provides only the Kvarkki interfaces and national requirements.

This specification is based on Kanta archive content profiles, nationally defined use cases for HIS systems and other functional and technical specifications. This specification is not comprehensive enough in itself for building a total radiology imaging solution (including HIS, RIS and PACS systems) that operates with Kanta archive.

Some of the less relevant or self-evident (eg. in glossary) parts of the Finnish text have not been translated but are erased or condensed for this English version.

2 Glossary

Term	Description	Reference
Accession number	Referral ID, typically from RIS. Synonym AC number.	http://medical.nema.org/
Adapter for Patient Data Repository	Component of Kvarkki architecture, responsible for e.g. XDS registration of imaging CDA R2 documents.	
Affinity Domain	An area covering one XDS registry. Also known as the home community. May serve several repositories. Communication between affinity domains is managed with XCA and XCA-I profiles in the IHE XDS model.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
Annotation	Additional entry made in the imaging study. Covers a number of different entries.	
Assigning Authority	An organisation responsible for giving identifiers for citizens. In practice, in Finland this is the Population Register Centre (1.2.246.21) with respect to personal identity codes, but the national code of conduct for temporary personal identity codes has still to be agreed on. An Affinity Domain normally defines the available assigning authorities.	
ATNA	Audit Trail and Node Authentication. An IHE profile	See IHE ATNA in this table
audit trail	In information systems: a log that verifies events and their times and performers.	See IHE ATNAin this table
CDA R2	A healthcare document format in XML, defined by the international HL7 community.	
CDA R2 non structured body	The body of a CDA R2 document that is not in XML format.	
C-MOVE	DICOM transfer command	http://medical.nema.org/
C-STORE	DICOM save command	http://medical.nema.org/
C-FIND	DICOM query/retrieve command	http://medical.nema.org/
DICOM	Digital Imaging and Communications in Medicine. A transfer protocol, file format and transactions for managing and transferring imaging examinations in	http://medical.nema.org/ http://en.wikipedia.org/wiki/DIC

	standard format.	OM
DICOM data element	A unit of information as defined by a single entry in the data dictionary. An encoded Information Object Definition (IOD) Attribute that is composed of, at a minimum, three fields: a Data Element Tag, a Value Length, and a Value Field. For some specific Transfer Syntaxes, a Data Element also contains a VR Field where the Value Representation of that Data Element is specified explicitly. See also PS 3.5, Section 7.1 ftp://medical.nema.org/MEDICAL/Dicom/2017a/output/pdf/part05.pdf	
DICOM tag	Tag is often used as shorthand terminology for 'DICOM data element'. A DICOM data element contains a piece of metadata, and the term tag actually refers to an ordered pair of numbers which identify the data element. The Tag is composed of a group number and an element number. For example (0010,0020) corresponds to 'Patient ID'. Refer to Glossary in DICOM PS3.5 for precise definition 'Data Element Tag' ftp://medical.nema.org/MEDICAL/Dicom/2017a/output/pdf/part05.pdf	
Document consumer	XDS actor that queries and retrieves documents from XDS data repositories.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
Encounter	An outpatient visit related to the treatment of an illness or another reason or an inpatient episode in a healthcare organisation. http://www.kanta.fi/sanasto	
Gateway	Gateway complying with XCA or XCA-I in each XDS domain. Operates in both initiating and responding roles.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
HIS	Hospital information system.	
HL7 v3	Service interface technology defined by the community. Web service based.	international HL7
HL7 interface	In this specification: concrete HL7 v3 compliant in the Kanta system.	services
IAN	Instance Availability Notification. Notification for informing status info about SOP instances	http://medical.nema.org/

IHE ATNA	Audit Trail and Node Authentication. Support for ATNA profile, obliges to log all functions on a device and use IHE CT and sets requirements for data security solutions.	http://wiki.ihe.net/index.php?title=Audit_Trail_and_Node_Authentication
IHE BPPC	Basic Patient Privacy Consents. Specification for the implementation of consent management, based on document XDS metadata and fixed access control policies that can be added to documents. Not used in Kvarkki.	http://wiki.ihe.net/index.php?title=Basic_Patient_Privacy_Consents
IHE CT	Consistent Time. In practice, utilisation of NTP time service with ATNA Secure Nodes.	http://wiki.ihe.net/index.php?title=Consistent_Time
IHE IOCM	Imaging Object Change Management describes the transactions for imaging objects in change management. Mainly instructions for applying DICOM-based interfaces. IOCM "*specifies how one actor communicates local changes applied on existing imaging objects to other actors that manage copies of the modified imaging objects in their own local systems.*"	http://wiki.ihe.net/index.php?title=Imaging_Object_Change_Management
IHE PIX	Patient Identity Cross Referencing. Provides tools for patient identification possibly with different identifiers. Not as relevant in Finland in a certain sense as individual and national personal identity codes are in use. On the other hand, one identifier is not enough in the case of temporary and old (at least in cases of gender reassignment) identifiers.	http://wiki.ihe.net/index.php?title=Patient_Identifier_Cross-Referencing
IHE XCA	Cross Community Access. Expands the use of XDS.b transactions between Affinity Domains or within one Affinity Domain (if multiple repositories are abstracted to be accessible via one interface).	http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing
IHE XCA-I	Cross Community Access for Imaging. Expands the use of XDS-I.b transactions between Affinity Domains or within one Affinity Domain (if multiple repositories are abstracted to be accessible via one interface).	http://wiki.ihe.net/index.php?title=Cross-Community_Access_-_Images_(XCA-I)

IHE XDS.b	Cross Enterprise Document Sharing. Specification for the IHE IT Infrastructure domain, containing basic transactions for searching document description data and actual documents and for their registration and recording in the repository. In this description, XDS.b is a synonym of XDS, in practice XDS.b is a new generation of the XDS definition, which includes, e.g. web services interfaces.	http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing
IHE XDS-I.b	Cross Enterprise Document Sharing for Imaging. Corresponds to XDS.b, but specialised for imaging objects, i.e. expands XDS.b. In practice, offers Retrieve Imaging Document Set (RAD-69) transactions based on DICOM WADO (RAD-55) and web services.	http://wiki.ihe.net/index.php?title=Crossenterprise_Document_Sharing_for_Imaging
IHE XUA	Cross Enterprise User Assertion. Enables transfer of user data and query situation data from Document Consumer to Registry or Repository (to Document Source). In the draft version the extendable profile was called XUA++.	http://wiki.ihe.net/index.php?title=Cross-Enterprise_User_Assertion_%28XUA%29
Image Manager	IHE actor that provides necessary operations for processing imaging objects (selecting key objects, etc.). In practice, implemented with PACS solution or may be integrated in Imaging Document Source.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
Imaging Document Consumer	Imaging Document Consumer is an IHE actor that retrieves imaging examinations from Imaging Document Source for browsing by professionals.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles

Imaging Document Source	Imaging Document Source is an XDS-I-compliant IHE actor that provides the necessary interfaces for archiving and sharing imaging studies. The Kvarkki DICOM archive is Imaging Document Source.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
imaging workflow	Controlled process for providing imaging study and report. Scheduled Workflow (SWF) domain.	
ITI-18	Registry Stored Query transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
ITI-38	Cross Gateway Query transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles

ITI-39	Cross Gateway Retrieve transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
ITI-40	Provide X-User Assertion transaction. Implemented as SAML elements in other transaction messages.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
ITI-41	Provide and Register Document Set-b transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
ITI-42	Register Document Set-b transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
ITI-43	Retrieve Document Set transaction	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
ITI-8	Patient Identity Feed transaction. HL7 v 2.x ADT message. HL7 v3 counterpart is ITI-44.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
jpeg	File format for images. A number of ISO standards define, e.g. the presentation and package methods.	
Kanta archive	Aka National Patient Data repository. The Patient Data Repository is a healthcare service data system in active use, and it is used with the patient records system. It allows centralised electronic archiving of patient records (CDA R2) and long-term storage of the data.	
KOS, KOS file, Key Object Selection	A DICOM information object definition and SOP Class which can be used to contain a variety of structured information. It is similar in structure to a DICOM Structured Report and used to contain pointers to one or more significant images, waveforms or other instances. KOS documents can store "bookmarks" to key images within a study for teaching or quick access purposes, are used to store key images in the IHE Key Image Note (KIN) profile and to convey image deletes in the Imaging Object Change Management (IOCM) IHE profile. In the Cross-Enterprise Document Sharing for Imaging (XDS-I.b) IHE profile, a KOS document acts as the so-called 'manifest' for a DICOM study. The KOS 'manifest' is stored in the XDS Repository and contains pointers back to the Imaging Document	

	Source which contains the individual images and objects which make up the study	
Kvarkki DICOM archive	A subsystem of Kvarkki for storing imaging examinations.	

Modality	An imaging device producing imaging studies in DICOM format, e.g. X-ray angiography, ultrasound, mammography, endoscopy.	
PACS	Picture Archiving and Communication System. Meant for saving and distribution that support the use of imaging studies. In practice, PACS implementations also have properties that support longer-term storage, but in accordance with modern architecture models mainly operative use is used for medium-term archiving.	
PAP	Policy Administration Point – in XACML scheme e.g. place of defining policies related to access control, My Kanta Pages, national professional interfaces or patient data systems in national architecture	see XACML
PDP	Policy Decision Point – in XACML scheme, e.g. decision-making point taking place on the basis of policies related to access control.	see XACML
PEP	Policy Enforcement Point – in XACML scheme, e.g. practical implementation of policies related to access control, i.e., restricting views, for example.	see XACML
PIP	Policy Information Point – in XACML scheme, e.g. storage place for policies related to access control.	see XACML
PRP	Policy Retrieval Point	see XACML
RAD-10	Storage Commitment transaction. In practice, confirmation of saving corresponding to DICOM.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles

RAD-16	Retrieve Images transaction. C_MOVE command in DICOM standard, utilised by XDS-I as RAD-16 transaction.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
RAD-55	WADO transaction, Web Access to DICOM Objects. Image transfer mechanism across the HTTP get protocol.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles

		http://medical.nema.org/
RAD-66	Rejection Notes Stored transaction. IOCM transaction used for storing change object for imaging study.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
RAD-69	Retrieve Imaging Document Set transaction. Transaction defined by XDS-I for retrieving imaging study objects.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
RAD-75	Cross Gateway Retrieve Imaging Document Set transaction. Transaction for XCA-I-compliant gateway to transmit retrieval request for imaging study to another domain.	
RAD-8	Modality Images Stored transaction. Defined and described in SWF profile, but functionally corresponds with storing of imaging study in the Kvarkki DICOM archive.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
Registry	IHE XDS actor, acts as a directory.	see XDS register
Register of social welfare and	Information about healthcare organisations that is	http://koodistopalvelu.kanta.fi/cobeserver/pages/classificationviewpage.xhtml?classificationKey=421&versionKey=501

healthcare organisations	required from all healthcare units and from the service units of the healthcare units related to Kanta architecture ('offices', 'place of supply of services') is gathered in the register of social welfare and healthcare organisations. Organisation units with a business ID have also been identified in the register.	
Repository	IHE XDS actor for storing documents. Synonym for the XDS repository.	see XDS repository
Retention class	Class determined by the Decree on Patient Documents.	
RIS	Radiology information system	
SAML	Security Assertion Markup Language. OASIS standard for distributing user identification and authorisation data in the information network.	
SCU role	Service Class User role in DICOM traffic	http://medical.nema.org/standa rd.html
SCP role	Service Class Provider role in DICOM traffic	http://medical.nema.org/standa rd.html
shared workflow	Imaging workflow with actors from several organisations	
SOAP	Simple Object Access Protocol. Web service protocol standardised by W3C.	http://www.w3.org/TR/soap/

sticky notes	Colloquial name for imaging study saved entries made in in manufacturer-specific format.	

Study InstanceUID	Identification code for imaging study	
Submission portal	Portal solution for storing data in XDS Registry and Repository for archiving. Metadata can be added manually through the portal or, for example, with the aid of context management or similar functionality. Not included in the Kvarkki configuration in this specification.	
TLS	Transport Layer Security (TLS), previously known as Secure Sockets Layer (SSL), is an encryption protocol for protecting internet applications across IP networks.	
transfer syntax	Content format of imaging study in DICOM format in transfer.	
trial implementation	Name of the definition status in the production process of IHE definitions. Draft version before approval.	http://ihe.net/Technical_Frame works/
Web service	Interface technology for network services defined in W3C.	
Web service transaction	Individual service implemented with web service technology. IHE XDS and XDS-I services are implemented with the web service technology, and IHE calls them 'transaction'.	
VPN	Virtual Private Network. A way of combining several networks of a company across the public network, forming a seemingly private network. Also extended to apply joining of individual remote workstations to the company's network.	
VRK	Finnish Population Register Centre. In terms of Kvarkki, responsible for the official personal identity code and the digital certificates used in healthcare services.	
XACML	eXtensible Access Control Markup Language. OASIS specification.	https://www.oasisopen.org/committees/download.php/2713/Brief_Introduction_to_XACML.html

XCA gateway	Gateway complying with XCA in each XDS domain. Operates in both initiating and responding roles. Transmits XDS search and retrieval messages.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
XCA-I gateway	Gateway complying with XCA-I in each XDS domain. Operates in both initiating and responding roles. Transmits imaging study retrieval messages.	IHE Radiology (RAD) Technical Framework Volume 1 IHE RAD TF-1 Integration Profiles
XDS submission set	Structure defined by XDS, including the documents of a single registry submission. Recorded in the registry.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
XDS archive	In Kvarkki specification, XDS archive refers to the entity formed by XDS Registry and XDS Repository that manages the storage and distribution of description data and KOS objects of studies recorded in the Kvarkki DICOM archive.	
XDS domain	see Affinity Domain	
XDS Viewer	(Mostly) browser-based application for using materials from the Registry, Repository and the Kvarkki DICOM archive over XDS interfaces. May also be used as a viewer in some systems. Solutions from different suppliers support different IHE profiles to a varying degree. IHE term Document Consumer and Imaging Document Consumer.	
XDS Registry	Place for registering XDS documents. ITI-18 (Registry Stored Query) and ITI-42 (Register Document Set) of the XDS.b profile transactions are stored here. Defines one Affinity Domain and is thus identified with homeCommunityId.	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles
XDS Repository	Place for storing XDS documents. ITI-43 (Retrieve Document Set) and ITI-41 (Provide and Register Document Set) of the XDS.b profile transactions are stored here. Each repository has its own repositoryUniqueId. There can be multiple repositories in one Affinity Domain	IHE IT Infrastructure (ITI) Technical Framework Volume 1 (ITI TF-1) Integration Profiles

Notation used in the sequence diagrams in this document:

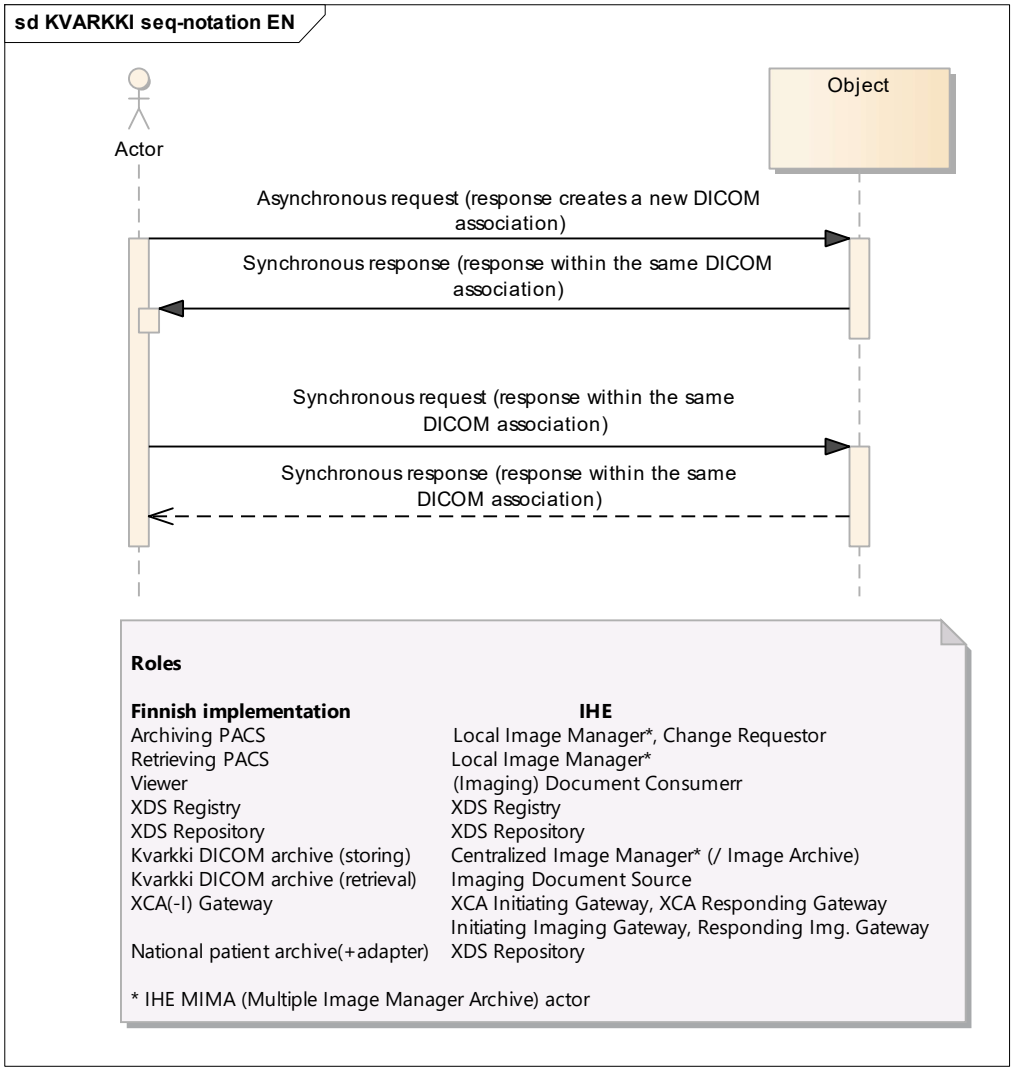

Figure 3 Notation used in sequence diagrams

3 Starting points

The starting point of Kvarkki architecture is to rely on the services and principles of the Kanta architecture. This specification document assumes that the functional principles of the Kanta archive will be implemented in the way they have been described in the Kanta specification descriptions (for example, cases of using patient data systems). The specification document does not describe these principles again, but it only identifies their interfaces and deals in further detail with cases where these principles are applied in a deviating way in the area of imaging due to, for example, different kinds of materials and technical limitations.

With respect to IHE specifications, the Kvarkki specification uses the latest specification versions for radiology and the IT framework, approved in 2015, as well as the specification draft versions for the same periods. [1] [2]

3.1 Data entities in Kanta and Kvarkki architectures

Kanta acts as the national data repository of imaging with respect to encounter data, patient records (also including imaging CDA documents[1], i.e. imaging referrals, whole sets of imaging study documents, and reports) and documents related to the sharing of patient records (consents, information and denials

[1] Imaging entries can be located under the RTG view or any report text-type view

and sharing notifications). Access control of data repositories possibly implemented at the regional level takes advantage of Kanta document sharing in real time (or separately using an intermediate storage solution as described in the Kanta descriptions) in connection with sharing events. The Kvarkki DICOM archive, is responsible for the storage and distribution of imaging studies in DICOM format in the architecture model. In addition to this task, retrieval of imaging CDA documents (in CDA R2 format in the Kanta archive) with the XDS interface will also be possible, for example, through the Kvarkki DICOM archive for the needs of XDS viewers. The supported national imaging-related HL7 CDA R2 implementation specifications in Kvarkki are V1.22 (at minimum) [9] and V2.21 (or higher) [10].

Imaging-related documents are accessible to the patient through My Kanta Pages (requests in CDA R2 format, study documents and reports and, in the target state, the imaging study itself in DICOM format).

Information concepts that are functionally related to Kvarkki architecture and the key properties related to them in the first stage of Kvarkki implementation are described in the following table.

Information/ document	Format	Location	Role in Kvarkki architecture	Storage interface	Retrieve interface
Encounter	CDA R2 document	Kanta archive	Establishing patient care context Interrelating the imaging data contents (primary key information) Allocation of denials	HL7 V3	HL7 V3
Imaging referral document	CDA R2 document	Kanta archive	Part of the imaging data content, connected to the encounter Part of the key medical data in imaging	HL7 V3	HL7 V3 or IHE XDS
Imaging study document	CDA R2 document	Kanta archive	Part of the imaging data content, connected to the encounter Recording of radiation exposure (temporary solution) Includes Study Instance UID reference for imaging study (secondary key information) Part of the key medical data in imaging	HL7 V3	HL7 V3 or IHE XDS

Imaging report document	CDA R2 document	Kanta archive	Part of the imaging data content, connected to the encounter Part of the key medical data in imaging	HL7 V3	HL7 V3 or IHE XDS
Imaging study document	CDA R2 document	Kanta archive	General name for a CDA document that includes one or several imaging referral, study and report entries.	HL7 V3	HL7 V3 or IHE XDS
Imaging study	DICOM study	Kvarkki DICOM archive	Part of the imaging data content, connected to the encounter Study/images Includes a Study Instance UID Synonym: DICOM study	DICOM	IHE XDS-I [3]
Metadata of an imaging study		XDS registry in the Kvarkki DICOM archive	XDS metadata of an actual imaging study. In XDS-I, saved as metadata of the manifest. Synonym: XDS metadata	XDS save request produced in an automated way in connection with DICOM archiving	IHE XDS
Content description of an imaging study	KOS file	XDS repository in the Kvarkki DICOM archive	Localisation of actual imaging study and the objects contained in it. Synonym: manifest	XDS save request produced in an automated way in connection with DICOM archiving	IHE XDS
Imaging study entity			All documents related to an imaging study in Kvarkki: study entries and DICOM study, as well as the manifest and XDS metadata Synonym: imaging study entries and DICOM study		
Patient data management	CDA R2 document	Key health data from	Part of the patient's key health data, consists of	HL7 V3	HL7 V3

service: aggregated data of imaging	(distributable format)	Kanta patient data management service	imaging referrals, study documents and reports Connected to patient encounters Synonym: key health data in imaging		
Informing the patient	CDA R2 document	Kanta Patient Data Management Service	Verifies that the patient has been informed	HL7 V3	HL7 V3 or simple WS interface
Patient consent	CDA R2 document	Kanta Patient Data Management Service	Verifies that the patient has given their consent to use the data in a care context and to share it from the national architecture	HL7 V3	HL7 V3 or simple WS interface
Patient denial	CDA R2 document	Kanta Patient Data Management Service	Verifies that the patient has given a sharing denial with respect to the data of the service provider, service provider register or encounter	HL7 V3	HL7 V3 or simple WS interface
Outsourcing authorisation	CDA R2 document	Kanta archive	Enables saving of data in or retrieval of data from the registry of another service provider Alternatively, can be managed with a more general arrangement based on Kanta address registry	HL7 V3	HL7 V3 (Kvarkki DICOM archive automatically verifies in an outsourcing situation) In Kvarkki, a DICOM study can be saved in the registry of another service provider on the basis of the encounter, i.e. the encounter determines the target registry (the correct logical registry of the Custodian) of the study
Sharing notification	CDA R2 document	Kanta archive	To be produced with regard to regional sharing and recorded in the national share log	HL7 V3	HL7 V3 (no typical use)

3.2 Data content in CDA R2 format and XDS interfaces in the Kanta Patient Data Repository

Imaging material (referral, study document, report) in CDA R2 format will be available through XDS interfaces already in the first stage of Kvarkki implementation. The Kanta archive is shown to the user as a single repository in Kvarkki: its functionality is transparent to the end user. Metadata complying with XDS in terms of their contents is available for the documents. XDS-I and XCA-I do not pose extra metadata requirements for the XDS adapter as a result of the imaging material, but the setting of some metadata requires extraction of information from the document contents.

The implementation of the Kanta archive will be supplemented to meet the needs of Kvarkki with the XDS adapter which, in the archiving of imaging CDA documents, registers them in the Kvarkki XDS register and carries out the retrieval services in accordance with XDS.

4 Kvarkki architecture in action

This chapter describes Kvarkki from the functional viewpoint. At first, a typical case of using the service is presented in a simplified way. After that, the necessary special operational functions and methods of use deviating from the basic model are described.

The technical solution or method of implementation are described in brief, and the description and plan are not comprehensive. The objective is to present the utilisation of key IHE profiles and the planned national application, adaptation and extension technologies. The rough technical description provides a reader with some knowledge of information technology with references to national and IHE specifications and the standards applied.

4.1 Basic model for saving and utilising studies[2] [3]

4.1.1 Saving a study

The following is a general outline of archiving imaging studies and their documents in Kvarkki.

[2] TF Volume 1: Table 10.1-1b: XDS.b - Actors and Transactions. The table includes references to a more detailed description of the transactions

[3] RAD Volume 1 Table 18.1-1: Cross-enterprise Document Sharing for Imaging Integration Profile – Actors and Transactions. The table includes references to a more detailed description of the transactions. The RAD table also includes transactions not pertaining to the XDS-I profile.

