

Integrating the Healthcare Enterprise



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**IHE IT Infrastructure Technical Committee
White Paper**

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**Template for XDS Affinity Domain
Deployment Planning**

15

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20

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1 Introduction

45 The concept of an XDS Affinity Domain is defined in ITI TF-1:10 and Appendix K. It is clear that many regulatory/professional organizations will need to define policies regarding coded terminology, privacy, document format and content, language support, etc. for an XDS Affinity Domain. In addition, there will be the need to define such policies on a national or regional basis for all XDS Affinity Domains within a geographic region. These policy decisions, necessary for successful implementation, may result in refinements of the XDS Profile itself.

50 This White Paper proposes a new template that should be used when defining policies for either an individual XDS Affinity Domain, or multiple XDS Affinity Domains within a particular nation or region. This template provides a consistent documentation format for specifying implementation decisions, policies, and possible refinements of XDS and related Profiles. Additionally, its' outline provides a comprehensive list of all relevant topics that XDS Affinity Domain implementers may find helpful in planning for deployment.

55 1.1 Expected Knowledge and References

It is assumed that the reader has a working knowledge of the IHE ITI XDS Profile and its dependent Profiles which can be downloaded from the IHE web site:

http://www.ihe.net/Technical_Framework/index.cfm

The key Integration Profiles and section number in the above document are:

- 60
- XDS – Section 10
 - PIX – Section 5
 - PDQ – Section 8
 - ATNA – Section 9

65 The existing Cross Community Information Exchange and the Cookbook for the Security Sections of IHE Profiles White Papers, as well as Basic Patient Privacy Consents Supplement provide useful information regarding areas that should be addressed when implementing an XDS Affinity Domain. These can all be found using the IHE web site link above.

70 In addition, refer to ISO/TS 22600-1:2006 Privilege Management and Access Control, Part 1: Overview and policy management. This describes the scenarios and the critical parameters in cross border information exchange. It also gives examples of necessary documentation methods as the basis for the Policy agreement.

2 Goals

This paper addresses the following goals:

- Describe the issues to consider when planning the deployment of XDS Affinity Domains.
- 75 • Define the areas of the XDS and related Profiles to consider refining for XDS Affinity Domains.
- Provide a standardized document template to be used when specifying the deployment policies for a single XDS Affinity Domain, or for multiple XDS Affinity Domains that are in a particular nation or geographic region.

80 2.1 Request for Feedback

The IHE IT Infrastructure Technical Committee requests feedback on the concepts described in this White Paper. In particular, we would like your thoughts on whether this paper addresses all the issues involved and what you think of the proposed organization of this template.

85 Comments and change proposals arising from this white paper may be submitted to <http://forums.rsna.org> under the forum:

IHE ITI White Paper XDS Affinity Domain Template

3 Overview

90 Currently, ITI TF Appendix L provides an informative checklist for the key policies that need to be addressed in order to deploy an EHR-LR document sharing environment for an XDS Affinity Domain. However, it has been recognized that this existing checklist is incomplete. Many additional implementation details may need to be defined, depending upon the scope of the XDS Affinity Domain in question and the degree to which particular rules are to be defined (i.e. for architecture, content, security, etc.). This White Paper proposes a new template that should be used when defining policies for either an individual XDS Affinity Domain, or multiple XDS
95 Affinity Domains within a particular nation or region. It takes the form of a template rather than a checklist because it acts more as an outline for all the issues that should be considered, rather than a checklist to be used to verify the correctness of a particular implementation. It is proposed that the checklist in ITI TF Appendix L will be replaced by a brief summary of the content of this White Paper, along with a reference to it.

100 **Appendix A: XDS Affinity Domain Definition Template**

The concept of an XDS Affinity Domain is defined in ITI TF-1:10 and Appendix K. It is clear that many regulatory/professional organizations will need to define policies regarding coded terminology, privacy, document format and content, language support, etc. for an XDS Affinity Domain. This template provides a consistent documentation template for documenting
105 implementation decisions, policies, and IHE Profile refinements, for either an individual XDS Affinity Domain, or multiple XDS Affinity Domains within a particular nation or region. In addition, its provides a comprehensive list of all relevant topics that should be considered for deployment of XDS Affinity Domains, and implementers may find it helpful in guiding their policy and refinement decisions.