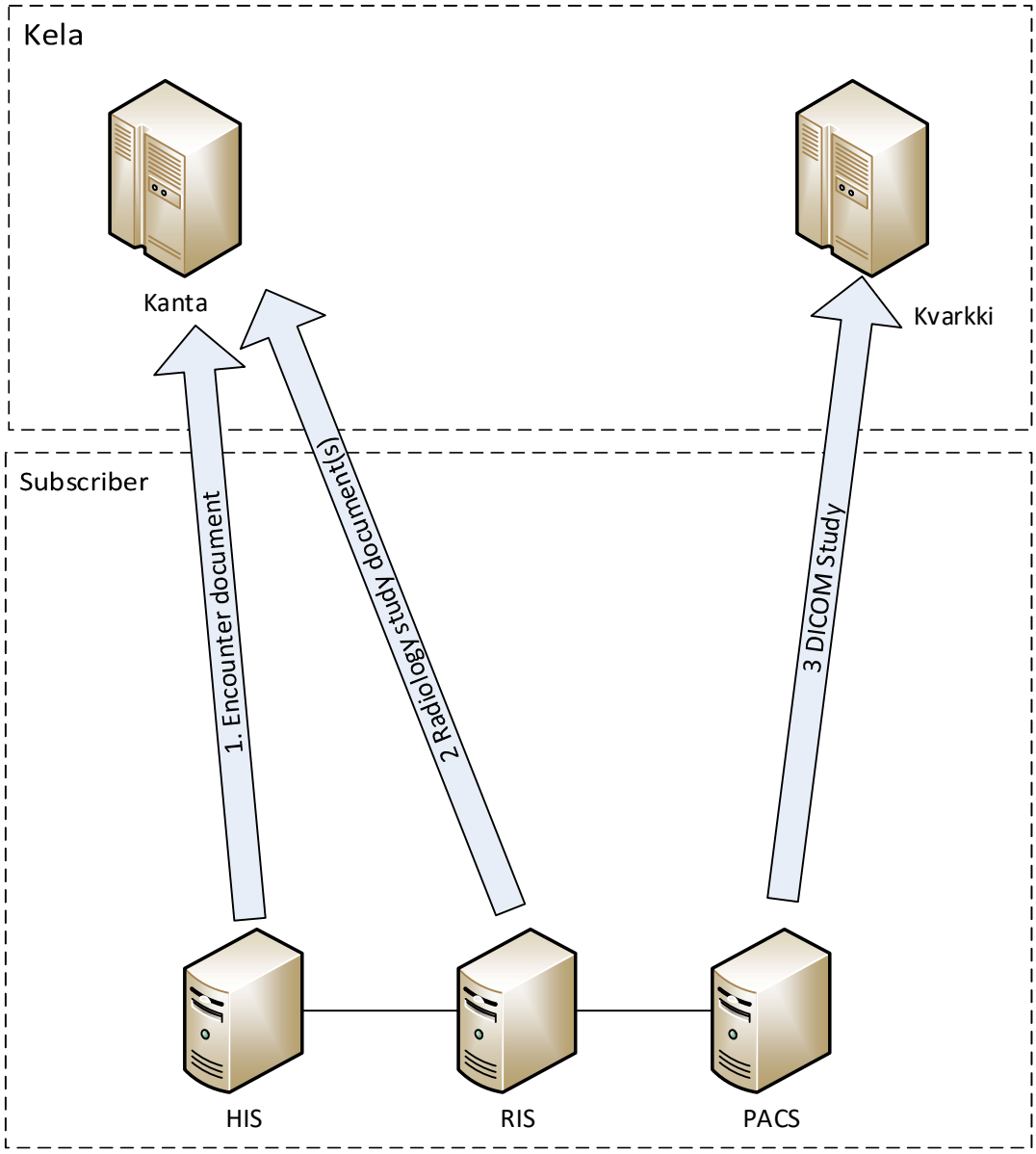

Figure 4 Archiving of an imaging study

The encounter document in CDA R2 format is recorded in the Kanta archive with Kanta services. Imaging documents created at a later date are attached to this encounter.

A referral is sent to the RIS system that establishes and AC number for the study. RIS establishes a CDA R2 imaging study document that contains a referral entry and saves it in the Kanta archive.

The study takes place in accordance with the imaging workflow. The study order is sent to the modality/PACS system where the study is carried out and checked. The imaging study is given a Study Instance UID identifier. After the study is completed, PACS triggers in the SCU role a DICOM C-STORE request to save the DICOM study in the Kvarkki DICOM archive. The study includes the Study Instance UID that makes it possible for the Kvarkki DICOM archive to connect the study to the encounter and, as a result, to the registry of the correct custodian. The study is stored in the Kvarkki DICOM archive. Various ways are supported by Kvarkki for ensuring the saving of studies that are described in chapter 4.1.3.

The DICOM storage automatically starts the formation of the content description of the imaging study, i.e. the manifest, and storing of the manifest to the repository with the XDS-I transaction RAD-68

(Provide and Register Imaging Document Set – MTOM/XOP). The Repository starts the ITI-42 transaction (Register Document Set-b), i.e. registering the study in the XDS Registry. These steps are described in the sequence diagram below:

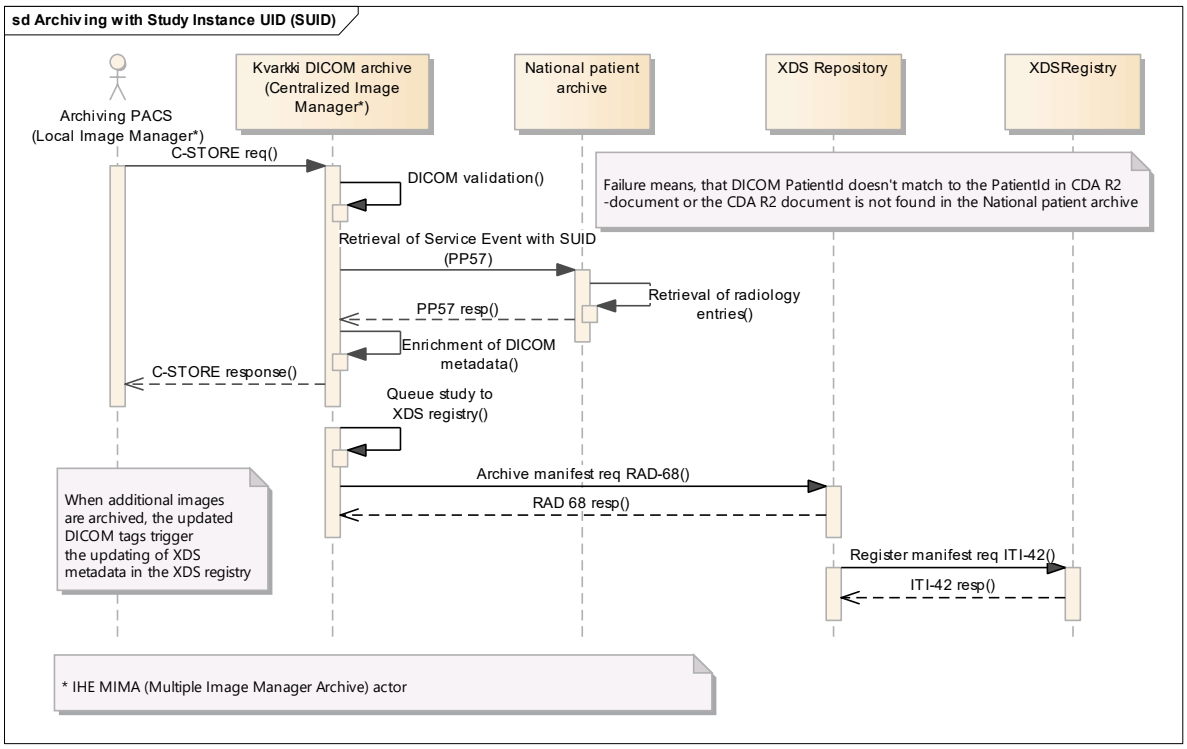

Figure 5 Archiving image with Study Instance UID

The study report or reports are saved in the RIS system in the workflow. RIS creates report entries for a study document in CDA format. RIS stores the document in the Kanta archive as a new version or as a completely new imaging study document.

Alternatively, the patient data system can also create and archive the AC number and study document. All imaging entries can be versioned to the same CDA R2 document or these entries can be combined into separate documents in accordance with the regional or local operating model or other situation factors.

The Kanta archive registers the imaging study documents in Kela's Kvarkki registry. All changes in the imaging study documents are also updated in the Kvarkki registry.

4.1.2 Retrieval of study

For retrieving a study, the user generally has the following options: the XDS-I-based approach directly from Kvarkki, navigation from the documents in the Kanta archive, which slightly deviates from the previous option, or direct DICOM retrieval of own images with a reference saved in PACS. Utilisation of studies from Kvarkki XDS-I system with a viewer application in the simplest way takes place with a three-phase retrieval as follows.

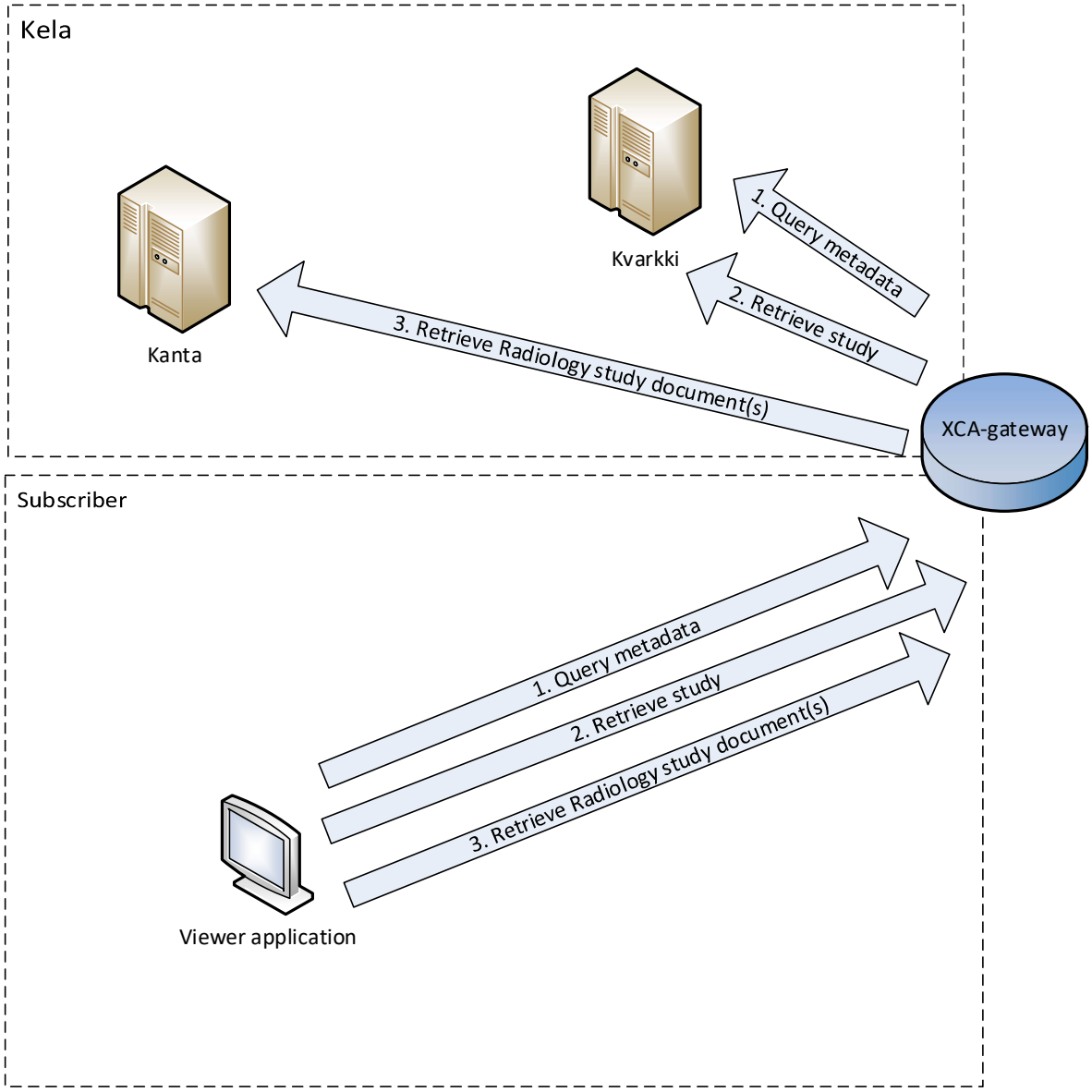

Figure 6 Querying and retrieving documents in the imaging study entity

An XDS query ITI-18, i.e. registry query, is carried out with the viewer. As a criterion for the query, at least the patient's personal identity code (possibly also, e.g. timeframe, study code or a part of it) must be provided. The query must also include identification data on the professional needed for consent management, which is sent in accordance with XUA, as well as other contextual information related to the query (encounter of the care context, emergency query, etc.), which are described in further detail in the section related to consent management.

The query is sent to the Kvarkki XDS registry via the XCA initiating gateway. Kvarkki registry servers that receive the query carry out the search and form a result set of the documents. With respect to the result set obtained, consent management connected to the registry carries out all possible exclusions on the basis of consent data and denials, based on the documents indicating the patient's organ donation saved by the patient in the data management service. The registry service returns the metadata of documents via XCA Gateway in the final available result set to the person performing the query. These steps are described in the sequences diagrams below:

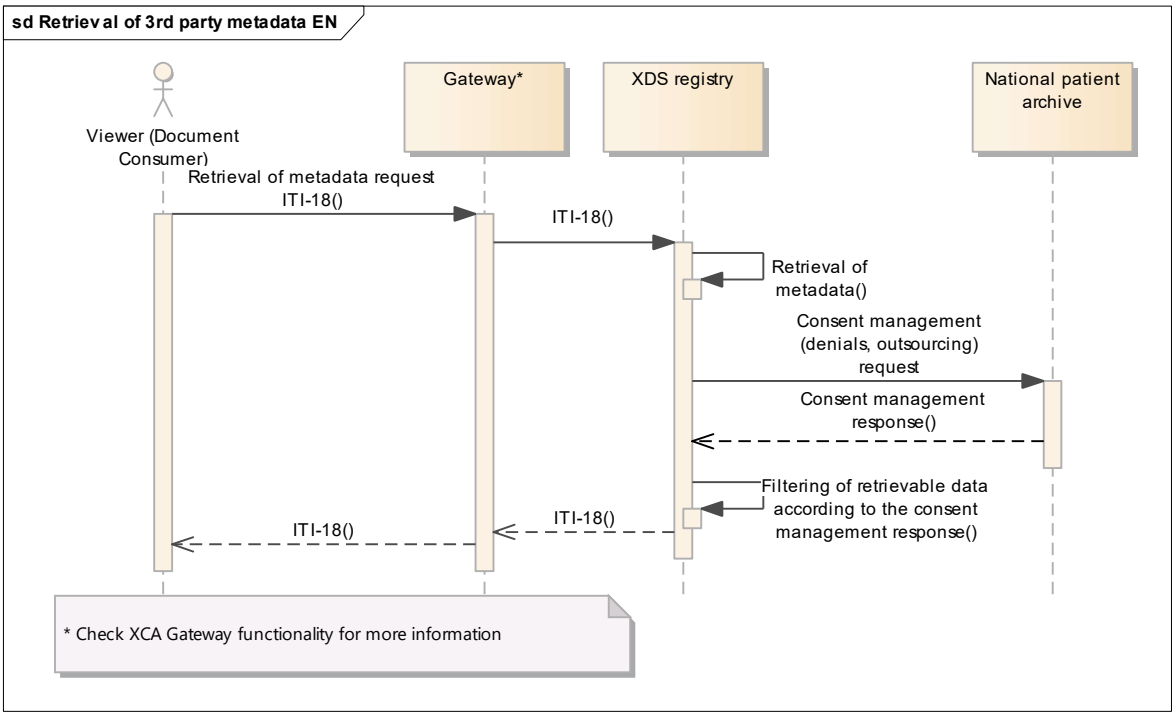

Figure 7 Retrieval of 3rd party study metadata

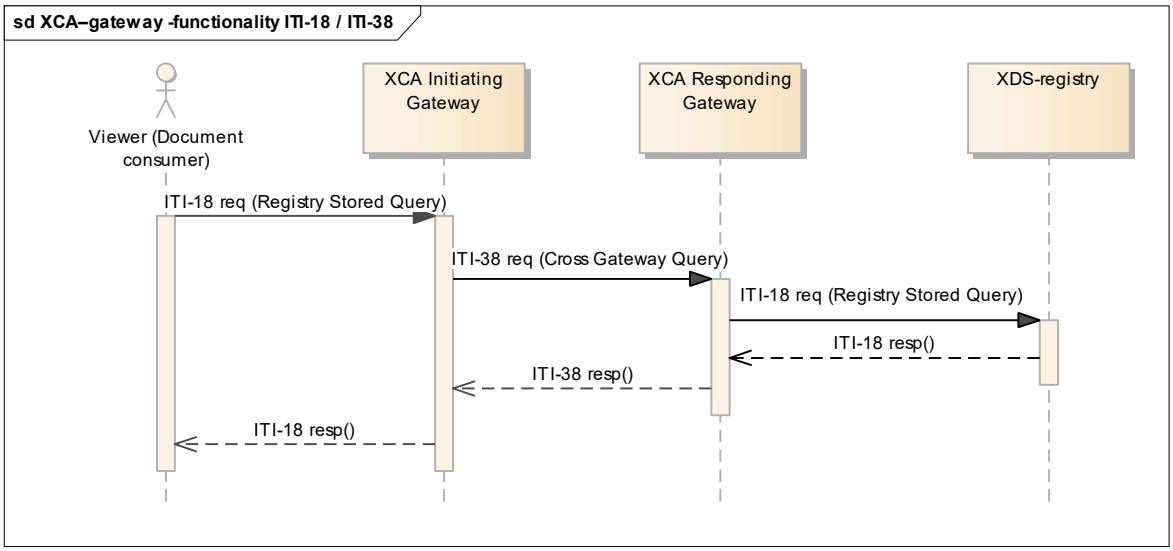

Figure 8 XCA gateway functionality (ITI18 / ITI 38)

After the result set has been returned, a search for the content description (manifest) in the imaging study is carried in a way that corresponds with ITI-43, i.e. Retrieve Document set transaction, via the XCA gateway. The gateway is able to carry out the search in the Kvarkki repository on the basis of the homeCommunityId and RepositoryUniqueId returned from the registry query. The manifest includes the 'location data' and object references of the study. These steps are described in the sequences diagrams below:

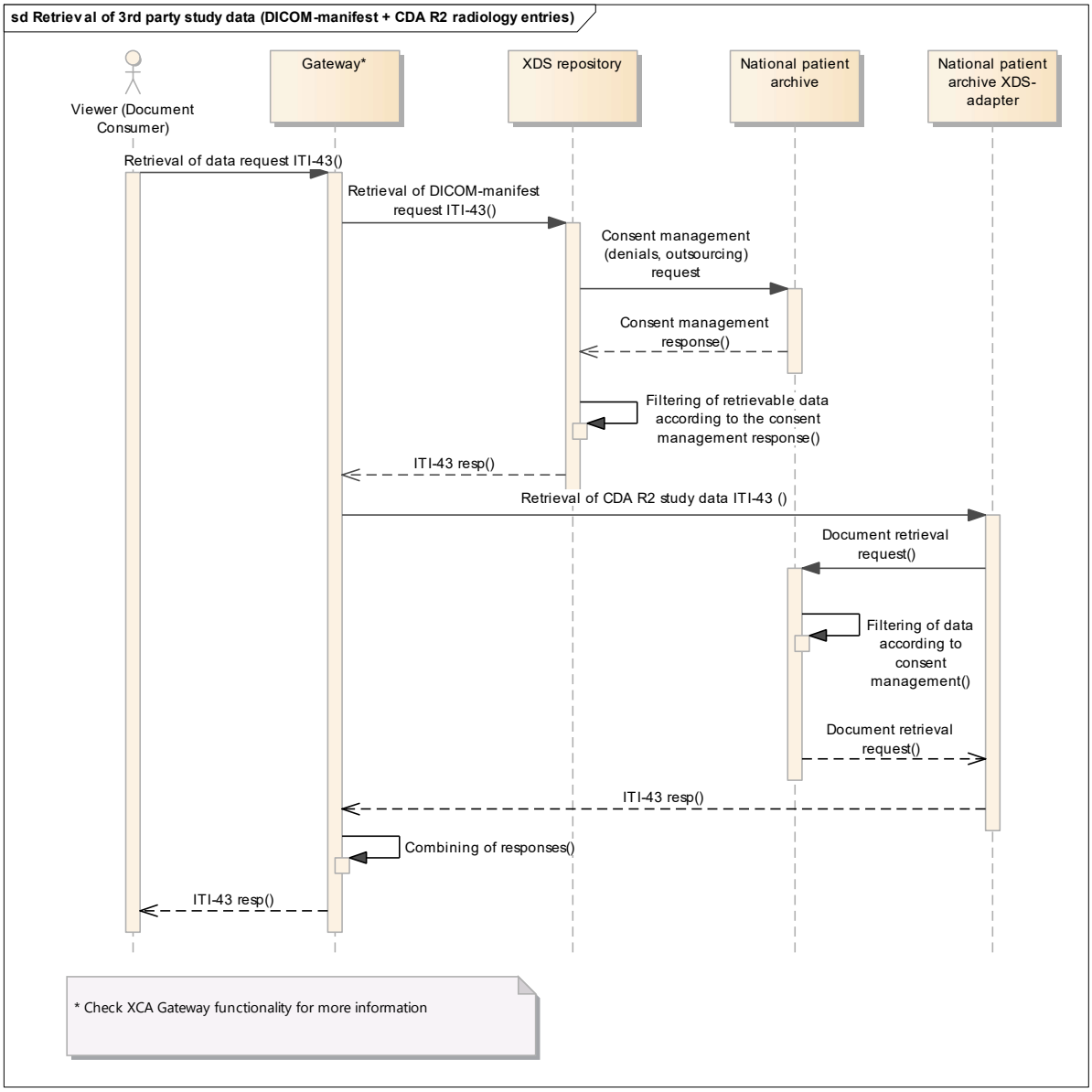

Figure 9 Retrieval of 3rd party study data (DICOM manifest + CDA R2)

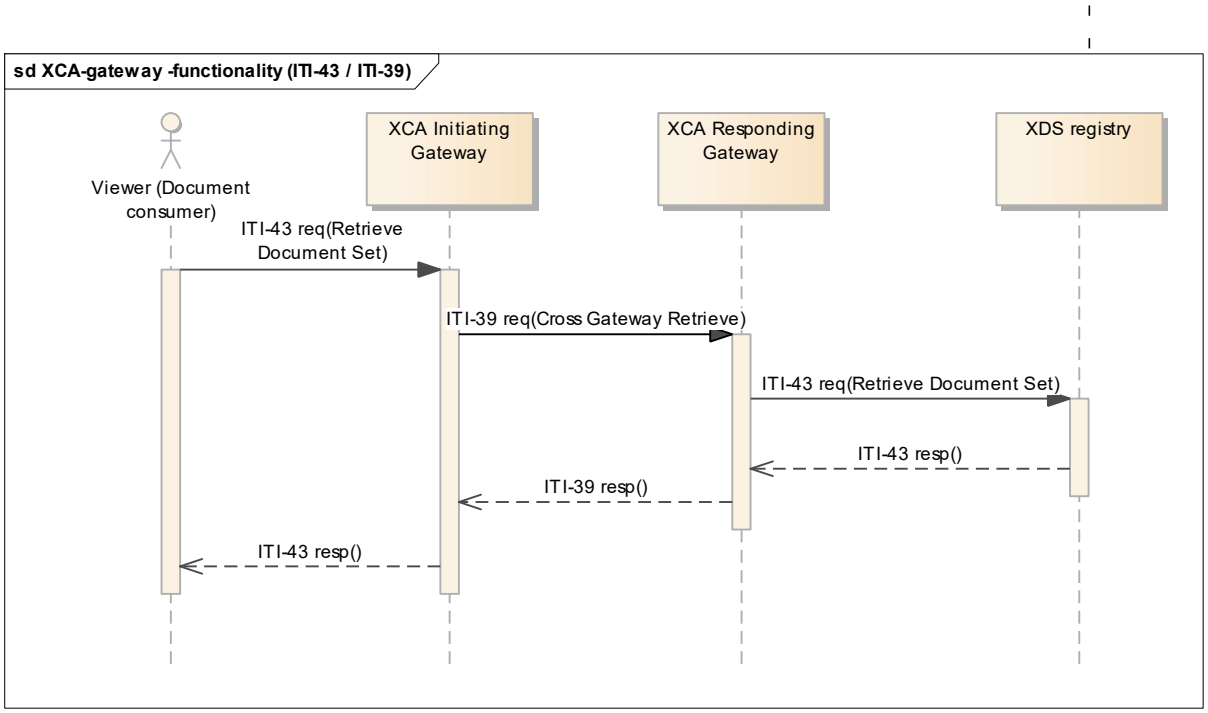

Figure 10 XCA Gateway functionality in ITI-43 and ITI-39

The actual imaging study or its objects are retrieved to the viewer with the RAD-69 (Retrieve Imaging Document Set) transaction via the XCA-I initiating imaging gateway. The content description of the imaging study includes the location data and object reference data required in the retrieval. These steps are described in the sequences diagrams below:

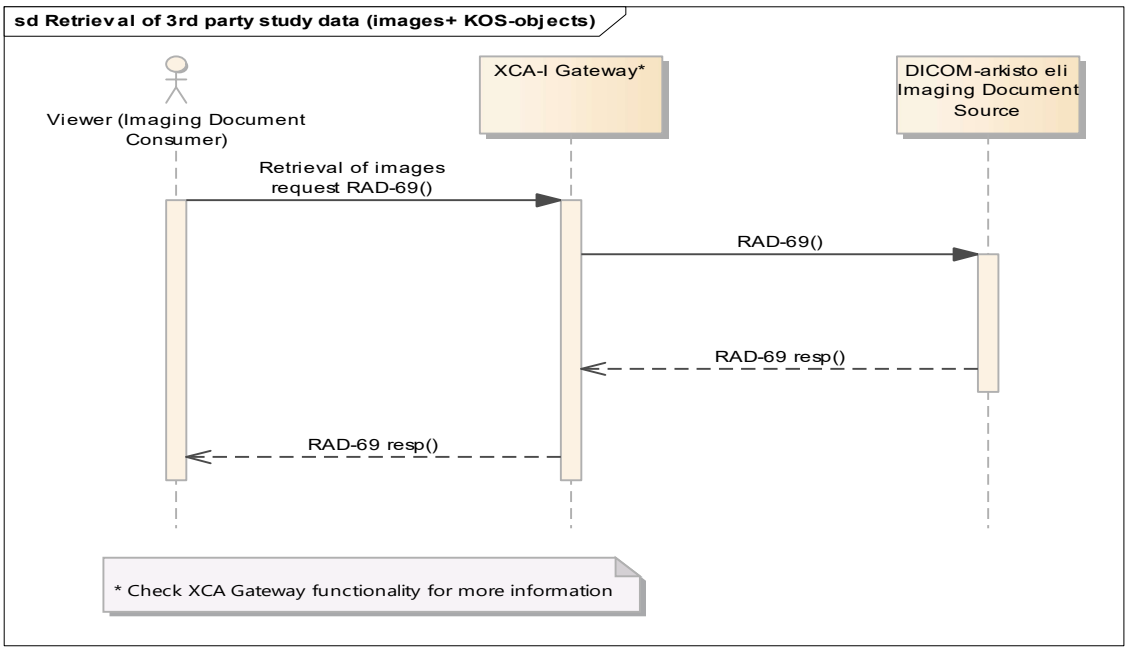

Figure 11 Retrieval of 3rd party studies (Images & KOS objects)

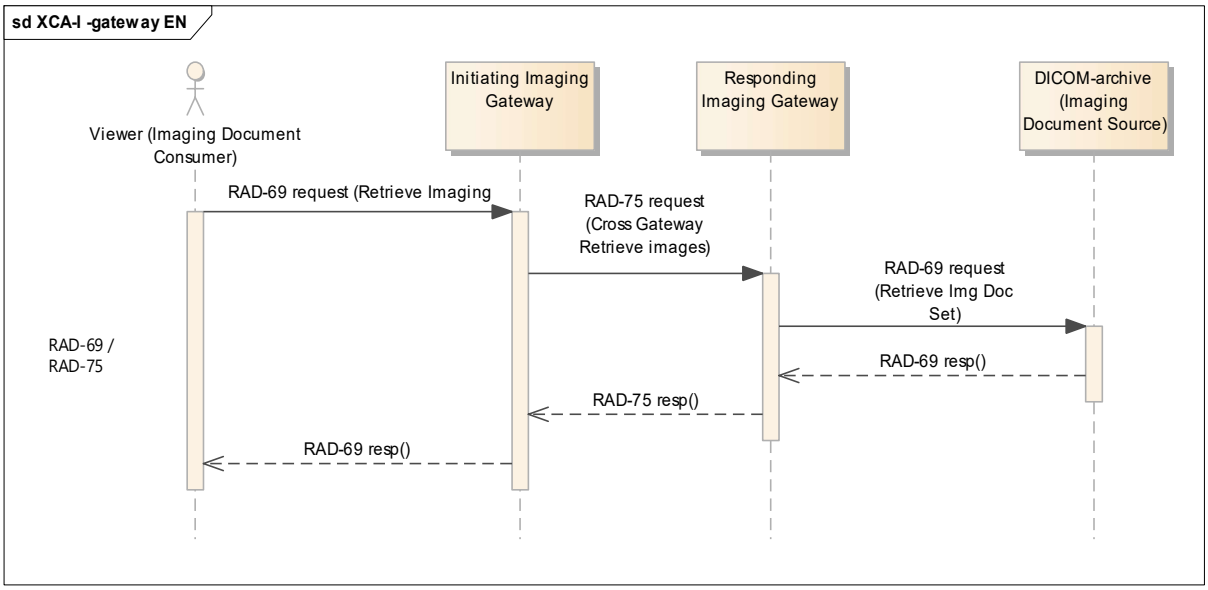

Figure 12 XCA-I gateway functionality

In addition, Kvarkki supports the search of own studies with a saved reference (see chapter 4.19). In such a case, it is possible to send a direct RAD 16 (DICOM C-MOVE) request, without using XDS interfaces, to the Kvarkki DICOM archive, which sends the study to the PACS system using a DICOM CSTORE service request.

The Kanta archive has registered the CDA documents in Kela's Kvarkki registry, and they were included in the result set of the registry search. The documents can be retrieved with an IHE Retrieve Document Set [ITI-43] transaction or with the HL7 V3 interface of the Kanta archive.

The user can utilise imaging studies archived in Kvarkki also from the key health data of imaging in the patient data management service or the imaging study documents saved in the Kanta archive. The study documents include the metadata (for example, the encounter id, service provider and service unit data, time qualifiers) and the actual contents of the document (for example, SUID identifier, i.e. Study Instance UID, and the imaging study code), which may be utilised in the limitation of Kvarkki searches. Opening a specific imaging study in the viewer takes place in the same way as described above.

4.1.3 Ensuring the saving of the studies

To ensure whether the study is archived in Kvarkki there are three options that deviate from one another in terms of transferring the responsibility of storing the study. DICOM Storage commitment is mandatory since it is the only way to transfer the responsibility of storing the study for the Kvarkki DICOM archive.

- DICOM Storage Commitment (ensures DICOM storage of study in centralised Kvarkki but does not directly cover XDS registration)
    - If the Storage Commitment request returns a successful response, centralised Kvarkki has approved and archived the study, in which case the study is also compatible with XDS registration.
    - Storage commitment ensures technically that the study can be read back into the client PACS system.
    - However, if registration fails and the client has received confirmation of archiving with Storage Commitment, it is a question of error situation at centralised Kvarkki and Kela is responsible for clearing the error.
    - Storage commitment has to be sent after archiving the study including KOS objects
    - Storage commitment is queued and efforts are made to send it to the client system for 24 hours.
- DICOM Instance Availability Notification – IAN (ensures saving of study in the Kvarkki DICOM archive of centralised Kvarkki and in the XDS register)

- If centralised Kvarkki sends information about the saving of the study with an IAN notification, the study is also XDS-registered
- IAN does not ensure technically that the study can be read back into the customer's PACS system so transferring the responsibility of storing is not possible.
- Kvarkki will send IAN notification to supported systems after registering the DICOM study. The sending of the IAN notification is queued and efforts are made to send it to the client system for 24 hours.

- Utilisation of XDS/XCA interfaces when ensuring the saving of studies in centralised Kvarkki
  - Similar to IAN: using XDS interface only does not transfer the responsibility of storing the study for Kela

The operation of DICOM Storage Commitment and DICOM Instance Availability Notification supported by centralised Kvarkki are described as sequence diagrams in below.

The use of DICOM storage commitment in Kvarkki is described in the sequence diagram below:

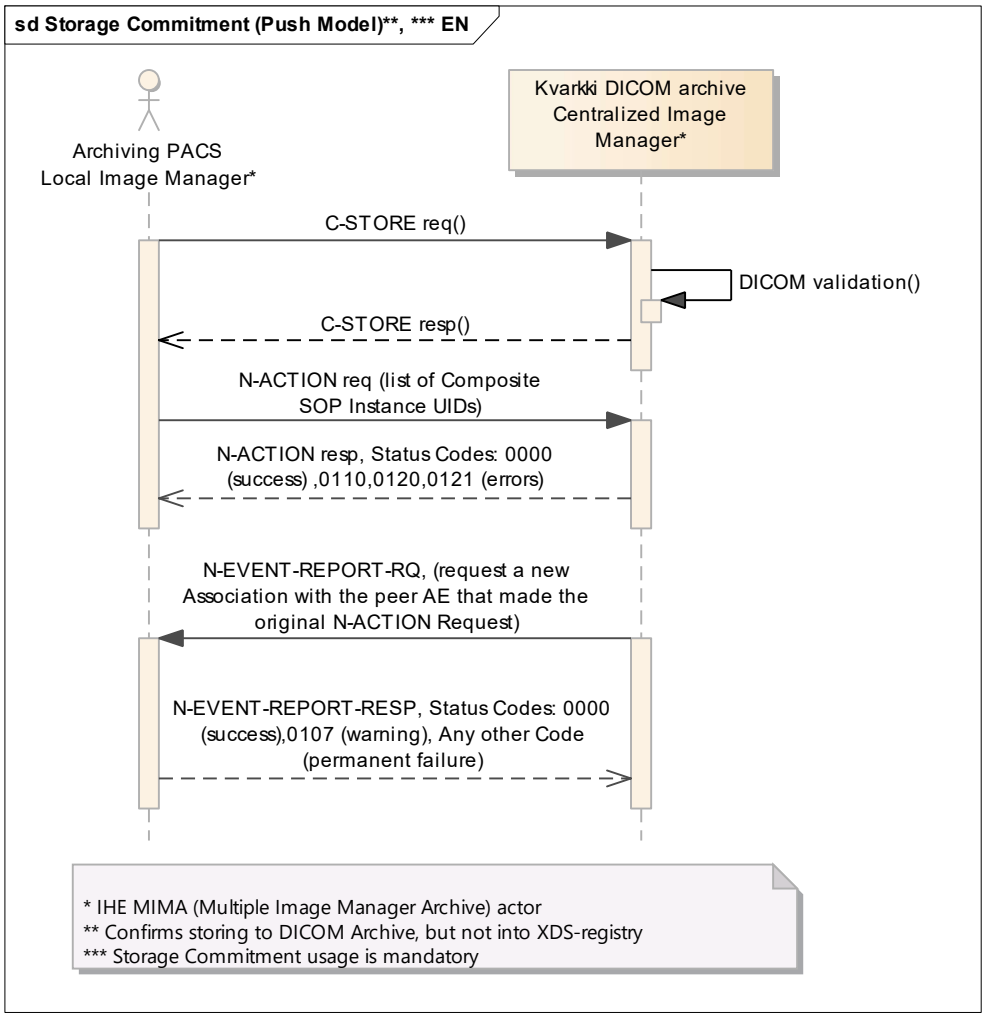

Figure 13 DICOM Storage Commitment usage in Kvarkki

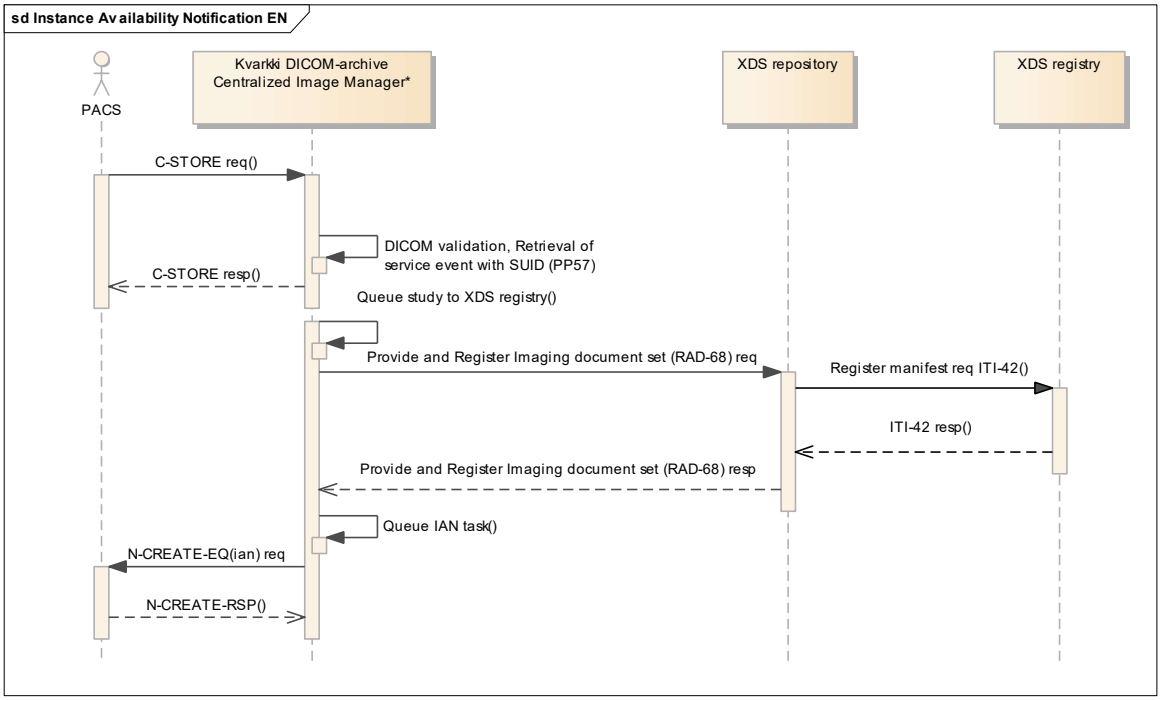

Figure 14 Operation of DICOM Instance Availability Notification in centralised Kvarkki

4.1.4 Time values (UTC) in the XDS-registry

According to the IHE specifications[4] All date time values in the Kvarkki XDS registry are stored using Coordinated Universal Time [UTC]. This involves the metadata of DICOM and CDA R2 documents that are registered in the Kvarkki XDS registry. UTC time is also used in XDS transactions so document consumer is responsible for the conversion to the local time when presenting the data to the user.

Kvarkki supports the DICOM tag Timezone Offset From UTC (0008,0201). If time zone is given in this tag Kvarkki will convert manifest's time values in the XDS metadata accordingly when registering the manifest. If the tag (0008,0201) is not given or it is empty, Kvarkki will convert manifest's XDS metadata according to the Finnish time zone when registering the manifest. Conversion will always take daylight saving time into account.

DICOM studies are always stored as is which means that no time value conversions are made to DICOM tags – only to the manifest's XDS metadata (e.g.serviceStartTime and serviceStopTime).

Concerning CDA R2 documents, The Kanta archive does not currently support time zones. Kvarkki will however convert time values to UTC when CDA R2 document is registered in the XDS registry. Conversion will be done according to the Finnish time zone taking daylight saving time into account. Kvarkki has however support for time zones for future use should the Kanta archive start utilizing time zones.

	Examples of time value conversions in Kvarkki		
	Incoming timestamp	**XDS-registry**	**ITI-18 -transaction**
Sans time zone	20170810153010	20170810123010Z	20170810123010
With time zone	20170810153010+0300	20170810123010Z	20170810123010

4.1.5 Offline status in the XDS registry

If the imaging CDA document is nullified in the Kanta archive, Kvarkki utilizes the DocumentEntry.documentAvailability metadata's offline value with the manifest that was referenced by Study Instance UID from the CDA document. Such cases can be e.g. a wrong service event id in the

[4] IHE Technical Framework Vol. 3: "All date time values in the registry are stored using Coordinated Universal Time [UTC]. "UTC" implies that time shall be converted from/to the local time"

CDA. The manifest's documentAvailability metadata is set to offline but availabilityStatus metadata remains 'Approved'. Manifest's metadata will then not be returned by default requests (MetaDataLevel=1).

However if the CDA document is corrected and archived again with correct data and the same Study Instance UID, the manifest will be set to online again and its metadata is updated with correct information e.g. correct service event id.

4.1.6 Technical solution and implementation

Kvarkki implementation is presented in the following figure, which contains the functional subsystems of Kvarkki, as well as the most relevant healthcare organisation systems and Kanta subsystems in terms of Kvarkki. The most important direct connections between the subsystems are presented in the figure without technical details. The latter chapters of the specification provide a more extensive and detailed description.

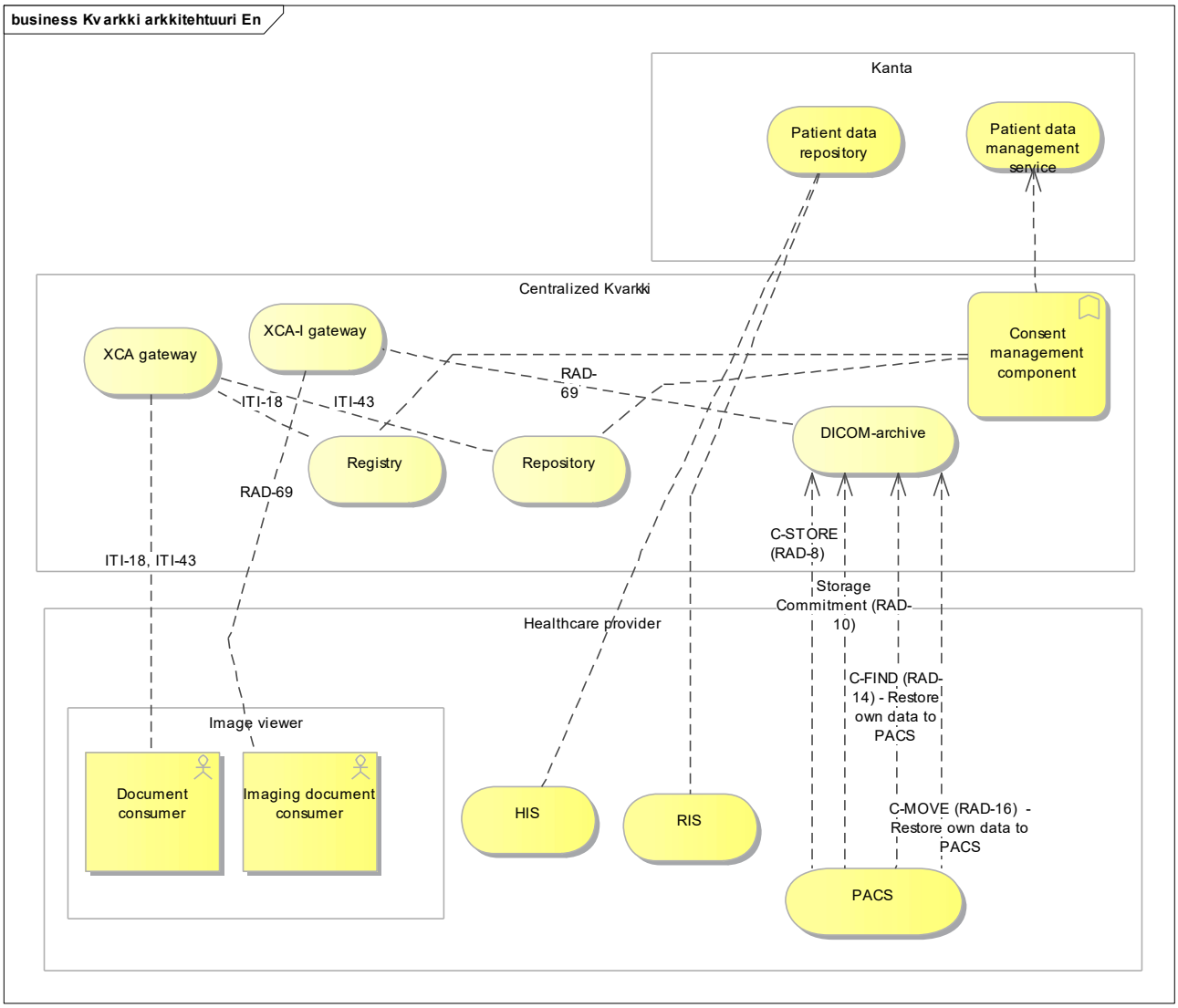

Figure 15 Kvarkki technical architecture with IHE and Kanta concepts

The subsystems and components, the role of which is not specified by IHE profiles and which have a specific meaning to Kvarkki:

- Consent management component
  - Carries out a consent management check when the Kvarkki subsystem returns patient data

- PACS
  - One or several in the PAC organisation that archives imaging studies in Kvarkki
- HIS
  - A hospital information system that establishes the encounter required by Kvarkki
- RIS
  - Radiology information system, plays a key part in the imaging workflow
- Kanta Patient Data Management Service
  - Source of consent documents for Kvarkki
  - The aggregator of aggregated information in imaging and the source of information for those utilising the imaging study entity
- Kanta archive
  - Source of encounter information for Kvarkki
  - Archive of imaging study documents

The following are in accordance with the IHE profiles:

- Registry
- Repository
- Imaging document source (The Kvarkki DICOM archive)
- XCA gateway
- XCA-I gateway
- Document consumer
- Imaging document consumer

4.2 Management of encounters with the Kanta archive; conditional archiving

The Kvarkki model complies with the Kanta archive principle that it is not possible to archive patient care documents for an encounter until the encounter document has been archived, i.e. the encounter has been established. Therefore, Kvarkki verifies the existence of the encounter document from the Kanta archive in connection with archiving the imaging study.

In normal situations, it is permitted to carry out archiving only with respect to the service provider's (=custodian's) own encounter. Outsourcing scenarios are described in the section on outsourcing in this document. The encounter IDentifier is unique for the archived imaging study, i.e. the study can be subject to one encounter only. Different encounters can (recommended procedure) refer to documents of other encounters with non-formal references. For example, the encounter IDentifier or the identifier that identifies the study may be used for the identification of the references: Study InstanceInstance UID. The processing of imaging comparison studies is handled in further detail in chapter 4.6 Searching, utilising and possible copying of comparison images to another encounter.

4.2.1 Technical solution and implementation

The encounter check is carried out by the Kvarkki DICOM archive. When storing the content description (manifest) in the repository and registering it, it is assumed that the Kvarkki DICOM archive has already carried out the check and the check will not be carried out again. The Kanta archive performs a encounter check always when archiving CDA documents, and a check is not needed in XDS registration of CDA documents.

Kvarkki searches the information about the existence of a encounter with a Study Instance UID from the Kanta archive with service request PP57[5].

DICOM has no standardised way to notify of archiving that has been prevented due to an unknown encounter (an encounter missing from the Kanta archive). The mechanism for the failed archiving due to an encounter error has been specified to be returned as a custom Cxxx DICOM error code,. PACS handles the error situation on the basis of the return values specified by DICOM. Kvarkki's custom DICOM error codes and recovery guide are provided in appendix 1.

4.3 Outsourced services

Kvarkki supports outsourcing in accordance with the principle of the Kanta specifications. In this context, outsourcing refers to the production of encounters, studies or their parts by someone else than the service purchaser responsible for the service. The technical implementation of outsourced services can be built in the Kanta and Kvarkki interface in three ways.

1) Outsourcing authorisation gives the service provider the privileges to search and/or archive documents in accordance with the general rules on outsourcing authorisations (patient-specific or service-specific outsourcing).

2) In permanent outsourcing scenarios (for example, regional imaging or laboratory organisation), documents may be saved in the purchaser's register without saving the authorisation of the outsourced service. In such a case, the imaging study is saved directly under the purchaser's name and the Kanta addressing service has specified that the service provider is allowed to use the purchaser's connection point. In this model, operations are treated as if they were carried out by the organisation itself and the organisation providing the imaging service is treated as if it were part of the purchaser of the service. Permanent outsourcing scenarios can also be implemented according to method 1).

3) A DICOM study is saved in another party's registry in accordance with the encounter in the Patient records archive, the custodian and registry information is not transferred in DICOM messaging.

Contents are saved into Kvarkki by different parties (the service purchaser, i.e. the subscriber, or the service provider) depending on whether the entire encounter, the study in its entirety or only the report is produced as an outsourced service. It is common in these situations that the archiving of the encounter is required before the study documents are saved. Situations and operations from the Kvarkki point of view are described elsewhere in this specification.

When an entire encounter is produced as an outsourced service, the operating model described in the Kanta archive specifications shall be complied with, where also the encounter is established by the provider in the purchaser's registry. After the study has been completed, the outsourced service provider archives the completed imaging study and the related imaging CDA documents for the encounter it has established in the purchaser's registry.

When a whole study is produced as an outsourced service, the purchaser of the outsourced service archives the CDA document containing the referral in the Kanta archive under the encounter it has established. The outsourced service provider retrieves the document or obtains the information on request from elsewhere, and carries out the imaging study. After the study has been completed, the outsourced service provider archives the completed imaging study and the related imaging CDA documents in the purchaser's registry for the encounter established by the purchaser.

When a report is produced as an outsourced service, the purchaser of the outsourced service shall archive the imaging study in Kvarkki under the encounter it has established and the imaging CDA documents, including the referral and study entries, in the Kanta archive. The outsourced service provider retrieves the archived documents and imaging study with any reference images, and produces the report. The report is saved in the imaging CDA document in accordance with the CDA definitions, and it is archived in the Kanta archive under the purchaser's encounter and the purchaser's registry.

In implementation method 1, the outsourcing authorisation gives the service provider the right to use patient information (documents) specified in the service purchaser's authorisation in accordance with own use, i.e. regardless of patient consents or denials. The right is taken into account in connection with

[5] Kanta.fi: Kanta kevyet kyselyrajapinnat [11]

the outsourced service and consent management checks in Kvarkki. However, usually the most extensive set of information is provided with the patient's consent.

4.3.1 Technical solution and implementation

The outsourcing authorisation document (form CDA R2) stored in the Kanta archive is required in outsourced service method 1 in order to deduct the archiving right. With respect to saving the CDA documents, the Patient Data Archive operates in accordance with the Kanta specifications. DICOM studies saved in the Kvarkki DICOM archive are allocated to the encounter in accordance with outsourced service method 3, and therefore an outsourced service authorisation is not needed. The purchaser and service provider must have an agreement on the provision of outsourced services which, however, will not be verified by Kvarkki.

In document queries, the verification is also carried out in the access control of the XDS repository and registry. The right to act in an outsourced service role is verified by automatically retrieving the outsourced service authorisation document by the Kvarkki DICOM archive and checking the authorisation from its contents. When using the outsourced service authorisation, the sender of the service request shall not include a reference to the authorisation, but the Kanta archive or the Kvarkki subsystem that provides the service will verify the authorisation if the sender of the message otherwise does not have a right to carry out the operation.

A regional operator may also carry out an outsourced service situation in other ways, but the arrangement must meet the national specifications with respect to the operational scope and reliability, and it is recommended to carry out the solution in accordance with the Kvarkki specifications. With respect to documents searched from the Patient Data Archive and the imaging CDA documents to be saved, the Kanta archive functions in accordance with the general outsourced service procedure.

When using a permanent addressing connection in the service request messages of the Kanta archive, the message frames will include the purchaser's information even if the sender is the service provider. This operating model requires an agreement between the purchaser and provider, and Kvarkki access control does not interpret the situation as an outsourced service. In an outsourced service of type 3, the Study Instance UID obtained from the DICOM traffic will connect the recording to the encounter in the Kanta archive, and on the basis of the technical verification of its connection the DICOM study can also be archived as an outsourced service.

In the query situation, the organisation data is produced in SAML attributes, which are described in chapter 7.2 of this specification. The outsourced service situation can be verified from the fact that the service provider's custodian information specified with the service request does not correspond to the service purchaser's custodian information of the encounter in the patient care context.