110 It is realized that not all of the items in this template will need to be defined for every XDS Affinity Domain, or at every national or regional level. The list of items that need to be defined will depend upon the scope of the specifications, and whether they are for a particular XDS Affinity Domain, region, and/or nation.

115 When defining the policies and Profile refinements for an XDS Affinity Domain it is essential that these do not contradict those mandated for all XDS Affinity Domains in the particular nation or region in which the XDS Affinity Domain will exist. In addition, these specifications for a particular XDS Affinity Domain should not duplicate those defined at a larger regional or national level. Instead the documentation for the particular XDS Affinity Domain should reference the document defining the national or regional policies.

120 **A.1 Introduction**

Define introductory text specifying the nature of the XDS Affinity Domain, or organization, region, or nation for which the XDS Profile extensions apply. If XDS Profile extensions are being defined at a national or regional level and are meant to be followed by all XDS Affinity Domains within them then this should be clarified here. The people and organizations involved
125 in creating these should be specified, as well as any professional or regulatory organizations that were involved in their creation and/or have approved them.

If the XDS Affinity Domain extensions are being defined at a national level and there is an official IHE organization for the country involved then this organization must approve the extensions and this must be stated here. It is the responsibility of the national committee involved
130 to determine whether testing of the extensions is necessary before they can be approved. It is still possible for national extensions to be defined for a nation that does not have an official IHE organization, however it will be necessary for the organization(s) proposing these extensions to demonstrate that they have the authority to actually define such extensions.

A.2 Glossary

135 Glossary of terms and abbreviations specific to the XDS Affinity Domain extension. Some examples of Terms and Abbreviations are shown for this template.

A.2.1 Terms

Access Control

140 Ensures that the resources of a data processing system can be accessed only by authorized entities in authorized ways.

[ISO/IEC 2382-8:1998]

Accountability

Property ensures that the actions of an entity may be traced to that entity.

[ISO 7498-2:1989]

145 **Etc.**

A.2.2 Abbreviations

EHR Electronic Health Record

HIE Health Information Exchange

IHE Integrating the Healthcare Enterprise

150 PHR Personal Health Record

Etc.

A.3 Reference Documents

List of all documents that are referenced in the XDS Affinity Domain extensions or were used as input in some way to the creation of these extensions.

155 A.4 Organizational Rules

The implementation domain shall provide a description of the organizational rules for the XDS Affinity Domain. It shall detail the administrative framework, functionalities, claims and objectives, the principals involved, agreements, rights, duties, and penalties.

Provide an introduction and then describe these functions in the following sub-sections.

160 A.4.1 Organizational Structure

Describe the organizational structure within the XDS Affinity domain. Considerations include, but are not limited to:

- Organization of XDS Affinity domain governance (options to consider include: central point of authority, collaborative governance, distributed governance, etc.).

165 List the founders, controllers, administrators, etc. of the XDS Affinity Domain. Their roles and responsibilities should be clearly defined, and contact information provided. It should be made clear who someone wishing to participate in the XDS Affinity Domain should have to contact in order to obtain information regarding participation in or access to the XDS Affinity Domain.

A.4.2 Organizational Roles

170 Explain the general roles of the organizations and individuals associated with the implementation and maintenance of this XDS Affinity Domain. For example, specify the roles played by government agencies, corporate entities, organizations, individuals, etc. associated with this XDS Affinity Domain.

A.4.3 Funding

175 Define general principles for funding of system implementation and maintenance (examples: central private/public source, taxes, documentation of general funding guidelines rather than explicit statement on funding source). Indicate the organizational roles associated with any of these general economic considerations.

A.4.3.1 Fee Structure

180 **A.4.3.2 Re-Imbursement Policies**

A.4.3.3 Insurance Policies

A.4.3.4 Fiscal plan for System Operation, Maintenance, and Innovation

A.4.4 Transparency

185 Document the manner in which accurate and timely disclosure of information will be provided by the various organizations that administer, organize, provide, and use the XDS Affinity Domain. Detail the procedures to follow in order to gain access to this information.

Provide guidelines regarding the types of information that organizations and individuals using the XDS Affinity Domain must be capable of providing should an audit of their participation or access be carried out.