4.4 Access control

Access control to the Kvarkki DICOM archive is based on similar mechanisms as with the Kanta archive. The mechanisms are described in the following diagram:

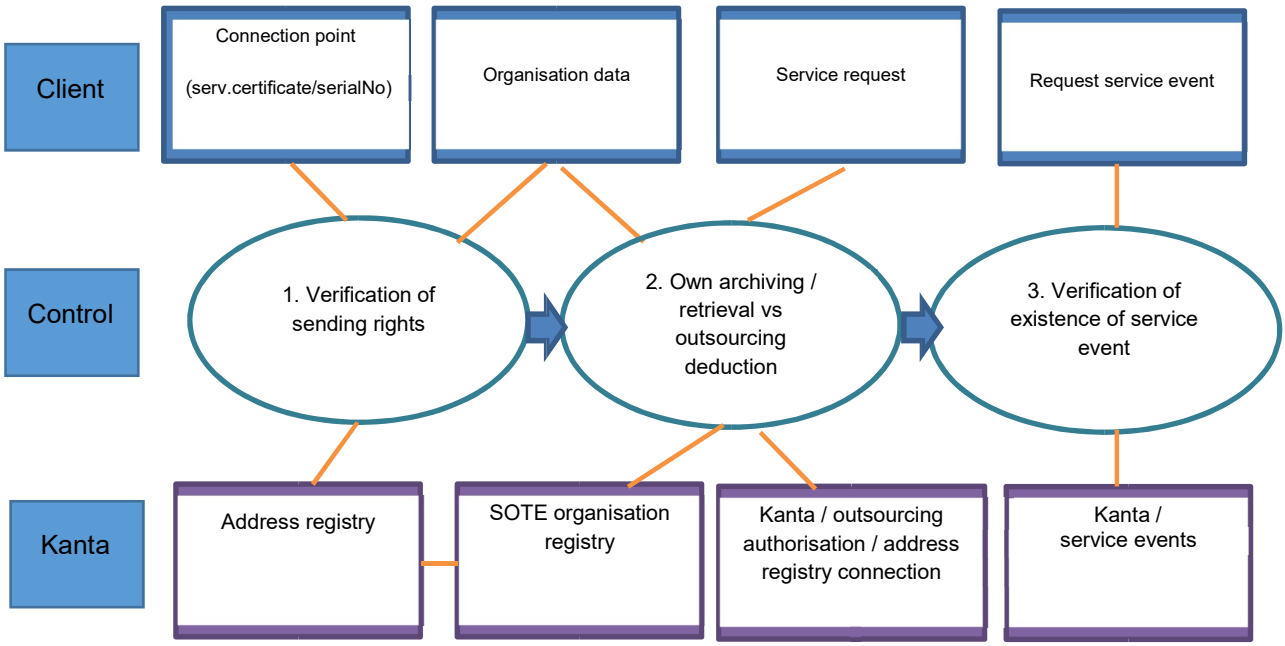

Figure 16 General principle of access control in archiving

The party's right to send messages to the Kvarkki actor is verified in control 1. Control 2 is implicit when storing a DICOM study. An actual 'own archiving vs outsourced service' deduction is not made, but the DICOM study can be attached to an existing encounter in the Kanta archive and the target register of storing is determined in accordance with the encounter as described in the chapter on outsourced services (alternative 3). Control 3 is required in all archiving and searches. In connection with archiving, the verification of the existence of an encounter means that it is verified that the encounter in which studies or other documents are being stored has been established. In connection with searches, an encounter means a so-called encounter in the patient care context.

Data communications with the centralised archive must always be TLS-based. The basic principle is that the message includes the information about the sender of the service request and that the service request arrives in the Kanta archive via a connection point defined in the addressing service. That way, it is also possible to identify a situation where the sender of the service request does not match the custodian in whose register the document is being saved. The user right of the sender of the service request is configured separately for each transaction.

Access control checks are made by the Kvarkki registry in registration and registry query transactions, the Kvarkki repository in archiving and retrieval transactions and the Kvarkki DICOM archive in study retrievals (RAD-69 & RAD-16).

The user right checks concerning documents and information subject to transactions are the responsibility of consent management and the verification of the existence of an encounter, also including outsourced service situations. These are described in the other sections describing the operating model.

4.4.1 Identification and verification of parties, and trust relationships

Certification, administrative processes, etc. provide the basis for the trust relationship between the parties mainly at the organisation level. The procedures ensure that a joining organisation and the systems used by it meet the Kvarkki connection requirements. As a result of these and the connection process, the party will be recorded as a Kvarkki user and added to the address directory.

Archiving, query and retrieval service clients have to be identified with sufficient reliability. A technically reliable procedure is used at runtime in order to identify the server of the other party. The other party is expected to use a certificate granted by a reliable certificate authority, in practice, the healthcare server certificate of the Population Register Centre. Based on the Kanta address directory or a similar regional solution, it is verified that the organisation is entitled to use the connection point in a technically reliable

way, identified with the certificate. When building a system configuration and installing certificates, verifications on the technical validity are made. Connection point requirements and principles for Kvarkki integrators are the same as in the Kanta services in general.

TLS identification (two-way authentication) and encryption are used in all DICOM traffic in Kvarkki. In addition, identification of parties is also based on configured Application Entity (AE) data. It is possible to use tunnelling in the connections, which is also sensible, depending on applicability.

The personal-level identity notified in the XUA element of XDS and XDS-I transactions of the user sending the request is not verified at the server. The owner of the sending system that sends request is responsible for the validity of data in the request.

With respect to the services in the Kanta archive, identification of parties in HL7 V3 connections takes place in accordance with the Kanta specifications.

4.4.2 Technical solution and implementation

Query or retrieval service clients have to be identified with sufficient reliability. With respect to servers, the identification of parties is based on a certificate-based procedure also supported by the ATNA profile. In addition, Kvarkki also uses IHE XUA profile designed for this purpose to identify the calling organisation and user in other than DICOM traffic. The profile defines SAML 2.0 as the technology to be used, as well as mandatory and optional elements of XUA in addition to the assertion elements required by SAML.

Data transferred by XUA is not expected to be fully obtained from the user identification and verification, but the data set by the sending system is trusted. It is ensured in a technically reliable way that the assertion received has been created with a trusted system, implemented by server certificates and TLS (two-way authentication). Two-way TLS has been implemented in the same way as in other functionalities of the Kanta archive as a two-way function, i.e. the Kanta archive is responsible for the fact that connection of the organisation party to the connection point will be verified in message traffic. In practice, the ID of the connection point is the same as the SerialNumber of the Subject section of the server certificate and the organisation ID is obtained from the SAML element urn:oasis:names:tc:xspa:1.0:subject:organization-id (see further in section 7.3 SAML table). In addition, the right of the organisation party and the connection point to use the requested XDS transaction is verified, for which the systems must produce the transaction ID in the SOAP Header wsa:Action field in accordance with the IHE definitions[6]. Every XDS transaction must include a unique WS-Addressing wsa:MessageID for logging purposes in Kanta system. The verification is based on the use of the Kanta address directory.

In web service transactions, Kvarkki expands the SAML elements used so that information about the patient care relationship is transferred with assertion, in practice, the encounter id of the care context and information about the organisation sending the request. Information about the connection point is obtained from the TLS certificate. Based on this data, the organisation's right to use the connection point is verified from the address registry. As stated above, in the case of DICOM it is not possible to use SAML assertions.

Authentication is managed with a two-way TLS procedure in the same way as with the Kanta archive. Therefore, there is hardly any difference between XDS-based traffic and the Kanta archive. In DICOM based communication the joining systems are identified with the server certificate and the Kvarkki DICOM archive and the systems joining it identified with the AE Title.

Based on the AE Title, Kvarkki can limit the rights of using DICOM services and obtaining the studies, and it can write both use logs and technical logs from the transactions. The joining PACS system can use its existing AE Titles in Kvarkki. THL's policies are complied with in access control in DICOM traffic:

1. The use of the Kvarkki DICOM archive is permitted only for PACS systems operating from an identified connection point (= systems with IDs (AE Title) specified as permitted in Kvarkki DICOM archive)

[6] https://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2x.pdf

2. The PACS system may use one or several IDs (AE Title) for calling (Service Class User - SCU) and providing (Service Class Provider - SCP) DICOM services
3. One or several organisations can use the same PACS system. The user rights in the Kvarkki DICOM archive are limited for each PACS system/AETitle, not for each organisation
4. An organisation may have several PACS systems that can save and search for the same material with the configuration of Kvarkki DICOM archive access control
5. Only the PACS system that has produced the data or other PACS system used by the same organisation has access to material saved in the Kvarkki DICOM archive. The user rights of the DICOM interface must not be extended to archiving PACS system and, with respect to searching, the PACS system of another organisation
6. The producer of the imaging material cannot move a study it has produced to the PACS system of another organisation through the DICOM interface.

The user rights of DICOM commands are configured for each AE Title when joining Kvarkki. An individual (one or more) corresponding AE Title (Called AET) is created for each AE Tile (Calling AET) of the client at the Kvarkki side, and the client's system uses this title as the DICOM call ID towards centralised Kvarkki. No other client has a right to use it.

If an organisation is using several PACS systems, they can be connected to the same call ID at the centralised Kvarkki side, in which case the different PACS systems of the organisation have access to the same studies saved in centralised Kvarkki. The main principle of using AE Title in centralised Kvarkki is described in the following diagram:

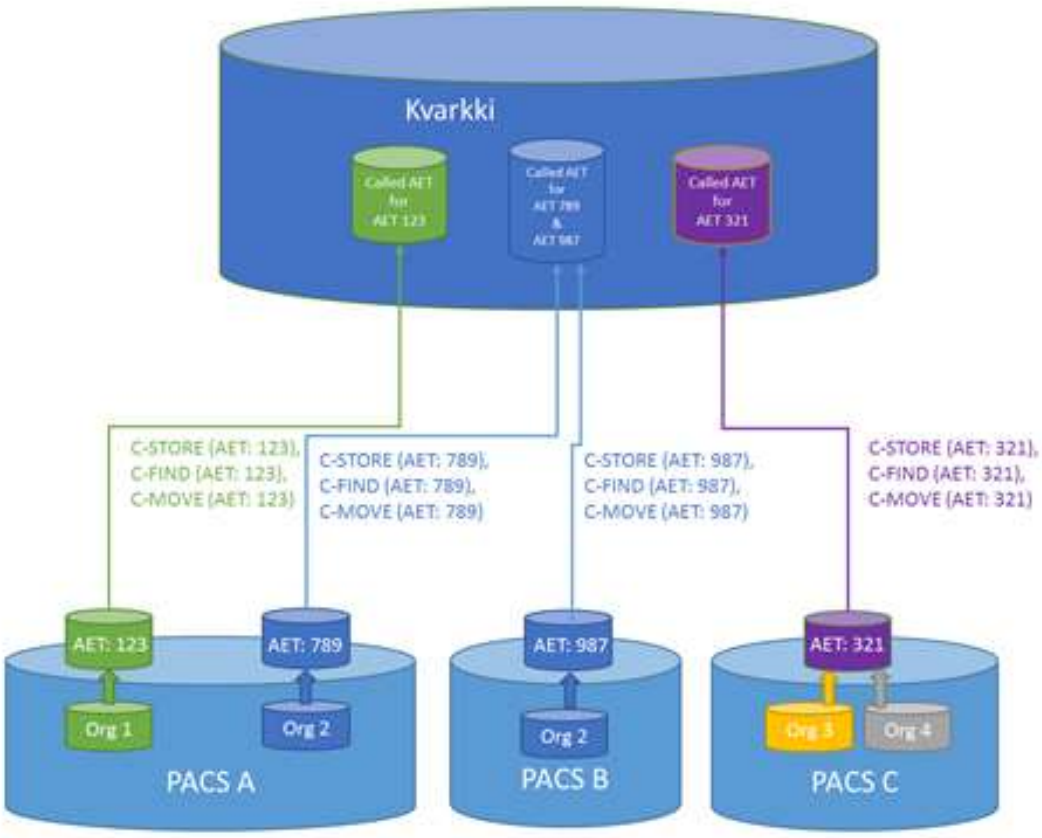

Figure 17 The use of AE Title in DICOM requests in centralised Kvarkki

DICOM traffic in the client's direction from centralised Kvarkki with respect to C-STORE and Instance Availability Notification services requires a gateway/port-specific Called AE Title at the client's side. If, for example, the client wants to receive IAN notifications in a different gateway than the C-STORE commands arriving from centralised Kvarkki, centralised Kvarkki needs from the client dedicated calling

AE Titles and gateways for both services. A response to the Storage commitment request is always sent back to the AE Title (and the gateway specified for the AE Title in question) that it was requested from. If all of the client's DICOM reception services operate in the same IP address/DNS and gateway/port, a minimum of one AE Title at the client's side is sufficient. The use of C-MOVE commands is technically limited as a default and therefore it is not possible to carry out unlimited commands to move studies into any PACS system using the C-MOVE command. As a default, the C-MOVE command can be used for moving studies only into the PACS system where the study was produced. There also can be multiple allowed C-MOVE destinations in the configuration.

4.5 Archiving of incomplete documents for reporting or patient transfers

An 'incomplete' imaging study can be stored in Kvarkki as soon as the required encounter document has been archived in the Kanta archive. However, from the viewpoint of Kvarkki architecture, a study is never actually incomplete, but it can be versioned by supplementing the imaging study entity and by implementing change management methods. Nevertheless, an imaging study produced by an aborted or failed examination must not be archived. The principle is the same as with the Kanta archive in general. However, archiving that is as quick as possible is important especially to enable patient transfers and outsourced reporting on the study. This may require a possibility to 'hasten' the storing of the study in the technical implementation of the imaging workflow. The stored imaging study is utilised in the outsourced service or shared workflow process when reporting on it and, if necessary, it can also be supplemented.

Completing an incomplete imaging study is manifested so that the entity of imaging documents includes all entries related to the study, including any reports. This deduction is left to be carried out by the person utilising the imaging study. It is not possible to deduct in a reliable way in all situations because archived documents do not show, for example, a missing requested additional report or a detected remedial need, and no report is supplied on all studies.

An imaging study that has been completed at a later date may have been shared from the Kvarkki DICOM archive as incomplete to another healthcare unit. This kind of sharing of a previous version can be seen, e.g. in the logs, and the contents of the shared study can be found out from the timestamps of DICOM objects in the latest imaging study version. Logs and a more detailed analysis of the study are used only in exceptional cases in separate studies. It is assumed that no user functions to examine the timestamps of objects in the imaging study are available.

Those who have retrieved an imaging study on a previous occasion will not be informed of the completion of an imaging study. This operating model corresponds to the Kanta archive in general.

4.5.1 Technical solution and implementation

The technical solution for an 'incomplete' study requires no special procedures, and studies are always processed as complete in the Kvarkki DICOM archive.

PACS must send updates of the imaging study, i.e. added or altered objects, to the Kvarkki DICOM archive whenever they have been saved in PACS.

DICOM Online Electronic Storage Secure Use Profile contains, e.g. rules for setting the statuses (statuses Original (OR) and AuthorizedOriginal (AO)), but it is not applied in Kvarkki at least in the first stage.

4.6 Searching, utilising and possible copying of comparison images to another encounter

The Kvarkki environment enables sharing of comparison images and other radiology documents across regional boundaries.

The aggregates on imaging in the patient data management service include the entries of all imaging CDA documents saved in the Kanta archive, and this can be a starting point for utilising the comparison images. Another option is to query for documents in the imaging study entity with XDS services. The query for imaging studies can be limited, e.g. on the basis of modality, anatomic region and the required time frame. As a result of the query, the user will see the studies in different areas matching the query,

as well as the imaging CDA documents saved in the Kanta archive. The encounter IDs related to the documents are also returned as metadata in the query.

The study selected by the user is retrieved to the workstation application for viewing. Studies used from the organisation's own area may possibly be utilised directly from PACS. If a comparison study has been produced by another custodian and it is necessary to make additions to it, it is saved as a local imaging study copy under the local name. A copy of a comparison study is saved in the same way as a new study by the workstation application to the local PACS system. A new Study Instance UID (0020,000D) must be created for the imaging study copy and new identifying object IDs must be created for all series (Series Instance UID - 0020,000E) and objects (SOP Instance UID - 0008,0018) that are part of the study. PACS will forward it in accordance with the normal archiving procedure to the Kvarkki DICOM archive, which takes care of registering the study/change in the XDS archive, and the study copy is archived in Kvarkki DICOM archive as a document of the archiving custodian.

Entries of comparison studies produced by the organization itself can be made in the above-described way in the copied study or in the original imaging study, which is still stored as a document of the original encounter. Using the original study requires that a reference to it will be saved as part of the patient data entries or report.

When using a study copy, entries are made on the imaging study copy taken of the original study, and it is attached to the encounter using the study. This also requires creation of new identifiers as mentioned earlier. It must also be noted that, in addition to the Kvarkki DICOM archive, the local PACS requires unique identifiers.

A note indicating that it is a copy shall be saved on the imaging study copy. The original imaging study identifier is saved in the imaging study object tags for traceability reasons.

If the person editing the comparison study is not able to set new identifiers for the study copy, the study copy shall not be archived in Kvarkki. In such a case, the study copy cannot be technically attached as part of the imaging study entity. As, for example, entries in the planning of a surgical procedure are significant data for the encounter in question, it is required that a free-form entry, which also enables locating the study, on the existence of an edited, unarchived study copy shall be made in the CDA documents. The healthcare provider is responsible for storing and deleting the unarchived imaging study copy.

The reports of comparison studies can be retrieved with the services of the Kanta archive or via the XDS registry query. Retrieved reports are not edited and the copy is not archived.

Comparison studies and their reports are referred to from the study and report entries of the CDA documents of the study to be produced. The reference is included in the description written by the user or similar, and Kvarkki is not able to understand or monitor the reference. If necessary, a query on the study referred to is made manually on the basis of saved reference data.

4.6.1 Technical solution

The workstation application acts as an XDS Document Consumer and performs the retrieval of studies in accordance with the XDS-I specifications: section 3.1.2 Retrieval of study. Any creation of new IDs and storage to PACS carried out after the retrieval are the functions of the workstation or another local system.

When using an imaging study produced in the organisation's own PACS as a comparison study, the study can be viewed from PACS. Editing of the imaging study requires that a copy is made of it and not only the new IDs but also the ID of the current encounter are set in it. Without these measures, the imaging study cannot be connected to the imaging study entity of the encounter that has produced and is currently using it. The study copy is saved in the local PACS system, from where it is archived into Kvarkki. Alternatively, it is possible to retrieve the organisation's own imaging study, which has been archived in Kvarkki, for editing.

A study with entries, brought from another XDS domain, is saved by the workstation application as a study of the local custodian in the same way as a new study. The Kvarkki DICOM archive requires a new unique Study Instance UID and unique object IDs for all imaging study objects to maintain the integrity of the Kvarkki DICOM archive in all supplementing, correction and retrieval situations. Before the storage, the DICOM TAG values of the study are replaced, e.g. as follows:

- DICOM tag, Original Attributes Sequence (0400,0561), Study Instance UID of the original study

In situations where the service provider is unable to archive the imaging study copy, it cannot be attached as a technical part of the imaging study entity.

Imaging study copies are usually saved in PACS, in which case it must be ensured that the study is not archived if the IDs have not been set according to the requirements.

4.7 Archiving of studies produced before Kvarkki for own use

- Instructions for archiving studies that were produced before the introduction of Kvarkki will be provided at a later date once the definitions are specified.

4.8 Description of query functions and use of query criteria

A query for imaging studies may begin with an imaging aggregate in the patient data management service extracted from patient care documents in imaging stored in the Kanta archive or with a query made in the XDS registry. All queries are patient-specific. Various query criteria are available in different stages of the query, depending on the route of the query. The technical query mechanisms are described in further detail in chapter 4.1.2 of this specification. The purpose of the chapter is not to specify user experiences with the software implementing the queries, but to specify the limitations and options for their implementation.

In a document query, clinical query criteria according to the IHE specification include PracticeSettingCode, HealthcareFacilityTypeCode and EventCodeList metadata, of which the latter is multivalued in the document and may include code values. XDS-I uses only the metadata attributes defined by XDS, and therefore there are hardly any named substance metadata concerning imaging. EventCodeList allows for multiple coded values to be included in the metadata, of which some are XDS-I-specific and others may be used as the affinity domain sees fit. IHE specification does not allow for the extra metadata attributes to be used as query criteria, the metadata is just returned in the query results. The Study Instance UID, AC number and Study Instance UID of the ID type, as well as encounter ID are stored in the ReferenceId attribute, which is also available as a query criterion. The possibility of use as a query criterion has also been described in further detail for each metadata in connection with the metadata model.

Generally, the XDS registry query allows no wildcards in the values of the query criteria. This is taken into account in the design of the metadata model, the most notable effect being the coded values of the anatomic region and modality in EventCodeList, which are deducted on the basis of the THL study code.

The registry query results in a list of documents with their metadata. Based on this metadata, the query performer chooses the relevant documents and retrieves the actual content. According to the selection, the document is retrieved with the retrieve transaction, and the querying application will show it to the user.

The encounter ID and possibly the Study Instance UID, on the basis of which the study documents can be found with a registry query, are available on the basis of the study entry obtained from the patient data management system or the imaging CDA document entry retrieved from the Kanta archive. The DICOM objects of the study can be retrieved in the above-described way with XDS-I mechanisms.

4.8.1 Especially protected information

According to the Kanta specifications, certain views (psychiatry and clinical genetics) constitute especially protected information. The view data is stored in the metadata of the imaging CDA documents in addition to the entry itself. The Ministry of Social Affairs and Health may prescribe by a decree in further detail regarding which client documents shall be classified as especially protected information. The Kvarkki metadata does not directly show whether or not a document registered in centralised Kvarkki contains especially protected information. The client system is responsible for deducting this with the aid of the view title of the imaging document.

The XDS metadata in the imaging study manifest do not have a view code for extra views, as the information about a query on the imaging study is not obtained with the imaging workflow. Therefore, any especially protected information cannot be deducted from the metadata of the manifest.

An imaging document consumer must use the view data obtained from the CDA documents also when deducting the especially protected information of an imaging study. A standard view RTG is registered in the XDS registry for the imaging study (manifest) without extra views, and therefore the imaging study itself cannot be handled as especially protected information.

4.8.2 Technical solution and implementation

The coded values of the anatomic region and modality are stored in the EventCodeList metadata in accordance with the Kvarkki metadata specification. It is also noticeable that only the modalities that are within CID 29 Acquisition Modality list are registered in the XDS registry. The codes can be used as query criteria together or separately, which enables queries with broad or exact matches.

The AC number, Study Instance UID and encounter ID are set for the manifest to be registered as a referenceId metadata. A query and retrieval carried out with reference obtained from the CDA documents is a mechanical function of the imaging document consumer, and the multiple stage process is not necessarily shown to the user.

The IHE specification recommends the use of only the query that returns the object references if the result set may be large. However, it is not possible to further limit the query with object references on the basis of data contents, but only to reduce the metadata queries into smaller units. Therefore, the Kvarkki solution basically recommends the use of a metadata query instead of references only. It is possible to limit the result set of a metadata query in advance with specified query criteria, but further instructions will be issued separately if the expanding result sets will cause problems at some stage. The XDS folder is unsuitable for use in the query functions because it has fairly limited query criteria (mainly the FolderCodeList). In addition, the folder may only contain references to documents in its own domain's registry, which will restrict its use in, e.g. comparison study references. Therefore, registry queries are made on documents. For the above reasons, the XDS folder structure is not used in Kvarkki.

The submission set is not a useful query area in a query on the archive contents, and in the Kvarkki architecture it will probably remain a necessary, albeit as such useless, technical structure.

4.9 Change management in imaging studies

In an environment such as Kvarkki architecture, there may be multiple copies or references of the same imaging studies in different systems (PACS, Kvarkki DICOM archive). When the changes are made in the studies, it is important that corrections and changes made in the study at a later date are also propagated in the archive.

Changes in the study can be divided into the following cases:

- New objects are added to the study
- Objects are removed from the study
- Metadata of the study is amended
- Changes are made to imaging CDA documents
    - Changes made to the imaging CDA documents are handled in the same way as other changes made in the Kanta archive by saving a new version of the documents. This is not described in further detail in this document.

4.9.1 New objects are added to the study

In the lifespan of an imaging study, new study objects may be saved in it, and these will be taken into account in accordance with the DICOM specifications when the new objects of the edited study are sent for archiving. The Kvarkki DICOM archive transmits the new imaging study for publishing as a new version of the study to the XDS archive.

4.9.2 Objects are removed from the study

It is not possible to use methods in accordance with the DICOM specifications to make changes to the study contents by deleting study parts or by marking them as deleted. Changes in the traditional imaging systems have been carried out so that a corrected/amended copy of the study has been removed and, after the change operations, a new copy is saved in a revised form in the PACS system. This leaves no trace of the corrections/amendments made in the studies.

IHE specifications are based on the principle that all changes made in the study will remain part of the study in both the imaging system (PACS) and the archive that is not dependent on the supplier. The changes that should cause the deletion of the objects form their own KOS object (change element) in accordance with the DICOM standard, which the IHE actors interpret and hide/show/share the objects that are not relevant in the current setting, for example, in a viewing situation.

An object is thus added to the study in a change event to signify the invalid parts of the study. The change element is a new object that may be transmitted from the PACS to the Kvarkki DICOM archive in a similar fashion as any addition of a new object would be in the case of an externalised archive in accordance with the DICOM standard. The Kvarkki DICOM archive is responsible for interpreting and taking care of the registration of the study/change in the XDS archive.

Including the changes in the study enables time-dependent examination of the study with regard to the timestamps, i.e. to find out the status of the study and the documents linked to it at a certain time, for example, when examining treatment decisions.

4.9.3 Changing metadata of the study

Changing the metadata of archived imaging studies (DICOM tag) is necessary in connection with corrections. It must be possible to handle changes in Kvarkki environments, and the original data source is responsible for the fact that all corrections are always also sent to the Kvarkki DICOM archive. Otherwise the patient data is not consistent between the operative system and the archive.

The IHE specifications do not take a stand on the need for changing the study metadata (DICOM tag) or the change mechanisms. The Kvarkki DICOM archive requires that changes to metadata are forwarded to the Kvarkki DICOM archive by sending the amended study for re-archiving. The Kvarkki DICOM archive collects the changes and takes care of the registration of the study/change in the XDS archive by saving the new manifest version with the altered metadata values, technically in the same way as when saving additional objects for the imaging study in the Kvarkki DICOM archive.

The change of metadata must cover the DICOM tags specified in connection with the Kvarkki XDS metadata so that the Kvarkki DICOM archive is able to collect and deduct the XDS metadata.

4.9.4 Basic principle of change management

The change notification is sent to the Kvarkki DICOM archive in a DICOM standard KOS object (Key Object Selection), which is attached to the study and named according to the correction/change scenario. As a result of the changes, it will be necessary to archive and register the study again in the XDS archive with the updated manifest document (in the form of a KOS element in accordance with the DICOM standard). These steps are described in the sequence diagram below:

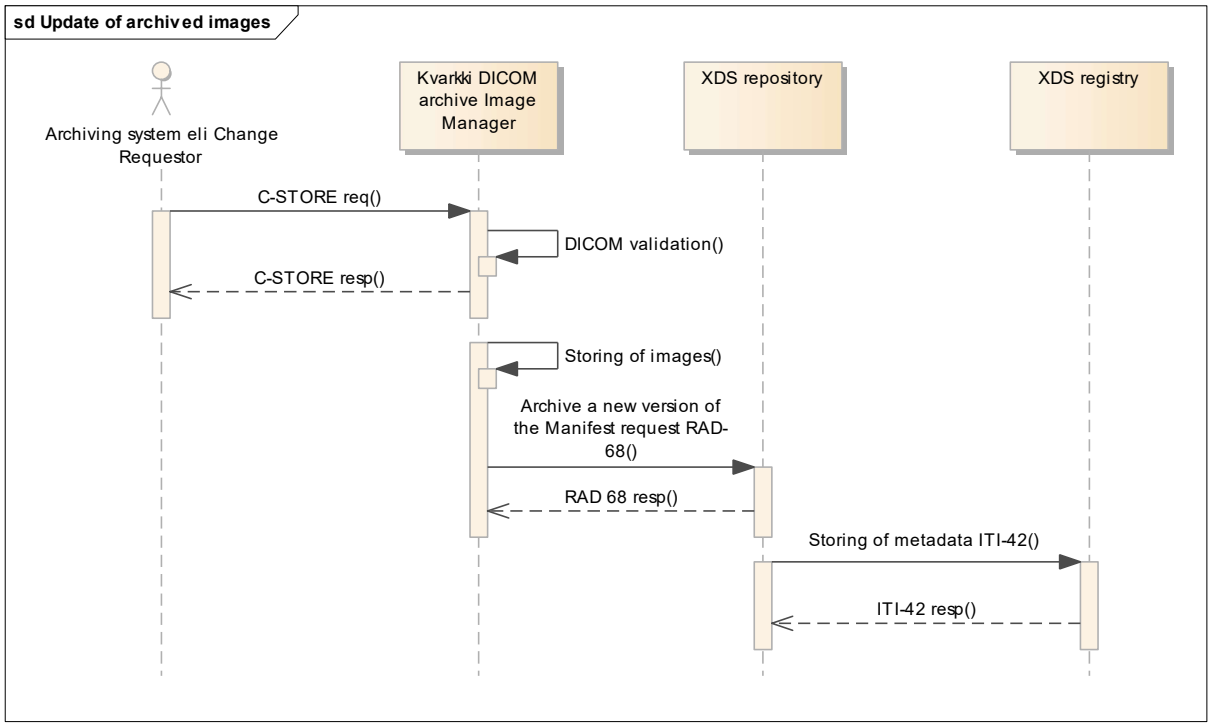

Figure 18 Updating the archived images

As a result of the IHE specifications, necessary KOS element types have been added to the DICOM specifications:

- “Rejected for Quality Reasons”
- “Rejected for Patient Safety Reasons”
- “Incorrect Modality Worklist Entry”
- “Data Retention Policy Expired”

The IHE profile also specifies how the archive must limit the removed objects when the imaging study is returned and how the system that retrieved the study shall show the study.CDA documents related to the imaging study and saved in the Kanta archive are corrected and supplemented in accordance with the specifications of the Kanta archive. The Kanta archive registers the new version of CDA document in Kela’s Kvarkki registry as described below:

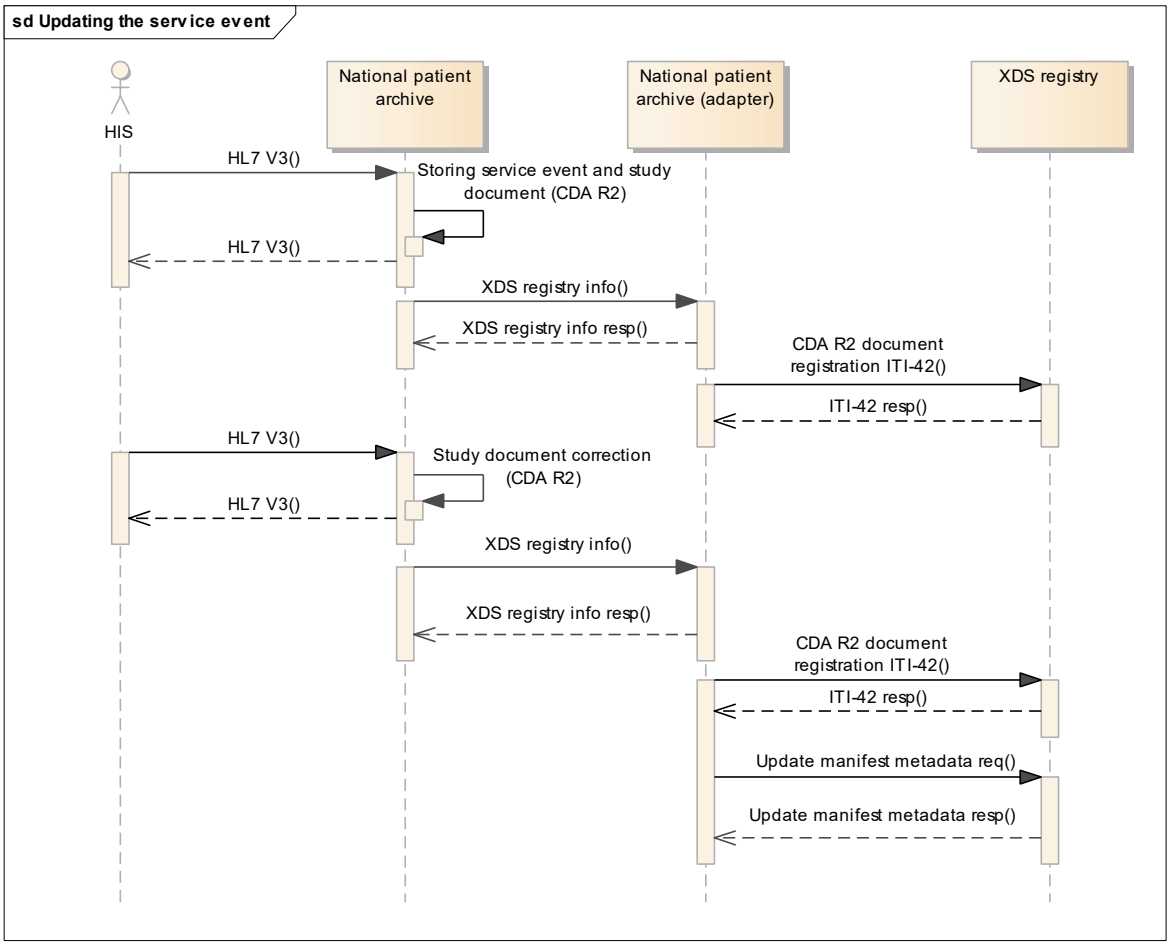

Figure 19 Updating the service event

The changes limiting the study contents of an imaging study as well as corrections are divided into the following change types, in which the interpretation of the change element, e.g. in a viewing situation differs from one another:

1. Marking of images as removed for quality reasons
    a. Images marked as removed are not returned to the person requesting the study in a query situation unless the queries are made especially for this reason to a specific AE Title that is configured for the subscriber for this purpose[7]
2. Marking of images/series as removed for patient safety reasons
    b. Objects marked as removed are not returned to the person requesting the study in a query situation.
    c. Any replacement objects are saved as part of the study (new series and image level IDs are created)
3. A wrong study has been carried out on a patient
    a. Images marked as removed are not returned to the person requesting the study in a query situation.
    b. Any replacement images are saved as part of the study (new series and image level IDs are created)
4. Study object/s has/have been removed due to the termination of storage time. Kvarkki clients are not allowed to send KOS objects of this type to Kvarkki since the Data retention periods are maintained and controlled by Kvarkki only.

[7] https://www.ihe.net/uploadedFiles/Documents/Radiology/IHE_RAD_TF_Vol3.pdf
chapter: 4.66.4.1.3.1

a. Objects marked as removed and the KOS object used for their imaging are deleted from the study. (However, according to current IHE specifications, this will not remove the entire study, only the out-of-date objects).

Handing related to the storage time and deletion of imaging documents is described in section 3.12 Retention control and deletion.The following sequence diagrams describe typical change management situations in Kvarkki:

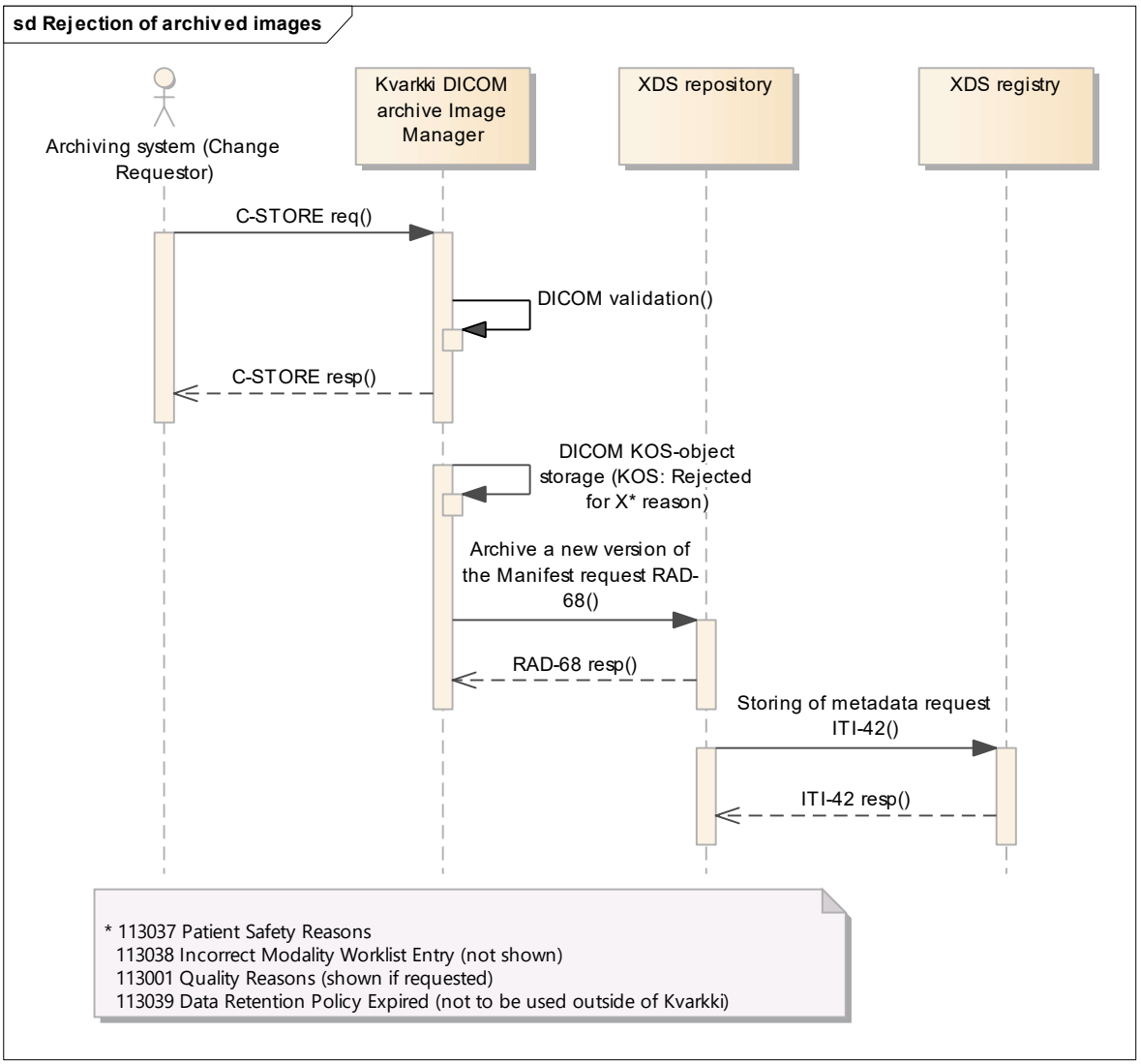

Figure 20 Rejection of archived images

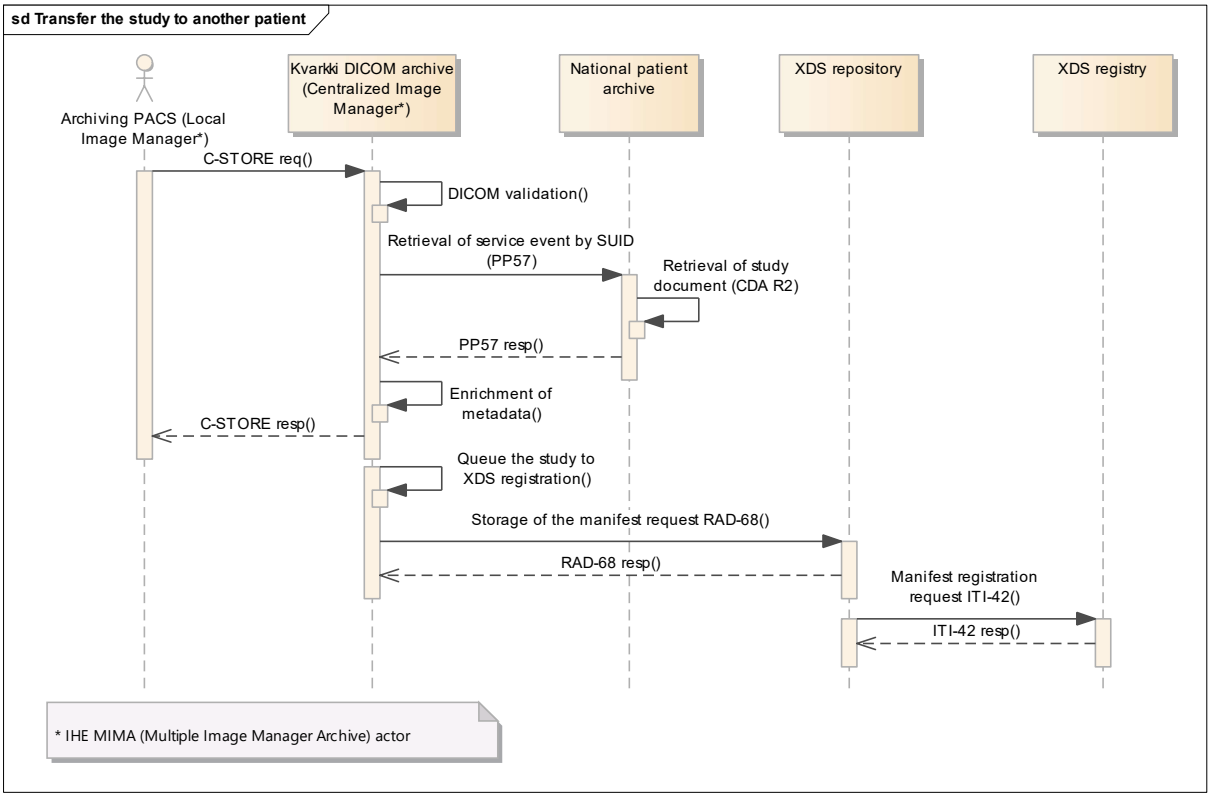

Figure 21 Transfering study to another patient

4.9.5 Reliability requirements of the process

The correction procedure of an archived study requires more effort than a study that has been saved in PACS only. In addition, the corrected study will not be automatically shared with the organisations that have already retrieved the incorrect version of the study, but it requires a separate query. Therefore, the workflow of the production process of studies must be as reliable and faultless as possible in order to produce fewer errors and to reduce the subsequent need for changes.

The imaging studies produced by the imaging workflow must be examined before they are archived in Kvarkki.

The corrections of detected errors must be made according to the guidelines regarding the KOS objects as specified earlier.

4.9.6 Changes made to own studies

As a rule, an imaging study may only be updated or corrected in the encounter that is responsible for producing it. If changes are made later in the utilisation of the imaging study, the procedure described in chapter 4.6 Searching, utilising and possible copying of comparison images to another encounter shall be followed. In such a case, changes may be made to the original imaging study which, however, remains a document of the original encounter.

Changes made in studies also result in a need for change in the study manifest (description document, KOS). The Kvarkki DICOM archive forms a new manifest and saves it in the XDS repository where it replaces (versions) the previous manifest.

4.9.7 Annotations and changes made to retrieved studies

If changes or markings are made to a study retrieved from an external archive for viewing, the study must be saved and published under the name of its own custodian, after which it must be handled and stored as if it was the organisation's own study. The operating model is described in section 4.6 Searching, utilising and possible copying of comparison images to another encounter.

4.9.8 Technical solution and implementation

The IOCM profile of IHE describes how to correct various errors in imaging studies, how the corrections are changed and distributed and how the corrections are expressed as DICOM objects in the imaging study. Kvarkki requires that the corrections and the archiving of corrected contents comply with IOCM. The Kvarkki imaging document source limits the objects returned in queries in accordance with IOCM.

Kvarkki does not set requirements for the error correction process in the service provider's own information system (see further information in the section Imaging Object Change Management (IOCM) in the IHE RAD TF-1 document). Kvarkki technical specification only refers to the way the information about changes made to the studies must be transmitted to imaging material archive.

Change information is saved as part of the imaging study in KOS elements in accordance with the DICOM standard, and these elements are named and typed according to the change scenario. PACS saves the change object in the Kvarkki DICOM archive in accordance with the RAD-66 transaction with a CSTORE command.

IOCM does not specify the versioning of the corrected study in the XDS-I archive. Versioning takes place according to the normal versioning principles. Kvarkki does not create new IDs to corrected studies, but it is the responsibility of the client. The Kvarkki DICOM archive (Imaging document source) creates a new version of the manifest document after saving the correction objects, and saves it in the XDS repository. This action is in accordance with the IOCM profile (9/2016) extension that is in trial implementation stage.

4.10 Logging of document sharing and use

In Kvarkki architecture, the statutory security requirements set on the Kanta archive are complied with in the case of log entries. The security of the Kanta archive/Kvarkki is based on the restriction of advance use on the one hand and on monitoring and control that takes place after the event on the other hand. To enable control after an event, the system maintains logs in which the information required by monitoring is stored with respect to all events.

Logs related to imaging studies are maintained at two different levels, in the National Patient Data Repository (Kanta archive) and in the regional imaging systems. Data sharing between custodians is either documented in the Kanta archive with a sharing notification or it takes place directly with a sharing log notification of the Kanta archive. Sharing information stored in both ways is accessible from, e.g. My Kanta Pages. Systems using the information will record the use of own and shared data userspecifically in the use log. The log is stored securely in the organisation that produces the log.

The requirements, specifications and instructions related to the Kanta archive and joining it are described on the kanta.fi pages.

When the Kvarkki system return material or other query results, the returning system forms an IHE ATNA profile and its log in accordance with XDS-I use, which is stored only in the returning system. The ATNA log in Kvarkki is technical and not a share or use log even though it is described as an audit log in the IHE specifications. The log is stored securely and in special cases it can be used for manual studies, but not via any service, interface or application.

4.10.1 Share log

Sharing events logged in Kvarkki include a registry query that returns documents of another custodian and retrieves a manifest of another custodian from the XDS repository. Retrieval of an imaging study from the Kvarkki DICOM archive is not logged because the retrieval of the manifest that includes the references used in the retrieval has been recorded in the share log. Retrieval of patient documents from other XDS repositories is reported into the share log. The share object is logged with the accuracy of the encounter and the view of the document.

The XDS adapter of the Kanta archive also reports all patient record retrievals done via XDS mechanisms to the share log.

4.10.1.1 Sharing from the Kvarkki DICOM archive

When requesting other than the custodian's own data from the centralised Kanta archive or the Kvarkki DICOM archive into a local system, data sharing takes place and it is recorded in the share log. The system sharing the data is responsible for recording the share (Kanta archive/Kvarkki DICOM archive).

Kvarkki DICOM archive produces a share log entry on the share. In the share log of the national Kanta archive, this means one event: the data is shared into a local/regional system. In a use log of a local/regional system, there may be several events corresponding to sharing: different persons use the data or the data is used several times. Sharing may be requested by persons who will never use the data themselves.

4.10.1.2 Sharing from a regional archive

Sharing of material between custodians within the same area (regional common registry) will produce a sharing event, which must be forwarded to the Kanta archive with a sharing notification. It is not necessary to submit a sharing notification for every single sharing event from the common registry, as sharing carried out for the same sharing recipient per each patient and 24-hour period can be gathered into a single sharing notification. The updated sharing notification is available in the National Code Service.

Therefore, the sharing notification includes sharing events carried out outside the Kanta archive as part of the notification log of the Kanta services. The sharing event is documented with a sharing notification document stored in the Kanta archive, on the basis of which the Kanta archive produces a share log entry. Logging of sharing is the responsibility of the system that shares or requests the sharing of material, depending on the solution.

4.10.1.3 Technical solution and implementation

A share log is carried out on registry and repository queries and on document retrieval from the XDS repository. No share log entry is produced on the retrieval of imaging studies. An imaging study is usually retrieved in many parts with multiple requests and it is not appropriate to produce a separate share log entry on each of these. A log entry that identifies the subject of sharing with an accuracy of the encounter, made when retrieving the manifest from the repository, is deemed to include subsequent retrievals of imaging study objects. Consumer systems must not carry out sharing queries on data repositories (e.g. on DICOM C_FIND DICOM archive) outside the XDS-I mechanisms and the logging actions implemented in them, which is ensured in the certification of systems accepted for this use.

Saving of share log data is the responsibility of the system sharing the data, i.e. in the case of Kvarkki the XDS subsystems, but the IHE XDS-I profile does not include this kind of function or an expansion option that would enable it. ATNA logging does not meet the requirements of Finnish legislation especially with respect to the logging of data contents, and document formation and archiving cannot be easily tailored with log saving. It is appropriate to implement a share log with product-specific tailoring technology.

4.10.2 Use log

All use of patient data must produce a use log that is stored in the system presenting to the user of the data. The log entry of use is the responsibility of the systems using the data however the requirement can also be fulfilled by other systems than systems presenting to the user of the data. Systems using the data shall record in the log the use of own and shared data user-specifically. With respect to data pertaining to the national solution, the use log data must include, e.g. an encounter ID and the user's entitlement to use the data. Especially the use of imaging documents obtained through sharing must always be identified with an accuracy of the encounter ID and possibly also the document.

The log is stored reliably in the organisation that produces the log, and the patient's checking right also applies to this log data. In accordance with the specifications, the patient administration events required for the verification of the care relationship are also recorded in the local use log.

The requirements of use logging are described on the kanta.fi pages in the appendix to the 'PTJ eArkisto käyttötapaukset' document.

4.10.2.1 Technical solution and implementation

The use log is the responsibility of the document consumer system. The Kvarkki server components are unable to produce a use log. The use log data should possibly also be recorded in the same log service with other applications or otherwise an ATNAcompliant log service will not be available to a system producing use log, such as a viewer. The Kvarkki specification does not include requirements or recommendations on the technical implementation of use logs.

The same ATNA-audit limitations apply to use logs as to sharing logs. It is not appropriate to expand the log situations and their data contents as expansions to ATNA audits implemented in products, but as separate added functions. That way, an ATNA log has a technical log status in Kvarkki even though in the IHE specification it is presented as an audit log. The recording method of the ATNA log (audit record in xml format in accordance with RFC 3881, recording with the syslog service (RFC5426 and RFC5424) meets the recording requirements of the use log.

4.11 My Kanta Pages

The imaging study documents are available to patients in the My Kanta Pages service in the same way as other patient records. There will be no special functionality in My Kanta Pages with respect to documents stored from an imaging study into the Kanta archive. Saving of imaging studies is not possible in My Kanta Pages service.

The viewing of imaging studies in My Kanta Pages can be delayed. If an imaging request, study document or report has been delayed, My Kanta Pages will take it into account so that the CDA documents are not shown while the delay is in force. Images are not shown in My Kanta Pages for the time being.

My Kanta Pages will show the sharing of documents in the imaging study entity together with other shares. The patient will see the sharing event of the imaging study entity as a sharing of the imaging view in the encounter, in accordance with the description of itemising the subject of sharing in connection with sharing logs.

With respect to consents and denials, Kvarkki uses existing consent documents without additions or a deviating application method.

4.12 Data collection on radiation exposure

Radiation exposure data is collected from all modalities that produce the data. Technically, the data can be collected from the modality from the DICOM metadata of the study, from the MPPS-message sent by the modality or through other method of recording.

The aim is to register radiation data as a part of DICOM study utilizing RDSR-objects (radiation dose structured report). If RDSR is not available the data can be written into a radiology CDA R2 document and sent to the Kanta archive. The CDA R2 includes options to report also other important information about the patient such as weight, type of study, radiation dose etc. The National patient data management service can utilize radiology data that is stored in CDA R2. The service can assemble views based on the radiology data in part of patient's health information overview.

4.12.1 Technical solution and implementation

Due to different system solutions, the suppliers collect radiation exposure data in different ways to be included in the CDA study document. The Kvarkki specification does not provide instructions on the method of implementation as this is part of patient data recording for the study document.

Radiation value data is collected into Kanta, but due to the complicated nature of the data contents it is not used in mechanical calculation in the data management service. Calculation takes place possibly in the special application for calculating radiation values. In the future the calculation may be based on the data obtained by RDSR objects.

4.13 Retention control and deletion

Retention control and deletion of imaging documents take place in accordance with the Kanta principles.