190 **A.4.5 Enforcement and Remedies**

Document the responsible organizations for enforcing rules regarding payment, access rights, performance requirements, security, etc. associated with the XDS Affinity Domain. Clearly differentiate the areas of responsibility for the different organizations. If it is not clear who will ultimately be responsible for certain areas then also document this here.

195 **A.4.6 Legal Considerations**

A.4.6.1 Legal Governance

Define policies regarding the governance of legal issues related to users, publishers, IT staff, and vendors involved in the XDS Affinity Domain or within XDS Affinity Domains of the region or nation for which these policies are defined.

200 **A.4.6.2 Government Regulations**

Reference any government regulations that apply to implementation, use, or access to the XDS Affinity Domain.

A.4.6.3 Liability and Risk Allocation

205 Distinguish any policies regarding liability issues and risk allocation for the XDS Affinity Domain. Document any policies regarding the provision of liability insurance for those publishing documents to, or using documents from, the XDS Affinity Domain.

A.4.6.4 Indemnification

210 Describe how indemnification is dealt with in this XDS Affinity Domain implementation. To give the reader a better idea of what to include in this section, we provide a few guiding scenarios:

- Indemnification of providers against lawsuits for data they publish that is misused by a user from a consuming system.
- Mechanism to isolate financial responsibility to a particular provider when a patient sues another for misuse of his/her data.
- 215 • Providers of data create indemnification agreements with all possible users of data.
- Recourse methods for providers to communicate problems with published data, rather than the use of that data.

A.4.6.5 Intellectual Property Rights to Published Documents

220 Define how intellectual property rights will be managed for documents published to the XDS Affinity Domain. For example, define whether property rights are maintained in any way once documents are published or if they are immediately waived.

A.5 Operational Rules

Describe the operational rules for the XDS Affinity Domain.

A.5.1 Service Level Agreements

225 Define how Service Level Agreements shall be created for the operational components of the XDS Affinity Domain.

A.5.2 Daily Governance

A.5.2.1 Policy Governance

230 Describe how the components of the XDS Affinity Domain are managed at an operational level. Considerations to comment on include, but are not limited to:

- Overall operation management (coordination of efforts)
- Sub-component division (if any)

- Day to Day operations management communication methods (meetings, summits, forums, etc.)

235 **A.5.2.2 Policy Change Procedures**

Define the procedures for managing proposed policy changes for the XDS Affinity Domain. Specify the manner in which individuals and organizations can propose policy changes, and the manner in which such proposals are reviewed and by whom.

A.5.2.3 Publication and Notification Policies

240 Specify the mechanisms used for publishing the policies and the means used to notify members of any changes. For example:

- If the policies are posted to an internet site then specify the url.
- If notifications are sent by e-mail then document this along with the mechanisms used for managing the list of addressees.

245 **A.5.2.4 Management When Systems are Unavailable**

Define policies for managing cases where various types of components of the XDS Affinity Domain are unavailable. For example, what type of workarounds should be used if the PIX Manager for this XDS Affinity Domain implementation is unavailable? Other considerations include, but are not limited to:

- 250 • Notification mechanisms for scheduled system downtime and maintenance.
- Notification mechanisms when a system or user of the XDS Affinity Domain detects that one or more components are unavailable.
- Notification of causes and resolutions for unscheduled system downtimes.

255 Detailed procedures for maintaining business continuity, recovery and disaster management in the event of failure should be specified in A.5.6 Disaster Recovery rather than in this section.

A.5.3 Configuration Management

260 Specify how change management issues (such as hardware upgrades, software upgrades, configuration changes, etc) are to be managed. Explain what authorization is needed in order to make changes to a component of the XDS Affinity Domain that will affect other components (such as those that will cause component downtime, require configuration changes on other systems, or effect functionality).

Define how configuration settings will be disseminated among systems in the XDS Affinity Domain.

265 Define the rules for DNS management and system naming conventions. Make sure to mandate the use of appropriate host names and policies that will attempt to guarantee their continued use as hardware is upgraded and replaced over time. This is important because host names are used in the <location> part of Metadata URLs, and thus URLs can be broken if host names are not maintained over time.