4.13.1 Legal requirements

Provisions applying to the retention of patient documents are prescribed in the Decree of the Ministry of Social Affairs and Health concerning patient documents (30.3.2009/298 Sosiaali- ja terveysministeriön asetus potilasasiakirjoista). The Decree prescribes a retention period for different patient documents, according to which the custodian (a healthcare unit or a self-employed healthcare professional in whose care the documents have been created) of the patient document must take care of retaining the document and of its appropriate deletion within the determined period. Kvarkki takes care of the retaining and the deletion functionality. In the case of archiving, the retention period is automatically calculated for the imaging studies by the rules of the Decree mentioned above. The determination of retention time and the rules for calculating the termination date are described in the Metadata model published at kanta.fi (https://www.kanta.fi/jarjestelmakehittajat/kuva-aineistojen-arkisto). Because of the need to identify the length of the retention period and even the permanent retention of all the images, there is still no deletion of the image files from the Kvarkki DICOM archive.

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4.13.2 The principles of retention control in Kvarkki

Imaging CDA documents (referrals and reports) are archived in the Kanta archive of the Kanta services, and therefore their retention and deletion is managed within the scope of services built in the Archive for archivists. The Kvarkki DICOM archive will not yet offer the same services for the retention control and deletion of imaging studies in the centralised archiving model.

In environments in accordance with Kvarkki architecture, there are references and/or copies of individual studies in several different data systems, such as in the PACS system that produced the study, in the Kvarkki DICOM archive and in the XDS registry. When deleting study data from the local systems, the deletion of references or copies of all studies must be ensured. Imaging study entity documents retrieved from Kvarkki for viewing must be handled in document consumer as temporary documents to be deleted soon after patient's care is completed, in which case they will be deleted before the retention period ends.

The DICOM standard does not specify a mechanism where two systems can share data concerning substitutive changes made on the study, only the new objects of the study can be shared between systems. XDS-I does not contain a record of retrieval from the archive and of the study copies created as a result. The control of retention and deletion of copies is not centralised in Kvarkki, and therefore systems saving the retrieved documents for treatment needs must ensure that the copies are deleted within the specified periods.

The IOCM (Imaging Object Change Management) profile has been added to the radiology specifications in IHE to enable sharing of changes made in the study (removal/amendment/addition) between systems. IOCM support is required of PACS systems integrating with the Kvarkki DICOM archive.

One of the change cases covered by the IOCM profile the deletion of a study (or its part) made due to the end of the retention period. Sending of such KOS objects to the Kvarkki DICOM archive is however prevented because retention control is handled automatically by Kvarkki.Other cases of IOCM use are dealt with in the section Change management of imaging studies.

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4.13.3 Technical solution and implementation

4.13.3.1 Deduction of the retention period

The Kvarkki DICOM archive deducts the statutory retention sub-category for a study according to the Finnish legislation on the basis of the metadata of studies. The metadata in question is described below:

- Study date

- Patient's date of birth
- Modality (Electrocardiography)
- Study codes (dental imaging study from which the person can be identified)

The Retention time is given in years. The calculation basis for the storage period indicates what information is used to calculate the end time of the retention period (eg birth date of the patient + 12 years). The expiry date of the storage period includes information on the date when the retention period for the document or imaging study expires. The Kvarkki DICOM archive automatically calculates the end time of the storage period. So far, data deletion has not been implemented.

4.14 Digital signature

Imaging studies in DICOM format are not signed digitally, but the transmission and storage solutions are trusted to ensure the data integrity. Imaging CDA R2 documents are signed as specified in the Kanta specifications.

4.15 Utilisation of Kvarkki DICOM archive in imaging workflow

In the referral, imaging and report workflow taking place within the same custodian, Kvarkki is utilised in the retrieval of comparison images, but not in the production of a new imaging study entity. The documents of the entity are archived in Kvarkki as and when they are completed.

In distributed workflow, the documents of the imaging study entity can be shared among the participants during the workflow with the aid of Kvarkki. Incomplete studies can be archived and updated and contents can be added according to the principles described in the previous chapter.

Outsourced procedures stored in the Kanta archive enable the archiving of imaging studies and the storing of imaging CDA documents in the imaging study entity also when users and systems of several custodians take part in the workflow.

Kvarkki does not include functions supporting the workflow, but workflow control takes places with methods for which Kvarkki does not provide instructions.

4.15.1 Technical solution and implementation

Workqueue view is currently not supported in Kvarkki because referrals for reports etc. are not archived during the workflow. Kvarkki does not set any limitations to utilize study material concerning shared workflow.

4.16 Management of retrieved study copies

Study copies retrieved by XDS-I and/or XCA-I are normally saved in the data system of the retrieving system for the needs of patient care. During retrieval, it is not known whether the study will be used in reports or treatment decisions. Retrieved studies must be handled as temporary in the document consumer and they must be deleted as soon as the study has been completed.

If a study is utilised in reports as a comparison study or for clinical decisions, it should be referred to in the study or report entry of the imaging CDA document in a way that it is possible to find the original study on the basis of the reference and retrieve it again. An organisation utilising for the purpose of archiving or use at a later date will not save the imaging study referred to.

For cases where entries are made on retrieved studies, see the section on comparison images.

4.17 Pre-Kvarkki studies as comparison studies

Studies produced before Kvarkki can be registered in Kvarkki and their CDA documents can be stored in the Kanta archive provided that their contents and metadata comply with the Kvarkki specifications. These kinds of studies can be used as normal material in Kvarkki.

4.18 Handling of studies obtained from external media

External studies refer to images brought up by the patient's own media and produced by an actor outside the Kvarkki environment. These images include, e.g. studies containing images taken at a private (not included in Kvarkki) medical centre or overseas or studies produced by a healthcare organisation that has not yet joined the Kvarkki entity. The images are brought into the organisation's own system (often PACS) and attached to the patient's active encounter, within the scope of which the patient has brought the images. The images are archived in the same way as own images so that the organisation using them will act as the custodian of the images. However, the information of the organisation that produced the images will be retained with them. The principle is that the images are brought to the Kvarkki environment, after which they will be accessible for all.

4.19 Technical retrieval of own studies

PACS system keeps the imaging studies for a certain period of time (e.g. for three years) in the local active storage. All study material is stored in the Kvarkki DICOM archive for long-term archiving where they are available within the scope of the retention period. Studies that are older than a certain period (e.g. three years) are removed from the active PACS, but a reference pointing to the centralised DICOM archive may remain in the PACS system database. Imaging data systems usually store references that enable, for example, re-retrieval of a study copy that has been archived or removed from the system without using the Kvarkki XDS-I and XCA-I mechanisms or navigation through patient record documents. Due to the implementation method complying with XDS-I, the DICOM-connection between the PACS and the Kvarkki DICOM archive has been configured for saving purposes, which means that the connection is technically available for retrieving studies. Kvarkki is unable to prevent this method of use, but healthcare organisations must ensure the manageability of the usage and the legal aspects for it.

When a PACS archive queries only own images located in the Kvarkki DICOM archive, the PACS system will retrieve the imaging study from the Kvarkki DICOM archive using direct DICOM C-MOVE transfer [RAD-16] from the Imaging Document Source (Kvarkki DICOM archive).

These steps are described in the sequence diagram below:

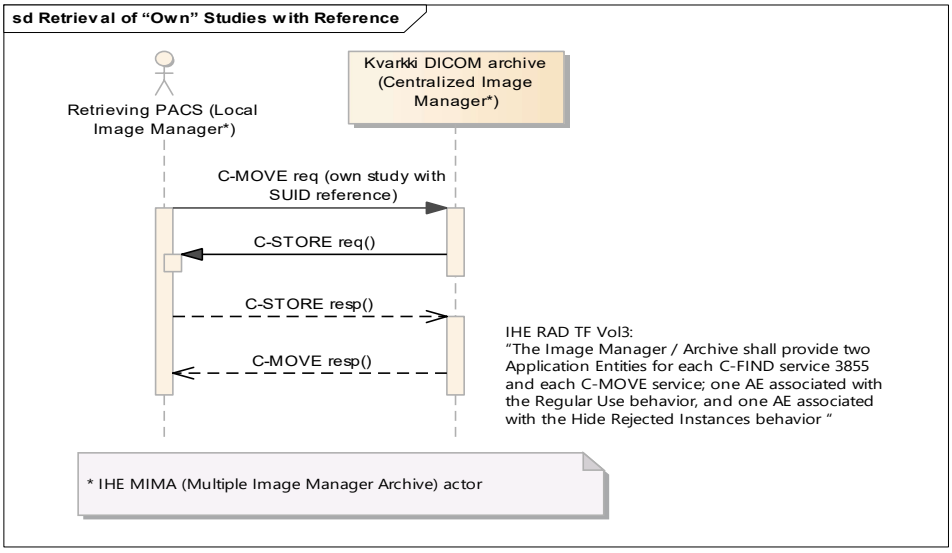

Figure 22 Retrieval of own studies with a retained reference

Kvarkki's consent management cannot be attached to a query made with DICOM operations. Healthcare organisations need to operate with stored references in a way that only own studies are retrieved and to take care of the consent management verifications and the formation and archiving of the sharing document on sharing taking place between custodians within the same domain. Ultimately, queries made by a client organisation in the centralised Kvarkki can be established from Kvarkki logs.

5 Management of referrals, study documents and reports

5.1 General

An imaging study and documents that are directly related to it are archived so that they form a uniform entity that can be retrieved in full. Retrieval may require several stages and it may include the use of references from retrieved documents. Retrieval of the entity can be performed by the XDS-I retrieval mechanism and with IHE transactions carried out on the basis of references included in CDA documents obtained from the Kanta archive.

In Kvarkki, an imaging study and documents are linked together using the metadata of the documents. The key connecting metadata is the encounter ID that is used both in the XDS registry with document objects and in the Kanta archive with encounter and patient care documents. In addition, the encounter ID exists at the time of archiving the first imaging document in the Kvarkki DICOM archive.

In case of several imaging studies for one encounter, the studies differ by their Study Instance UID (and probably also by AC number), which are also metadata elements for the manifest and CDA documents. The Study Instance UID link the documents to the imaging study entity at the metadata level. However, a CDA document with just a referral entry does not have a Study instance UID, and therefore it is only linked to the encounter and not to the imaging study.

The registered content description of the imaging study (manifest) in the repository contains references to the actual imaging studies that are that way linked to the imaging document entity. Registered documents have the encounter ID as metadata, which can be used by the system searching imaging studies as a query parameter for the Kanta archive or other systems.

The imaging study and report documents stored in the Kanta archive contain the study identifiers (Study instance UID and possible AC number) as well as the encounter ID. Any system that has used these IDs to retrieve an imaging study or report document from the archive can also query and retrieve the imaging study from Kvarkki.

Instead of the three report alternatives specified by IHE, the Finnish imaging CDA document in accordance with the specification for Kanta imaging CDA R2 document structure shall be used.

5.2 Second opinion

According to the imaging CDA document specification, an imaging study can have a preliminary, final or second opinion status, and they can be included in the same document or in separate documents. The report may also apply to several imaging studies.

Second opinion is not specifically supported by Kvarkki as described in connection with outsourcing and archiving of incomplete studies. The imaging study and imaging CDA documents archived in Kvarkki are available for the party producing the second opinion. If the second opinion is produced as an outsourced service, the procedure described shall be used in connection with outsourcing. If the second opinion is produced within the same organisation, it can be archived as an entry in connection with other imaging CDA documents or as a separate imaging report document. Second opinions are linked to the imaging document entity as a document in the same way as the original report. The link to the entity is formed on the basis of the encounter ID and the study instance UID of the second opinion. Any entries made in the imaging study created while producing the report are archived as additional objects into Kvarkki as an imaging study update.

Creation of referrals for second opinions, workqueues, process direction and reporting are managed outside Kvarkki in the way described in connection with outsourcing or with internal systems used in the organisation.

5.3 References to comparison studies

In order to refer to a comparison study used in connection with an imaging study, a free-form reference, which enables locating the study, shall be attached to the study or report entry of the imaging CDA document in question.

5.4 Technical implementation

Due to Finnish specifications, it is possible to include the encounter ID in the documentEntry metadata in the XDS registry. In the Kanta archive, the encounter ID is a key metadata. Therefore, the encounter ID can connect the study documents to each other, but an encounter can have several imaging studies, and their distinction from one another with metadata is not fully supported.

To maintain the correct encounter ID on all documents related to an imaging study entity, including the metadata of the manifest, the imaging study can only be altered in the encounter producing the study. All subsequent updates of the study, for example, planning of an operation or the use of an imaging study as a comparison study supplemented with entries, are made on a copy of the study in question.

The Study Instance UID that identifies the study is obtained from the DICOM tags of the imaging study into the manifest XDS metadata and inside the entry of the imaging CDA documents, from where it is extracted into the metadata of the CDA document.

The XDS submission set is a document entity formed for the purpose of each registration event, and it is saved in the registry. A submission set may also include a reference to a previously registered document. However, it is not possible to update a submission set when registering new documents, i.e. it cannot be used for connecting all documents of an imaging study entity.

The submission set is not utilised when retrieving a study entity, and it remains a necessary, albeit, as such, useless technical structure in Kvarkki architecture. Retrieval of submission sets will show the kinds of sections in which the study documents have been archived.

6 Handling of patient data and taking temporary identifiers into account in Kvarkki

In the Finnish Kvarkki implementation, the basis for patient data management is that the abovementioned official personal identifier is used in as straightforward and efficient way as possible. In Finland, the codes produced by the Population Register Centre are generally and commonly used in all healthcare (and other) systems. Only situations where the temporary identifier is used require special provisions. [4]. Kanta architecture recognises the need for temporary identifiers. A temporary patient identifier is needed in the treatment of, e.g. unidentified/new-born/foreign patients. A patient may be treated in several healthcare units identified only by a temporary identifier. When a patient is transferred for treatment in another healthcare unit, the temporary identifier given to them shall be used, if it is known. The international IHE specifications handle extensively the problematics related to patient identification as it is common in different countries to maintain local patient identifiers (regions, hospitals) and it is necessary to be able to retrieve studies recorded for the same person using different identifiers for data (XDS) sharing.

Kvarkki basically complies with the methods of Kanta / the Kanta archive in the handling of patient data. When archiving patient care documents, it is possible to use either the temporary identifier or the official personal identity code. Documents in the imaging study entity that have been archived using a temporary identifier shall not be shared with other custodians, but they are only meant for own use by the custodian that produced them. However, in Kvarkki (and in other Kanta architecture) the objective is to enable sharing of documents archived with a temporary identifier with other custodians.

The Finnish HL7 specifications have for long had a model for a temporary identifier (organisation base + identifier). This model specified by Kanta services technically makes any temporary identifier nationally unique. Organisation is responsible for ensuring that two different patients will not have the same temporary identifier in any case. However, the patient data systems have insufficient support for the base to indicate the temporary nature of the identifier and a risk has been recognized: temporary identifiers are not always unique and they are sometimes even recycled. This may lead into a

problematic case where two different patients' data would get merged. Before national solution is introduced, temporary identifiers cannot be stored in Kvarkki and must only be used within the organisation that has created them.

Kvarkki supports a model where two official patient identifiers can be merged together in the Kvarkki DICOM archive and the XDS registry. A case like this would be e.g. gender reassignment where the patient receives a new patient identifier. In order to merge two patients' data, an HL7 V2.x ADT-A40 message can be sent to Kvarkki (see appendix 5). This functionality does not include transmitting the information to all required systems e.g. the Kanta archive. Organisations must update their CDA R2 documents in the Kanta archive separately. It is noticeable that the ADT-A40 message sent to Kvarkki will merge two patient identifiers despite who is the custodian of the data. In the Kanta archive custodians are able to update only their own data. Kvarkki also supports ADT-A08 messages if it is needed to update patient information (e.g. patient name) in the Kvarkki DICOM archive. It is notable that either ADT message updates the manifest's (KOS object) DICOM tags. The updates triggered by ADT messages are processed only in the XDS registry and DICOM study's metadata. E.g. the old name will remain in the manifest's DICOM tag as long as the study is updated and the manifest is updated.

In order to retain the integrity of the data between Kvarkki and the Kanta archive, organisations must take care that their data is always up-to-date in the Kanta archive if patients' identifiers change in their registries. The use of the Kanta archive requires the custodian to update an official personal identity code for a document as soon as it is available. The temporary identifier will also remain on the document. A document that has been updated with the official personal identity code will not be returned in the results to queries using the temporary identifier as a search criterion. The organisation that has archived the study is obliged to verify that the patient data of a study is as up-to-date as possible, i.e. the use of temporary identifiers should be eliminated as soon as it is possible. Correspondingly, in Kvarkki this would mean that when a patient has been officially identified, all studies identified with a temporary identifier must be updated to the official identifier in all of the archives/registries where they exist.

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7 Consent management

The Act on Electronic Processing of Client Data in Social and Health Care [8] and the Health Care Act set out the preconditions for sharing patient data and the mechanisms for informing patients, as well as the patient's consent and denial management in a centralised way. Data about the information given to the patient, consents given by the patient and denials defined by them is stored in the Kanta patient data management service. Before a consent is given, it is required that the patient has been informed of the national data system services and that the patient can restrict their consent with denials, which may concern service providers, service provider registries[8] or individual encounters. [5].
In Kvarkki, when a document is shared between custodians, consent management verifies the conditions of sharing on the basis of the informing, consent and denial documents stored in the Kanta patient data management service. The verification takes into account the national consents and.

In Kvarkki, deduction of consent management is performed in transactions returning patient data. The deduction is based on the data of the requesting organisation and the patient care context obtained from the query message, on the custodian and encounter data of the document to be returned and the consent management documents stored in the patient data management service. As a result of the deduction, documents without consent are filtered from the result set. Own use and rights obtained with outsourced certification are taken into account in the verification.

Sharing of documents archived with a temporary identifier and documents archived only for the custodian's own use is excluded from the consent management verification.

When retrieving data from the Kanta archive using the HL7 interface, the archive will carry out a normal consent management verification.

[8] service provider or service provider's registry is subject to a denial only in public healthcare where it is also planned to introduce purely service event-specific denials.

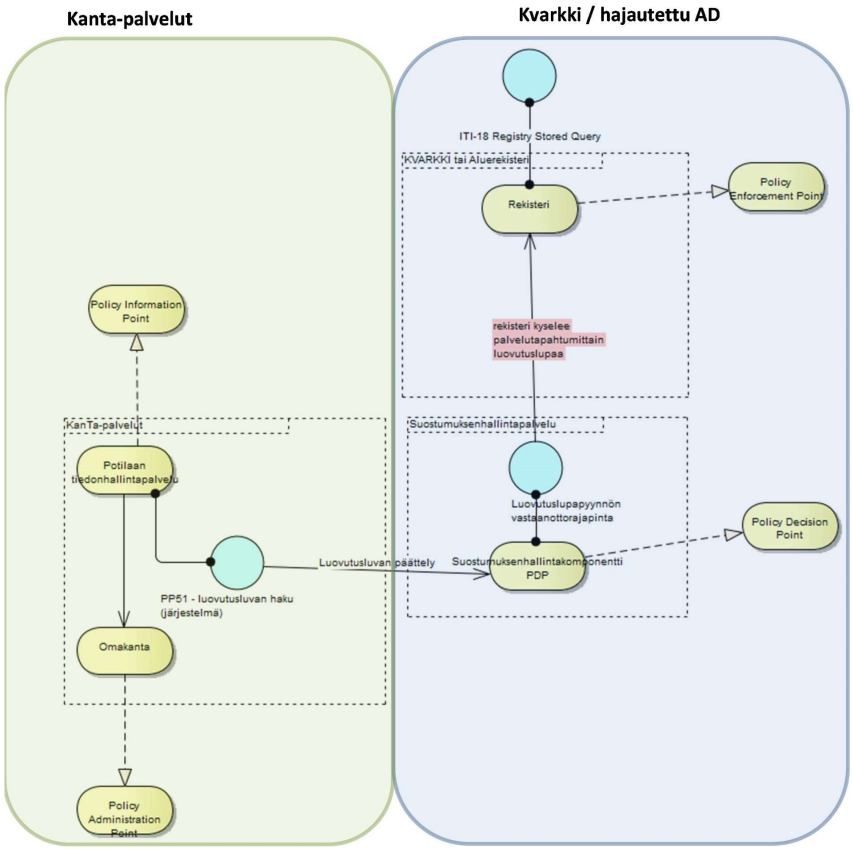

Figure 23 Kvarkki consent management scheme

The consent management verification is done in all the XDS Registry and Repository queries except for those that are recognised as ‘own’. In practice, this means ITI-18 (Registry Stored Query) and ITI-43 (Retrieve Document Set) queries. These queries are enclosed in queries ITI-38 (Cross-Gateway Query) and ITI-39 (Cross-Gateway Retrieve) between XCA gateways, but the actual consent verification is not done at the gateways, but in each actor sharing the data. A consent management verification carried out in connection with an ITI-43 transaction, which retrieves the imaging study content description (manifest), is also deemed to cover the RAD-69 (Retrieve Imaging Set) transactions made on the basis of the references in the manifest. For the time being Kvarkki doesn’t validate XUA assertion’s signature nor all of the mandatory XUA attributes of the RAD-69 requests. However The RAD-69 request must include the id of the organization (urn:oasis:names:tc:xspa:1.0:subject:organization-id) in XUA because of access control.The following figure shows the service request types presented in the general level in the above. As previously stated, there is usually no need to a request in stage 1, i.e. a query for object references. The consent management functionalities must be included in all stages 1-3.

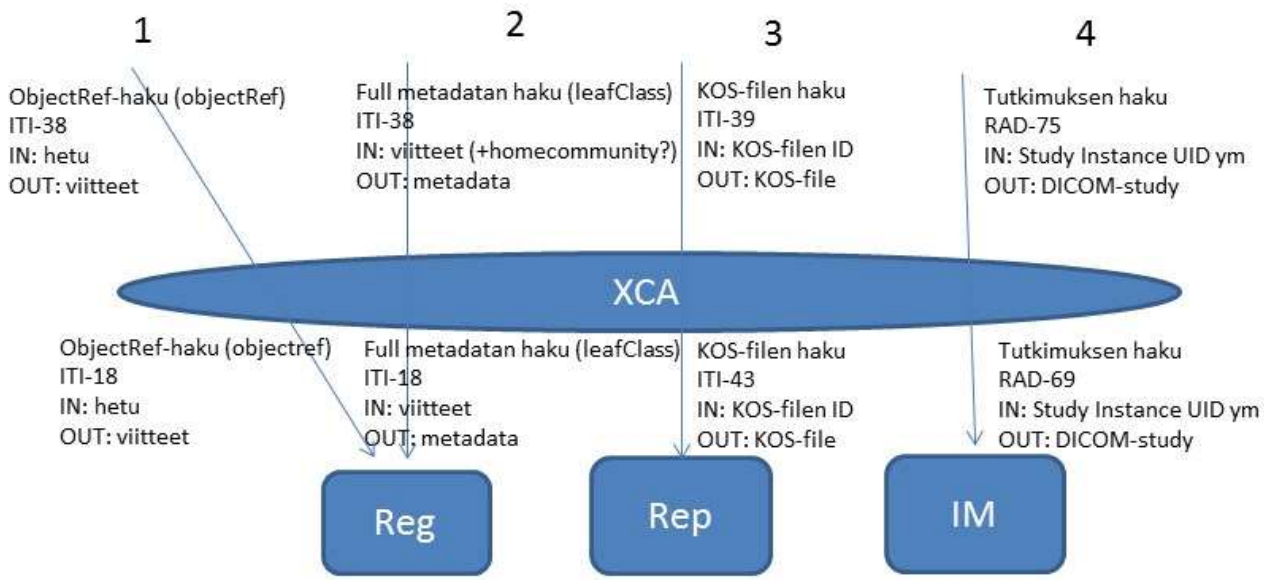

Figure 24 IHE transactions in the XDS-I context in the retrieval process

Information, consent and denial mechanisms and their applications are described in further detail in the document Use cases for HIS systems [6].

The CDA R2 form structures of the information and denial document are available in the code server. The identification code for form specification of the information document is 1.2.246.537.6.12.2002.332 and that of the denial document is 1.2.246.537.6.12.2002.331.

7.1 Consent management of retrieved studies in subsequent use

The Kanta principles and requirements, which are described in the Kanta specifications, are complied with in the utilisation of in imaging study entities or documents included in them, which have been retrieved from Kanta.

When using imaging studies and other documents that have been retrieved from Kvarkki and which have been in intermediate storage, it must be noted that they have been shared for the purpose of a certain encounter. In addition, the patient may have changed the sharing denials after retrieval. Use control is not covered by Kvarkki consent management.

Utilisation of studies is logged in accordance with the use log description.

7.2 Technical solution and implementation

IHE BPPC is not a profile used in the Finnish context at least at the moment. Kvarkki PoC has introduced a frame of reference used partly in XACML (eXtensible Access Control Markup Language) which identifies the following roles:

- PAP (Policy Administration Point) (Kvarkki: Viewing of own data or PTJ)
- PDP (Policy Decision Point) (Kvarkki: Consent management service)
- PEP (Policy Enforcement Point) (Kvarkki: XDS registry and XDS repository)
- PIP (Policy Information Point) (Kvarkki: Kanta patient data management service)
- PRP (Policy Retrieval Point) (Kvarkki: Interface of the patient data management service??)

Corresponding roles are utilised in Kvarkki consent management. In practice, only the PDP interface or, if PDP is implemented in a distributed setting locally, the PIP interface, is seen (e.g. to the XDS registry) of the consent management component of the Kanta service.

The following is an indicative interaction diagram on the functionality related to consent management in the Kvarkki service. Detailed context data related to retrieval is presented in the table after the diagram.

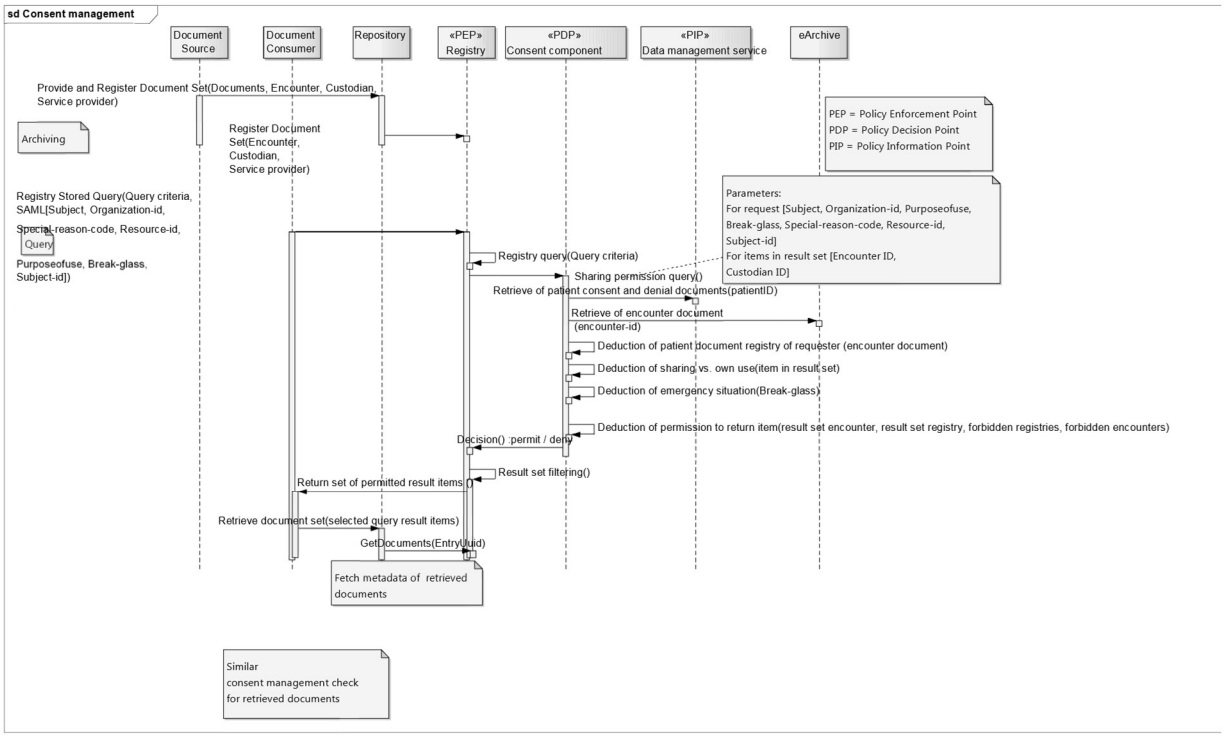

Figure 25 Consent management verification in the Kvarkki service

IHE does not describe the technology of the policy enforcement point specified in the architecture description, nor is it a profile option. XUA with its data content extensibility is included in the IHE requirements and therefore it enables the sharing of data of the requesting body and the user context needed in the deduction of consent management in the policy enforcement point and Policy Decision Point. The IHE specification also allows for metadata extension with the data required in consent management deduction. Consent management deduction is implemented with a component tailored for Kvarkki, using the sharing permission request of the patient data management service.

The tailored consent management is a component implementing the PDP role, verifying the sharing rights when documents or their metadata are returned from Kvarkki. The component discovers the returned encounters on the basis of the metadata or search criteria of the returned documents. The return permission of returned encounters is requested from the patient data management service, and the returned document set is filtered on the basis of the response.

In Kvarkki, the policy enforcement point is implemented in the XDS services returning the data to the requesting organisation. Due to the IHE specifications, implementation has to be based on product specific characteristics, which enable linking of a tailored handling component. PEP uses the Policy Decision Point component in accordance with the architecture description.

It is not appropriate to carry out a consent management verification on the RAD-69 transaction returning an imaging study of the Kvarkki DICOM archive. Normally, the study is retrieved with several requests a few objects at a time. As the queries are based on references included in the content description (manifest) of the imaging study, the right to the manifest also covers the imaging study objects.

The authorisation to share documents is requested with the service request PP51 (sharing authorisation request) from the Patient Data Management Service. The functionality corresponding to the consent management component must be implemented in every system that shares patient information, and it must call the above-mentioned PP51 service request from the Kanta services. The PP51 service request is described in further detail in a separate specification[9].

[9] Kanta Kevyet kyselyrajapinnat [11]

The data needed for the deduction of the sharing rights in consent management is added in each transaction in accordance with the IHE XUA profile to the Security element of the Soap header section, which complies with the SAML2 specification (page 15) [7].

The Basic Attribute Profile of SAML2 is used in Kvarkki.[10] This is an Attribute assertion statement in accordance with the SAML Core specification:

This SAML specification defines three different kinds of assertion statements that can be created by a SAML authority. All SAML-defined statements are associated with a subject. The three kinds of statement defined in this specification are:

- Authentication: The assertion subject was authenticated by a particular means at a particular time.
- Attribute: The assertion subject is associated with the supplied attributes.
- Authorisation Decision: A request to allow the assertion subject to access the specified resource has been granted or denied.

In connection with XDS, assertion is shared in accordance with the Provide X-User Assertion transaction (ITI-40). Assertion is signed with the XML signature in the required by ITI-40: Assertion shall be signed by the X-Assertion Provider as defined in SAML Core. An external X-Assertion Provider in accordance with ITI-40 transaction (Secure Token Service / SAML IDP) is not used in the Kvarkki context. A system signature certificates granted by the Population Register Centre is used as the signature certificate of Assertion, and it is verified in Kvarkki. Kanta's specification and application guide for digital signatures is complied with in the technical formation of the signature.[11] Assertion must be signed in all IHE XDS Transactions (ITI-18, ITI-43 & RAD-69), although with RAD-69 the signature is not technically validated for the time being.

The message attributes required by the Assertion element in accordance with the SAML2 specification:

- Version
- ID
- IssueInstant
- Issuer

SAML2 elements and attributes (IHE IT-Infrastructure Volume 2b 9/2013[12] and according to the SAML v2 specification[10]) used in the Kvarkki context:

Data	SAML attribute	Kvarkki use	Mandatory /optional[11]	RefReference:
Validity period	SAML generic, SubjectConfirmation: NotBefore and NotOnOrAfter	**At most for 8 hours from creation**	P	SAML
Service provider's organisation ID	Attribute: urn:oasis:names:tc:xspa: 1.0:subject:organization -id	AttributeValue: organisation OID character string (service provider level). When Joint connection according to the codeSystem 1.2.246.537.5.40200.2014 is in question, AttributeValue as instructed: • Case 1: Private service provider's OID who has joined Kanta services directly	P	IHE

[10] http://docs.oasis-open.org/security/saml/v2.0/saml-profiles-2.0-os.pdf

[11] http://www.kanta.fi/documents/12105/3450131/S%C3%A4hk%C3%B6isen_allekirjoituksen_m%C3%A4%C3%A4ritys_ja_soveltamisopas_2014-06-18

[12] http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2b.pdf

		• Case 2: Private service provider's OID who is hosting the joint subscription E.g. <saml2:AttributeValue>1.2.246.10.1234567.10.0</saml2:AttributeValue>		
Service provider's organisation name	Attribute: urn:oasis:names:tc:xspa: 1.0:subject:organization	AttributeValue: organisation name as character string E.g. <saml2:AttributeValue> Sairaanhoitopiiri X</saml2:AttributeValue>	O	IHE
Service provider's service unit	Attribute: urn:kanta:kvarkki:organizat ion-unit	AttributeValue: organisation's service unit OID as character string E.g. <saml2:AttributeValue>1.2.246.10.1234567.10.1.10.1</saml2:AttributeValue>	O	Kvarkki
Name of professional	Attribute: urn:oasis:names:tc:xspa: 1.0:subject:subject-id	AttributeValue: name of retrieving person as character string E.g. <saml2:AttributeValue>Pekka Lääkäri</saml2:AttributeValue>	O	IHE
National personal identity code of professional	Attribute: urn:oasis:names:tc:xspa: 2.0:subject:npi	Coded with HL7v2 CX data type. AttributeValue: ID of retrieving person in the format '121212-923A^^^&1.2.246.21&ISO' If the personal ID of the professional is not available, the Terhikki number (registration number of the professional may be used in the format '01234567890^^^&1.2.246.537.26&ISO' where 1.2.246.537.26 indicates the root of the Terhikki number	P	IHE
Patient identifier	Attribute: urn:oasis:names:tc:xacml :2.0:resource:resourceid	Coded with data type HL7v2 CX. AttributeValue: patient's personal identity code in the format '170474-970K^^^&1.2.246.21& amp;ISO' where VRK's root 1.2.246.21 indicates the official identity code. The root may also be the root of a temporary organisation-specific ID number, in which case sharing queries are not possible.	P	IHE
Specific reason for viewing patient data	Attribute: urn:oasis:names:tc:xspa: 1.0:subject:purposeofuse	Purpose of use is always patient care when queried through this interface, and as a default, the field will not be submitted. The original purpose of use of the PurposeOfUse element has been applied to better meet the Kanta context.	O	IHE

[10] http://docs.oasis-open.org/security/saml/v2.0/saml-core-2.0-os.pdf

[11] All fields must be supported in the implementation, optionality is only related to mandatory data in the message in different situations.

		If the sharing query is based on a specific reason, the field value is given from the code set Specific reason for viewing patient data - 1.2.246.537.6.240.2012 If the code value is 99 (Other reason), an explanation must also be entered in the field urn:kanta:kvarkki:special-reason-expl (described later in this table) AttributeValue: With the code, codeSystem, xsi:type and xml namespace (xmlns) data E.g.: <PurposeOfUse xmlns="urn:hl7-org:v3" xsi:type="CE" code="99" codeSystem="1.2.246.537.6.240.2012" codeSystemName="THL - Potilastietojen katselun erityinen syy" displayName="Muu syy"/> Whether it is emergency case, attribute shall have the code value '13' from the code system 1.2.246.537.6.240.2012 E.g.: <PurposeOfUse xmlns="urn:hl7-org:v3" xsi:type="CE" code="13" codeSystem="1.2.246.537.6.240.2012" codeSystemName="THL - Potilastietojen katselun erityinen syy" displayName="Hätähaku" syy"/>		
Professional's role	Attribute: urn:oasis:names:tc:xacml :2.0:subject:role	If used, shall be given as specified in the IHE specification chapter 3.40.4.1.2.1 Subject-Role Option. However no validation is done to this attribute because Kvarkki does not utilize the Subject-Role Option	O	IHE
HomeCommunityId	Attribute: urn:ihe:iti:xca:2010:hom eCommunityId	Home Community Id, no particular use, but required by the IHE specification	P	IHE
Custodian	Attribute: urn:kanta:kvarkki:custod ian-id	AttributeValue: service provider's custodian's OID as character string When Joint connection according to the codeSystem 1.2.246.537.5.40200.2014 is in question, AttributeValue as instructed: • Case 1: Private service provider's Custodian OID who has joined Kanta services directly (same as urn:oasis:names:tc:xspa:1.0:subject:organization-id) • Case 2: lessee organisation's Custodian OID (same as urn:kanta:kvarkki:private-hosted-organization) E.g. <saml2:AttributeValue>1.2.246.10.1234567.19.1</saml2:AttributeValue>	P	Kvarkki

Registry	Attribute: urn:kanta:kvarkki:regist ry-code	Value according to the registry code of the patient document of the service provider (1.2.246.537.5.40150). AttributeValue: with the code, codeSystem, xsi:type and xml namespace (xmlns) data (see the xml example below) E.g. <RegistryCode xmlns="urn:hl7-org:v3" xsi:type="CE" code="2" codeSystem="1.2.246.537.5.40150.2009" codeSystemName="KanTa-palvelut - Potilasasiakirjan rekisteritunnus" displayName="Julkinen terveydenhuolto"/>	P	Kvarkki
Registry specifier	Attribute: urn:kanta:kvarkki:regist ry-specifier	AttributeValue: Registry specifier in occupational healthcare in ISO OID format or Coded with data type HL7v2 CX E.g. 1 <saml2:AttributeValue>1.2.246.10.1234567</saml:AttributeValue> E.g. 2 <saml2:AttributeValue>170474-970K^^^&1.2.246.21&ISO</saml:AttributeValue>	O (mandatory if attribute `urn:kanta:kvarkki:registry-code` has value '4'	Kvarkki
Care context encounter ID (OID)	Attribute: urn:kanta:kvarkki:encoun ter-id	Encounter during which sharing request (urn:kanta:kvarkki:sharing = true) is made. In an outsourced situation, the service organiser's encounter ID. AttributeValue: encounter OID as character string E.g. <saml2:AttributeValue>1.2.246.10.1234567.30.12345</saml2:AttributeValue>	O (compulsory after all in sharing situation or outsourced situation)	Kvarkki
Special reason explanation	Attribute: urn:kanta:kvarkki:specia l-reason-expl	AttributeValue: Free text explanation when the patient records have been viewed without verification of care context. E.g. <saml2:AttributeValue>Selite tähän</saml2:AttributeValue>	O (must be used if the special reasons is of type 99)	Kvarkki

Joint connection	Attribute: urn:kanta:kvarkki:private- hosted	AttributeValue: Value according to code 1.2.246.537.5.40200.2014, or empty. Kanta services - Connection models for private service providers: 1.2.246.537.5.40200.2014 1 = Private service provider joined Kanta services directly 2 = Private service provider joined Kanta services through joint subscription E.g. <PrivateHosted xmlns="urn:hl7-org:v3" xsi:type="CE" code="2" codeSystem="1.2.246.537.5.40200.2014" codeSystemName="Kanta-palvelut - Yksityisten toimijoiden liittymismallit" displayName="Yksityinen toimija yhteisliittyjänä"/>	O	Kvarkki
Lessee	Attribute: urn:kanta:kvarkki:private- hosted-organization	AttributeValue: lessee organisation OID as character string E.g. <saml2:AttributeValue>1.2.246.10.89101112.10.0</saml2:AttributeValue>	O (must be used if Joint subscription is of type 2)	Kvarkki
Lessee's service unit	Attribute: urn:kanta:kvarkki:privatehosted-organization-unit	AttributeValue: lessee organisation's service unit OID as character string E.g. <saml2:AttributeValue>1.2.246.10.89101112.10.1.1</saml2:AttributeValue>	O	Kvarkki

8 Valuation

From the functional point of view, valuation improves the utility value of studies and facilitates their utilisation. Moreover, it reduces archiving of study material of little value and the need for storage space for archived imaging studies.

According to the regulations on the storage of patient documents, a technically incorrect imaging study is deleted immediately. The deletion from the imaging study of this kind of material must be carried out before the study is archived, also with regard to studies archived when incomplete.

References of the most valuable objects in terms of the use of the imaging study are stored in the study as KOS objects (key object selection). The selection and storage are normally carried out by the radiologist or other expert interpreting the study. The KOS types in accordance with the DICOM CID 7010 Key Object Selection Document Title are used as follows:

Code	Definition	Purpose of use
113000	Of Interest	Significant objects
113002	For Referring Provider	
113003	For Surgery	

113006	For Therapy	
113007	For Patient	Objects shown to the patient primarily in My Kanta Pages
113008	For Peer Review	Objects that are significant in terms of a second opinion request
113013	Best In Set	Best objects in terms of their technical quality entered by the person carrying out the study
113020	For Report Attachment	Objects that are the basis for a report or that are referred to

Corrections to the study carried out before archiving, in which study objects are marked to be removed, must not be archived, as is the case with the objects removed in this way.

In order to diminish the size of the study to be archived, the radiologist marks the image objects to be archived. The method of implementation may be system-specific, but the use of KOS is recommended. Only image objects marked to be archived are moved to the Kvarkki DICOM archive. The implementation of marking should be based on at least partial automation with respect to the images or series of images used by the radiologist in their report.

9 Content requirements of studies

In KVARKKI architecture, local PACS systems archive the imaging studies into Kvarkki DICOM archive by moving them to the Kvarkki imaging document source. The studies are saved in the Kvarkki DICOM archive in DICOM format in the way described in the DICOM standard. The archivist of the imaging study is responsible for the conformity of the contents.

Imaging studies must be archived using a format in which all systems retrieving studies from Kvarkki will show the key contents of the imaging study in full and in the correct way. Especially all information used as a basis for reports must be shown correctly. The inclusion of manufacturer-specific elements in an archived study is permitted, provided that the data contained in them is also included in elements that are in accordance with the standard and required by the Kvarkki specifications.

Imaging studies must include data, which is described in connection with the metadata model, in DICOM tags.

A unit producing imaging studies to be archived must not use only entries (sticky notes, etc.) recorded in the PACS database in the imaging study entries.

These requirements will be specified at a later date. Conformity will be verified with joint testing carried out before joining Kvarkki.

The requirements for systems showing imaging studies are presented in the chapter in question.

KVARKKI complies with the DICOM standard version 2014b. Introduction of more recent standard versions is under plan and will be decided on separately.

The following diagram describes the DICOM data model at the upper level:

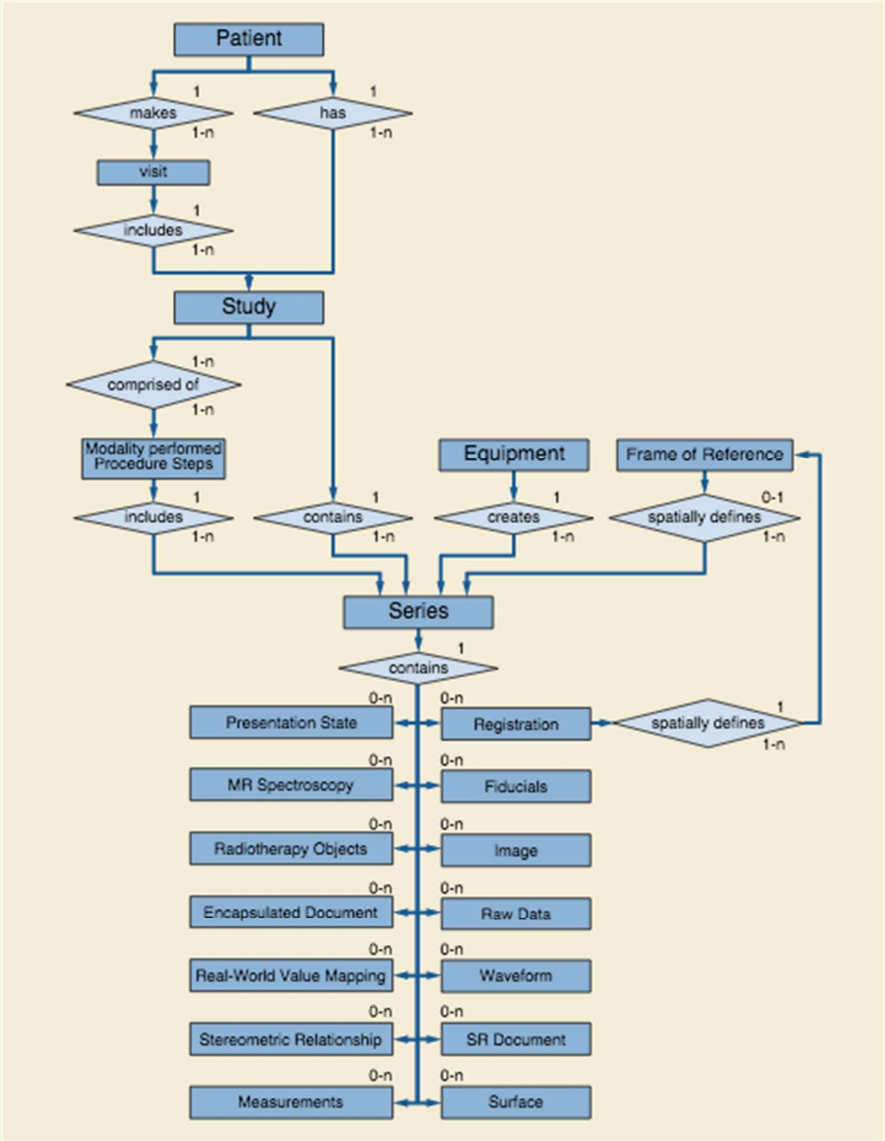

Figure 26 DICOM Information Object Definitions, DICOM PS3.3 2014b

Any permanent changes made in the imaging stage, such as a correction of a side marker, must be done directly to the pixel data of the image before the images are archived.

Annotations, grayscale alterations and other values related to showing the images are stored as DICOM Presentation State objects.

The DICOM standard specifies that all instances pertaining to the same study must have identical study-level data. Correspondingly, all series instances must have the same series-level data.

The supported character sets to be used are Latin-1 (ISO_IR 100) and Unicode UTF-8 (ISO_IR 192). Latin 1 is the recommendation of the ENV 41 503 standard for the Western European region.

9.1 Studies in non-DICOM format

Natively, studies that are in non-DICOM format (for example, ordinary photographs) can be converted to DICOM format and stored via the local/regional PACS in the national Kvarkki DICOM archive in DICOM format. The archived study is processed in Kvarkki in the same way as normal imaging studies, and they must have the data that complies with the specification in DICOM tags. Kvarkki specifies the contents permitted in further work to enable management of uniform use of metadata (practiceSettingCode, classCode, formatCode, typeCode, mimeType) in document grouping and the utilisation possibility of studies.

Alternatively, studies in non-DICOM format can be sent to the Kanta archive in the CDA R2 non-structured body section in the HL7 V3 framework via the Kanta service channel. Matters related to this

method of archiving are not specified in Kvarkki. It will be decided in the (possibly later) implementation stage of Kvarkki whether the Kanta XDS adapter will register these documents in the XDS registry.

It is also technically possible to record in the XDS repository in native, unpackaged format. The possibility of using this kind archiving method will be outlined in further specifications. This method of archiving also requires extensive installation of metadata in the specified way. The general XDS metadata model to be drawn up must also be taken into account. It is possible to archive documents in the encounter that is in the Kanta archive.

A Kvarkki subscriber must draw up a description of the archiving methods of material in non-DICOMformat and its content format. Kela lays down requirements and approval criteria for joint testing with respect to studies in non-DICOM format.

9.2 Technical solution and implementation

Kvarkki controls the integrity and conformity of imaging studies to be archived by carrying out validations in connection with archiving. The Kvarkki DICOM archive is connected to a validation component, which carries out the inspections. The inspection includes, for example, the following:

- Verifying with a patient care record that contains the patient's personal identification code, Study Instance UID and the imaging study entries that a service event for the patient has been recorded in the Kanta archive
- It is noticeable that from the Modalities in Study (0008,0061) tag only values from CID29 are registered in the XDS registry
- Requirements of the study in accordance with the Kvarkki metadata table are verified:
    - Study description (0008,1030)
    - Patient ID (0010,0020)
        - What is also notable about the Issuer of Patient ID (0010,0021) handling in Kvarkki: at the first phase the tag is not checked and it is assumed that an official patient identifier is used. This is due to the decision that in the first phase of Kvarkki temporary patient identifiers are not supported. However when Kvarkki will start supporting them the Issuer of Patient ID will also be mandatory.
    - Study Instance UID (0020,000D)
    - Study Date (0008,0020)
    - Study Time (0008,0030)
    - Study code is verified (studyDescription 0008,1030, 5 first characters are validated)
        - The value used must be valid in the code set: THL – Classification of Procedures (1.2.246.537.6.2.2007)
        - The anatomic area (XX345) and the specifier for the anatomic part (XXX45) are picked from the study code and they are mapped into the code set for the anatomic part and set in the XDS metadata

10 Transfer and saving formats, and compression

KVARKKI architecture aims to minimise delays caused by data transfer and data conversions by recommending a common saving and transfer format for DICOM image files used in every DICOM archive.

The Kvarkki DICOM archive in the KVARKKI architecture recommends 1.2.840.10008.1.2.4.80 – JPEG-LS Lossless Image Compression file format as the saving format. However, images are stored in the format that SCP sends them to Kvarkki.

It is also recommended to use the same saving format and transfer syntax in local PACS systems. Using lossy compression as a transfer syntax is permitted when archiving imaging studies in DICOM format only if the lossy compression is used natively in the PACS system.

The DICOM standard also allows a few other saving formats and transfer syntaxes. According to the standard, some of these must be supported in any case, for example, the native format Implicit VR Little Endian. However, as the files are in a compressed format in the archives, the images must first be uncompressed when sending in native formats and only after that sent on, and therefore it is recommended to use as the transfer syntax the same format in which the archive stores the images.

Kvarkki's supported transfer syntaxes when storing images are listed below:

Name	UID
Implicit VR Little Endian	1.2.840.10008.1.2
Explicit VR Little Endian	1.2.840.10008.1.2.1
JPEG Baseline (Process 1)	1.2.840.10008.1.2.4.50
JPEG Extended (Process 2 & 4)	1.2.840.10008.1.2.4.51
JPEG Lossless, Non-Hierarchical, (Process 14)	1.2.840.10008.1.2.4.57
JPEG Lossless, Non-Hierarchical, First-Order Prediction (Process 14 [Selection Value 1])	1.2.840.10008.1.2.4.70
JPEG-LS Lossless Image Compression	1.2.840.10008.1.2.4.80
JPEG-LS Lossy (Near-Lossless) Image	1.2.840.10008.1.2.4.81
RLE Lossless	1.2.840.10008.1.2.5

See the up-to-date list about transfer Kvarkki syntaxes here: http://dcm4chee-arc-cs.readthedocs.io/en/latest/networking/specs/storage/storage.html#scpimagets

When selecting the saving format used in local PACS systems, the saving format used by any current DICOM archive implementations, the practices in the transition period and any conversion needs must be taken into account.

11 Affinity domain specifications

A separate document has been drawn up on affinity domain specifications. The document consists of a nationally defined section that supplements this specification, as well as of a guide for the contents of a regional affinity domain specification.

The specification is preliminary and it will be completed in connection with the implementation of Kvarkki.

12 Metadata model for the imaging study entity

This chapter presents the principles of using metadata that is essential in terms of the functioning of Kvarkki, as well as the required extensions especially in so far as is necessary for Kvarkki with respect to the Finnish application method.

The data extracted from the DICOM data elements of the imaging study in the registration of the manifest into the IHE XDS-I metadata has been compiled. With respect to CDA documents saved in the Kanta archive, key data with respect to XDS registration has been evaluated. CDA documents and DICOM tags of the imaging studies are mainly examined as a source of XDS metadata, i.e. the equivalent to XDS metadata in these documents are specified.

A description in table format on the equivalences of the metadata and the requirements resulting from the specifications is enclosed to this specification. The description is preliminary and it will be completed in the further specifications. The metadata model has preliminarily also taken into account the use of the XDS registry for registering other than patient care documents in imaging.

12.1 Rules for using data fields

The XDS specification includes a group of metadata and their semantic definition. In Kvarkki, it is aimed to use metadata in accordance with the IHE semantics as far as possible.

Solutions with respect to metadata for which the application of the instructions in the IHE specification is not trivial in terms of their contents and source are described in the following. The main principle in the solution has been to use the eventCodeList attribute for coded data and to use the refrenceIdList attribute for ID data as these can be used flexibly for multivalued metadata. When these metadata attributes are used, it is possible to set general national metadata for the metadata model that are specific for imaging. These attributes also enable the use of this metadata as query parameters.

The metadata referenceIdList is specified by the Reference ID option in the XDS profile, and the option must be available with support in the XDS registry products. According to the XDS rules, products that do not support the referenceIdList will handle its data as XDS extra metadata elements and the FindDocumentsByReferenceId-type registry query is not available.

Extra metadata is utilised in certain special cases[13].

Imaging studies produced before joining Kvarkki do not contain the required data in tags and cannot necessarily be connected to the encounter. Less strict requirements are set for manifests produced from these kinds of imaging studies, and the metadata needed for the implementation of query limits is set for the manifest. The requirements related to these will be specified further in connection with more detailed planning.

12.1.1 Documentary metadata

Documentary metadata in this connection includes: the service purchaser, service provider, service purchaser's unit, encounter, custodian, registry, registry specifier. The encounter document stored in Kanta is the master for 'documentary' metadata.

In the archiving of an imaging study, the imaging document source (Kvarkki DICOM archive) retrieves the documentary metadata from the Kanta archive on the basis of the encounter ID (which is retrieved with the help of Study Instance UID found from the DICOM study) and sets them in the XDS metadata of the content description (manifest) of the imaging study. Kanta has a service for retrieving the key data of active encounters.

In order to conclude the sharing permit in consent management, no other documentary metadata for the document is needed, but only the encounter IDentifier as the function can be established in the centralised sharing permit query service.

The author is a recurrent, hierarchical metadata in composite format that presents the data of organisations and persons including their roles. Organisation and custodian data constitute their own author recurrences, and their data (ID and name) is presented in the authorInstitution substructure. Different structures are identified with the authorRole substructure in the same author recurrence. It is also possible to provide the data of professionals related to the document in the authorPerson subelement in the same author element. The author element is used as follows:

- Professional's data: own author recurrence with an authorPerson substructure that includes the professional's data, authorRole substructure gets the value 'Professional'. If the document has several professionals, the entire author recurrence (authorPerson is not recurred).
- Service purchaser (service provider): own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Service purchaser'.
- Service provider: own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Service provider'.
- Custodian: own author recurrence with an authorInstitution substructure, authorRole substructure gets the value 'Custodian'.

[13] Extra metadata is utilised when necessary, mainly when it is not necessary to use metadata as a query criterion (extra metadata attributes cannot be used as a limiting query criterion). It must be noted with respect to extra metadata that only ebRIM Slot compliant data coding is available.

Out of this data, only the data concerning the professional (authorPerson) may be used as a query parameter in ITI-18 queries. Other author substructures (e.g. authorInstitution) cannot be used as query parameters[14].

The encounter ID is mandatory for all registered documents and stored in the referenceIdList metadata in the document entry. The encounter ID can therefore also be used as a query parameter in an ITI-18 FindDocumentsByReferenceId query.

In possible XDS solutions in the distributed model, it is also obligatory to delete the documents at the end of the storage period (view code + other logic). For the needs of retention management, the documents have the storage time class and continued storage time as metadata. See further in 4.13 Retention control and deletion.

A manifest created of an imaging study produced before joining Kvarkki has an extra metadata-type of metadata to indicate that it belongs to this kind of document class.
In the XDS solution, there is an obligation to also manage the metadata in change situations (custodian changes, etc.). In further planning, the retrieving implementation method that retrieves documentary data from the Kanta archive in connection with registry queries and retrieves will be assessed especially with a view of simplifying change situations in the distributed model. In this implementation method, not all documentary metadata would be stored and maintained in the XDS metadata.

12.1.2 Substance data

The metadata classifying the document type are classCode and typeCode and title.
Metadata in classCode in given the document's 'rough' type, the code set for this classification is

1.2.246.537.5.5001.2011. Metadata typeCode describes 'a fairly detailed' document type and specifies the classCode value; the code set for this classification is also 1. 2. 246. 537. 5. 5001. 2011. In addition to these, the document type is specified further by giving it a study code in the title metadata.

The metadata healthcareFacilityTypeCode includes a division into public healthcare, private healthcare, occupational healthcare and self-employed service provider. The method of use complies with the Kanta archive.

In the CDA R2 documents, the main view of the document is given in the practiceSettingCode metadata. The main view is determined by the document source code set AR/YDIN – Näkymät 2002 1.2.246.537.6.12.2002. For documents other than CDA R2 documents, the standard value 'RTG' is used in imaging.

Views other than the main view of the CDA R2 document are set in the metadata eventCodeList. These are obtained from the tableOfContent element in the CDA R2 header. It is necessary to bring all views into the metadata to evaluate especially protected information because especially protected information is based on the view data of the CDA R2 document.

The procedure code for THL's radiology is saved in the eventCodeList metadata in accordance with the code set THL – Classification of Procedures. In connection with registering, the imaging document source and the Kanta XDS adapter will deduct the corresponding code values from the anatomical region and modality code sets on the basis of the procedure code, and these are also saved in the eventCodeList metadata.

Documentary data of the encounter ID is saved in the referenceIdList metadata (see the metadata model for a specific listing). Other data may include:

- registry specifier
- Study Instance UID
- AC number
    - and the issuer (if available)

[14] If there is a need to use the organisation / custodian data as query parameter, the data must be specified in the referenceListId metadata.

A combination of demographics data is saved in the metadata sourcePatientInfo in accordance with XDS.

12.1.3 Preparing for regional reform (2020)

The regional reform concerning the health, social services and regional government will establish the new counties and reform the structure, services and funding of health and social services as well as transfer new duties to the counties. The regional reform model that is due to come into force on 1 January 2020. Kvarkki supports the reform by extending the Metadata model with an own author recurrence and a new role that is the placeholder for the active custodian after the regional reform. The active custodian author concerns both the public and private sector healthcare organizations. The old custodian information in the Metadata model (Rekisterinpitäjä) is valid until 1.1.2020. Starting from 1.1.2020 Kvarkki will begin to use the new active custodian information (Aktiivi rekisterinpitäjä) as the primary source for the custodian. See the latest Metadata model specification for more information: Metatietomalli.

Kvarkki will automatically take care of populating the active custodian information in the XDS registry with the same principles than the Kanta archive. Before the regional reform Kela will update all the entries that have Approved status in the XDS registry with the new active custodian information. After the reform the new active custodian information will always be populated according to the information provided in the service event document archived in the Kanta archive. At the moment of writing this document it is still unclear whether there will support in Kvarkki if the service event is still archived with the old custodian information after the regional reform.

13 Key code sets to be used

The main principle is to use existing code sets used in Kanta CDA documents to ensure uniform contents. An up-to-date list of code sets to be used must be verified from the Kvarkki metadata specification.

14 Utilisation of IHE profiles and their options

Due to Finnish legislation and the architecture principles of national healthcare systems, profiles that support the functional entity of Kvarkki are to be used in Kvarkki. As an example, the identification of the person carrying out a query on data required by consent management needs the XUA profile and the correction of archived material needs the IOCM profile of change management.

Many profiles include options, each of which is utilised according to the functional or contentual need of Kvarkki. Many profiles also have plenty of application alternatives.

According to the IHE principles, the affinity domain provides instructions for the application of profiles. In Kvarkki, the major part and, with respect to shared use, the common part will be provided with national guidelines.

Kvarkki does not directly utilise IHE profiles related to the workflow. Imaging also involves profiles (Access to Radiology Information (ARI), Consistent Presentation of Images (CPI), Consistent Presentation of Images (CPI), NM Image (NM)), which are not utilised by Kvarkki or the compliance of which is not required.

IHE specifies a number of content profiles in relation to imaging. The content profiles concerning the imaging studies themselves, i.e. the DICOM objects, are suitable for use in Kvarkki. Content profiles concerning CDA documents define contents on which HL7 specifications have been drawn up in Finland, e.g. in connection with the Kanta project. With respect to imaging CDA documents, Kvarkki utilises existing Finnish content formats specified by HL7.

Profiles in the IHE draft level (trial implementation) are utilised where it is required by the functionality of the first stage of Kvarkki. An alternative would be to draw up a separate specification, but in the longer term the conformity with IHE profiles is an advantage. Draft profiles are estimated to be included in the official version within 1–2 years with mainly the same contents as the draft.

The following sub-chapters present the extent and method of utilising each profile in Kvarkki.

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

The Cross-Enterprise Document Sharing for Imaging profile is important with respect to the Kvarkki model [2].

The profile defines the formation and content of the manifest formed from the archived imaging study by the imaging document source, as well as its storage in the XDS repository and further its registration in the XDS registry.

The Imaging Document Consumer is required to support the option transaction of the Retrieve Imaging Document Set [RAD-69] in order to be able to retrieve the imaging studies from the Imaging Document Source of another domain. It is also possible to use WADO Retrieve [RAD-55] and Retrieve Images [RAD-16] transactions locally and regionally.

The profile defines three alternatives for the structure and saving of the report. Instead of these, Kvarkki uses the imaging study document defined in connection with the Kanta archive and its storage in the Kanta archive. This solution is closest to the CDA Imaging Report with Structured Headings alternative of the profile, but the document is not stored in the repository.

The profile also defines the transactions Retrieve Presentation States [RAD-17], Retrieve Reports [RAD-27], Retrieve Key Image Note [RAD-31] ja Retrieve Evidence Documents [RAD-45], which are not used by Kvarkki. The transactions use DICOm operations and their use is not included in the XDA-I profile.

14.2 Cross-Enterprise Document Sharing, XDS.b

The profile is essential in terms of the Kvarkki model; it is a content-neutral profile that forms a basis for a similar profile in imaging.

The repository implements the Asynchronous Web Services Exchange option for improved management of delays in the transfer of large documents. Users of the services may use synchronic or asynchronic services, i.e. the implementation of this option is not mandatory for the Document Consumer.

The registry implements the Asynchronous Web Services Exchange option. The option does not offer any functional benefits, but its use is consistent with the repository.

The registry implements the Reference ID option, which enables saving a reference from outside the domain and using it as a query criterion in document retrieval.

The Basic Patient Privacy Enforcement option is not used.

The optional transactions Patient Identity Feed [ITI-8] of the registry actor are used in Kvarkki to update temporary identifiers in the registry data. Its HL7v3 equivalent ITI-44 is not used in Kvarkki, and the Patient Identity Source actor is not included in the Kvarkki configuration. The patient's demographic data is not maintained in the Kvarkki registry.

14.3 Cross-Community Access , XCA

XCA is a key profile in the query functionality between domains, and XCA-I expands and specifies it for the needs of imaging. Archiving and updating transactions are not included in the profile.

Of the option specified by the IHE profile, Initiating Gateway implements Registry Stored Query [ITI18] and Retrieve Document Set [ITI-43]. Initiating Gateway also implements the XDS Affinity Domain Option and the Asynchronous Web Services Exchange option.

14.4 Cross-Community Access for Imaging, XCA-I

The role of this profile in Kvarkki can be seen as a possibility to use XCA Gateway to abstract the interfaces of registries and repositories.

The profile expands the XCA profile. Archiving and updating transactions are not included in the profile.

Responding Imaging Gateway implements the Cross Gateway Retrieve Imaging Document Set [RAD75] and the Retrieve Imaging Document Set [RAD-69] transactions.

14.5 Cross Enterprise User Assertion, XUA

Kvarkki transmits the data of the service request sender and patient care context to the actor offering the service for using in the consent management deductions. The data is transmitted in a way specified by XUA, i.e. with SAML 2.0 technology. There is no need in Kvarkki for all of the data transmitted in the profile but, on the other hand, the dataset will be expanded according to the national need.

In XDS and XDS-I transactions implemented in a concrete way as a web service in Kvarkki, the specified XUA assertion elements are located in the header section of the SOPA query message, while the message content specified by the functional XDS and XDS-I profiles is in the body section of the SOAP message. The same XUA element content is used in all transactions.

The Subject-Role and Authz-Consent options of the profile are not utilised.

14.6 Consistent Time, CT

CT specifies the use of Network Time Protocol (NTP) servers in the clock settings. NTP works well in Kvarkki, and it is also in accordance with the operating model required by Kanta.

14.7 Audit Trail and Node Authentication , ATNA

The identification and authentication of parties takes place in Kvarkki in accordance with the ITI Audit Trail and Node Authentication profile.

The audit trail specified by the profile does not meet the requirements of share and use logging, and it is not utilised in Kvarkki for these purposes. The audit trail produced by the systems in accordance with the profile has a technical log status in Kvarkki.

14.8 Consistent Presentation of Images (CPI)

Some of the profile principles are utilised in the study content requirements, but the profile is not complied with in its entirety. Transactions specified by the profile are not used within Kvarkki.

14.9 Key Image Note (KIN)

The principles of the profile are utilised in the study content requirements with a purpose of supporting interoperability in the processing of entries.

14.10 Evidence Documents (ED)

The principles of the profile are utilised in the study content requirements with a purpose of supporting interoperability in the processing of entries.

14.11 Imaging Object Change Management (IOCM)

IOCM covers changes for object rejection for quality or patient safety reasons, as well as corrections resulting from carrying out an incorrect study. Furthermore, removal of objects after the retention period is included in the profile. A profile included in the radiology specifications approved from the Kvarkki point of view specifies the changes to be made in the imaging study. There is a specification in the trial implementation phase on the expansion of IOCM, covering corrections to be made, e.g. in the XDS repository and registry.

Changes made by the organisation in the imaging studies produce an altered content in Kvarkki in accordance with IOCM. Kvarkki requires that changes in the correction of imaging studies and in other change management are saved as DICOM objects in the studies in accordance with the IOCM

principles, and the changed imaging study is archived into Kvarkki. Information about the changes is saved in the XDS repository and registry in accordance with the IOCM expansion proposal.

The section concerning workflow in the IOCM profile is not used in Kvarkki.

Due to saving of imaging CDA documents in the Kanta archive, a change in accordance with IOCM will not cover them, and this has been specified separately.

The IOCM procedure to remove objects after the end of the retention period is used as part of the deletion process.

14.12 Patient Identifier Cross-referencing (PIX ja PIXV3)

The principles of the Patient Identifier Cross-referencing (PIX) profile are complied with in the management of temporary identifiers.

The PIX profile transactions, i.e. HL7 version 2.5 messages are used as they are in use in the current systems. There is no decision in Finland regarding the introduction of HL7 V3 messages in accordance with PIXV3.

14.13 Unutilised profiles

IHE specifications include profiles, the use of which could be considered in Kvarkki, but which Kvarkki does not utilise directly or they are utilised within and between systems related to the imaging of healthcare service providers. Some of these kinds of profiles are discussed here briefly.

14.13.1 ITI Technical framework

The Basic Patient Privacy Consents (BPPC) is not suitable for consent management complying with the requirements of Finnish legislation.

Enterprise User Authentication (EUA) can be used in the systems of healthcare service providers and be connected to the implementation of the XUA profile. It is not needed in Kvarkki because user-level identification is not used in Kvarkki.

The Patient Synchronized Applications (PSA) profile applies to the use of HL7 context management. There is no use for the profile from Kvarkki's point of view, but context management is widely used in the systems of healthcare service providers.

There is no need for the Cross-Enterprise Document Reliable Interchange (XDR) profile in the XDS environment.

Patient Administration Management (PAM) is not utilised because Kvarkki does not take part in patient management.

The Cross-Enterprise Document Media Interchange (XDM) profile is not utilised because saving in the personal health record is not part of the functionality of the first stage of Kvarkki.

The Patient Demographics Query (PDQ) and Patient Demographics Query HL7 V3 (PDQV3) profiles are not used because Kvarkki does not retrieve patient data. The profiles may be in use in the systems of healthcare providers.

Cross-Enterprise Document Workflow (XDW) specifies the use of the document to be archived in the workflow coordination. The profile is not used.

14.13.2 Radiology

Scheduled Workflow (SWF) and Post-Processing Workflow (PWF) concern workflows in the study stage, and they are not utilised or required by Kvarkki. However, utilisation of the profiles is recommended in the systems of healthcare organisations.

The Radiation Exposure Monitoring (REM) profile is not used in Kvarkki, but the radiation exposure is saved in the imaging CDA document. The profile may be in use in the systems of healthcare organisations.

Access to Radiology Information (ARI) is not necessary in the XDS-I context.

The Portable Data for Imaging (PDI) profile is not utilised because saving in the personal health record archive is not part of the functionality in the first stage of Kvarkki.

15 Software requirements

The functional and technical requirements of Kvarkki subsystems and systems integrated in Kvarkki from the viewpoint of these systems are compiled in this chapter. The chapter does not include requirements that have not been presented in the previous chapters, but it describes them from a different perspective as a kind of reference list with a purpose of facilitating the entity of Kvarkki and the systems connected to it, as well as the preconditions for introducing Kvarkki.

15.1 XDS profile options and expansions

Kvarkki uses the referenceIdList metadata to connect documents to an encounter and to connect imaging documents with the Study Instance UID. The ReferenceIdList metadata is specified by the Reference Id option of XDS.

The software used must support the Reference Id option. With respect to the XDS registry, support means the possibility of using the FindDocumentsByReferenceId format in the registry query (ITI-18) in addition to saving the multivalued referenceIdList metadata. The encounter and Study Instance UID linking in registry queries can only be utilised with this query format.

With respect to viewers and other systems acting as a document consumer actor, the support for the Reference Id option means an ability to use the FindDocumentsByReferenceId format in registry queries.

The Imaging Document Consumer is expected to support the option transaction of the Retrieve Imaging Document Set [RAD-69] in order to be able to retrieve the imaging studies from the Imaging Document Source of another domain.

It is recommended that the Document Consumer and Imaging Document Consumer support the Asynchronous Web Services Exchange option, which enables the management of delays in the retrieval of large documents.

XDS determines the Document Metadata Update option, which is in the trial implementation stage. The option is needed in the document deletion functions after the end of the retention period and possibly in some change management functions. Support for the option is not required in the first stage of Kvarkki.

15.2 Requirements for the support of non-IHE profile features in products

Implementation of consent management in the way described in this specification requires that the product used for the implementation of a domain-specific Kvarkki configuration supports the connection of a tailored policy enforcement point implementation to the handling of queries in the registry, repository and imaging document source. The IHE specification does not require this kind of support.

The imaging document source must support the connection of the inspection of tailored saving right when saving an imaging study. Tailored implementation inspects the existence of an encounter and the archivist's right to save documents in it. The function has been described in chapter 4.2 of this specification. The IHE specification does not require this kind of support.

The management of document retention time and deletion functions are not included in the IHE profiles. Due to national requirements, the implementation is tailored, but it requires that the product has service, e.g. to delete documents.

15.3 XUA support in the client program

In all XDS and XCA transactions, the inviting client must include in the query the information about the user's identity and patient care context, as well as other information specified by XUA. The patient care context is an addition to the data required by IHE XUA, specified in Kvarkki, and Kvarkki defines the specifications also with respect to other data contents.

The user's identity must be sufficiently reliable in accordance with the trust relationship and the principle of the identification of parties. The client software must be integrated into the patient care context so that the encounter ID and other patient care context data are available.

The client must be able to include in the query the specified SAML2 elements and the data required in them.

15.4 Reliable presentation of imaging studies in viewer functions

An application handling the contents of imaging studies and presenting to the user must present the contents of the study reliably and in their entirety. A study that meets the content requirements for studies must be shown correctly and consistently. The reject KOS must be handled in the right way when handling objects that are in accordance with IOCM and removed for quality or patient safety reasons.

15.5 Production of an imaging study that meets the requirements

The modalities, PACS and radiology tool programs used must save the imaging study objects according to the DICOM standard applied and the Kvarkki content specification.

The inclusion of manufacturer-specific presentation and saving formats in an archived study is permitted provided that the data contained in them is also included in elements that are in accordance with the standard and the Kvarkki specifications.

16 Data communications

Message traffic is point-to-point according to the XCA model, i.e. the XCA gateway of the domain of the person making the query call sends the query to the gateway of one or all other domains. XCA does not contain a functionality to enable a domain to act as a hub. All XDS and XDS-I transactions are either synchronic or asynchronic web service calls.

16.1 Encryption

The use of data encryption is required in Kvarkki service requests. The traffic of XDS and XDS-I transactions is encrypted, using VRK's healthcare server certificates. TLS two-way authentication is in use.

Encryption takes place in accordance with the TLS 1.2 specification (or the latest Kanta data communications specifications). If PACS does not support this, the connection must be tunnelled.

17 Management of error situations

The Kvarkki DICOM archive does not enable any manual error correction functions focusing directly at the archive.

The correction of contentual or metadata errors in archived material takes place in the systems that have archived the material, e.g. as described in connection with change management and temporary identifiers. With respect to the Kvarkki DICOM archive, content corrections constitute document versioning.

Error situations detected in connection with studies made into the Kvarkki DICOM archive or the archiving of new versions of studies are handled in the way described in the DICOM standard.

Sufficient technical control must be organised in order to detect technical malfunctions. Malfunctions must be remedied through routine procedures in service production while providing instructions for the operations. These kinds of error situations do not give rise to the need to correct the data contents of the archive.

17.1 Error codes returned by the Kvarkki DICOM archive

Immediate errors detected in connection with the archiving and change processing of studies are returned as errors of FAILURE class in C-STORE processing in accordance with the DICOM standard, stating that the requested archiving of the study has not been carried out. (DICOM standard section PS

3.4 [3]) The response statuses returned in the C-STORE processing of centralised Kvarkki are described in the DICOM Conformance Statement:

http://dcm4chee-arc-cs.readthedocs.io/en/latest/networking/specs/storage/storage.html#id10

Further revisions are also carried on studies archived in centralised Kvarkki due to national requirements, in which case the status codes used also belong to the FAILURE error class defined by the DICOM standard (error reason):

- Error: Cannot understand (Cxxx)
    - Errors related to the sent contents, it is not worth trying to resend it as such. Archiving of the study may only be successful through corrections of the contents carried out by the client with the aid of information obtained from the error code.
- Refused: Out of Resources (A7FF)
    - Technical errors within Kvarkki are always returned with the same Out of Resources code A7FF. In these cases, error correction is Kela's responsibility as one of the Kvarkki subsystems is not working correctly in this situation. The client may attempt resending once the error has been corrected.

Both of these enable returning of the code and the corresponding comment (error reasons). In the error reason, the error code returned by the Kvarkki system and the reason for the error in question are returned to the client.

Dicom tags returned from further revisions in Kvarkki:

(0000,0900) Status (of the format Cxxx or A7FF)

(0000,0902) Error Comment (reason in English, a total of max 64 ASCII characters)

Error situations interpreted from C-STORE Failure due to extra verifications, and the corresponding error codes with their recovery instructions have been listed in further detail as an appendix to this specification (Appendix 1), which will be maintained as and when new revisions are taken into use. The errors are described in English for the purpose of any overseas PACS suppliers.

Error situations interpreted from the DICOM Storage Commitment are described in the DICOM Conformance Statement of centralised Kvarkki:

http://dcm4chee-arc-cs.readthedocs.io/en/latest/networking/specs/storage/storage.html#id12

17.2 Technical error correction

At the technical level, it is possible to correct error situations that are mainly due to operational malfunctions. The mechanism used is almost exclusively retrying.

- The system may automatically retry to perform the service call
- A retry of the service call takes place as the user's manual function

Instructions will be provided for the delay of automatic resending and the permitted number of tries.

17.3 In the operating processes

Error situations requiring corrections carried out by the operating process.

- Correction of errors detected in the verification of archiving

- Described in connection with change management
- Described in connection with temporary identifiers
- Corrections if imaging CDA documents (correction procedure in accordance with the Kanta specifications)

In archiving, Kvarkki may detect errors in the contents of an imaging study. The error is indicated with a structure according to DICOM Failure Status Class and specific error codes. An error situation must be followed by an indication to the body responsible for sending so that failed archiving will be noted and reacted to in the appropriate way (e.g. correction and rearchiving of study).

18 Needs for change in other specifications

During the specification work, the following needs to change definitions and regulations were identified.

18.1 Handling of temporary identifiers

A national model is needed for the handling of temporary identifiers. The proposal drawn up by THL is being processed at the instigation by the Ministry of Social Affairs and Health.

18.2 Laws and regulations

The requirement for the retention period of data concerning radiation exposure should be specified. Currently, the retention period differs from that of the CDA document that contains this information.

18.3 Code sets

There is a need to specify the code sets to classify documents suitable for use in XDS metadata. See 13 Key code sets to be used

19 References

[1] IHE IT Infrastructure (ITI), 2017.

[2] IHE Radiology (RAD) Technical Framework, 2017.

[3] The DICOM Standard

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[7] Assertions and Protocols for the OASIS Security Assertion Markup Language (SAML) V2.0, OASIS, 2005.

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[11] Kela, Kanta Potilastiedon arkiston kevyiden kyselyrajapintojen kuvaus 1.0.5.3, (zip), 18.5.2018.

Appendices

Appendix 1: Error codes and recovery instructions for national further revisions of DICOM validation in connection with C-STORE

(the appendix is available at: http://www.kanta.fi/fi/web/ammattilaisille/kuvantaminen-kvarkki- with the name: Kvarkki_tekninen_määrittely_Liite1)

Appendix 2: XUA digital signature guide (In Finnish)

(the appendix is available at: http://www.kanta.fi/fi/web/ammattilaisille/kuvantaminen-kvarkki- with the name: Kvarkki_tekninen_määrittely_Liite2)

Appendix 3: example requests

(the appendix is available at: http://www.kanta.fi/fi/web/ammattilaisille/kuvantaminen-kvarkki- with the name: Kvarkki_tekninen_määrittely_Liite3)

Appendix 4: XDS Error codes

(the appendix is available at: http://www.kanta.fi/fi/web/ammattilaisille/kuvantaminen-kvarkki- with the name: Kvarkki_tekninen_määrittely_Liite4)

Appendix 4: ADT messages

(the appendix is available at: http://www.kanta.fi/fi/web/ammattilaisille/kuvantaminen-kvarkki- with the name: Kvarkki_tekninen_määrittely_Liite5)