Note that security related configuration should be defined in the appropriate sub-sections of A.11

270 **A.5.4 Addition of New Components**

Specify procedures for adding new components to the XDS Affinity Domain. Explain who is authorized to grant permission for new components to be added and how are they can be contacted. Define procedures for providing the necessary configuration and security information to the managers of components that will need to communicate with a new component.

275 Define rules regarding the migration of data from one type of system to another, particularly when moving data from one XDS Repository to another. One can envisage some common scenarios for which rules should be defined:

- 280 • Rules for handling the case where an additional XDS Repository is added to an XDS Affinity Domain and a subset of the data in existing Repository(s) is to be migrated to the new system.
- Rules for migrating data if all the data in an XDS Repository is going to be migrated to a new system or another system that is already also acting as an XDS Repository for the Affinity Domain.
- 285 • Rules regarding the migration of content that is originally to be stored long term on local systems acting as XDS-I Sources to a centralized long term archive or vice versa. The rules must define how the XDS-I Repository Manifests will be

A.5.5 Data Retention, Archive, and Backup

290 Define policies regarding the responsibilities for data retention, archive, and backup for the various types of components of the XDS Affinity Domain. For example, specify how long access to documents published to an XDS Repository of the XDS Affinity Domain must be maintained, and how long their data integrity must be guaranteed. State the backup requirements for the Repository.

295 Specify the manner in which security audit logs, both electronic and non-electronic, will be retained and made available for compliance audits and legal review. Define the time period for which such audit logs must be maintained.

A.5.6 Disaster Recovery

Define disaster recovery practices for the various types of components of the XDS Affinity Domain. Define procedures to follow when disaster recovery is needed, and what notification must be provided in such cases. The types of procedures should include, but are not limited to:

- 300 • How to recover
- What process/workflow to invoke
- Where to recover
- Expectations
- Service Level Agreement (SLA) for recovery

- 305
- Notifications/Communications
 - Business impact analysis
 - Emergency procedures for lack of access.

A.6 Membership Rules

A.6.1 Acceptance

310 Define the types of organizations and individuals that can become members of the XDS Affinity Domain so that they will be permitted access to its components and data. Specify how they can apply for membership.

315 If there are any different rules for handling the membership of organizations and individuals whose physical location is considered part of another XDS Affinity Domain then define these here. For example, if the XDS Affinity Domain is defined for a specific geographic region, such as a Province or State, but an organization or individual located outside of this region wants to become a member. In addition, if there are any special rules for handling the membership of organizations and individuals who are already members of a different XDS Affinity Domain then define these here also.

A.6.2 Types of Membership

320 Specify whether or not there are different types of membership that define how published data can be accessed (i.e. read-only, publish-only, etc.). If there are then define what these membership types are, and the mechanisms used to enforce the rules for the defined types. Note that in addition to types of membership for individuals who are part of the XDS Affinity Domain, there may be the need to define types for those who would not normally be considered part of the Affinity Domain (i.e. for those who are external to the regional or organizational boundary of the Affinity Domain but require or want access, possibly on a temporary basis, through a portal, etc.). If the technical implementation details are defined in the later sections (i.e. A.10 Patient Privacy and Consent, or A.11 Technical Security) then just provide a general overview here and then references to the technical details in the appropriate sections.

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330

A.6.3 Membership Policies

335 Define any rules regarding management of members status. How does an individual or organization apply to no longer be a member? How is the list of members maintained and distributed? Is the list of members public? If not then what is the policy regarding requests for access to this list? Handling of membership in multiple XDS Affinity Domains.

A.7 Connectivity to the XDS Affinity Domain from External Systems

A.7.1 Interoperability Strategy

340 The Policy Agreement shall identify the procedure for how to reach the data over the domain borders. There are many ways to bring this about and it is therefore very important that this is specified in the Agreement.

A.7.1.1 External Connectivity Through Portals

345 If access by 'portal' (or other means) will be supported for users that would not normally be considered members of the Affinity Domain then specify the policies and technical details for such support here. For example is any means supported for access to users who are from outside the region of the XDS Affinity Domain but want temporary access to it.

A.8 System Architecture

350 In order to secure both information retrieval and publishing, the system architecture of the applications has to be specified and understood by all parties. The Policy Agreement shall therefore contain detailed information regarding the architecture of systems supporting the various Actor/Profiles, and the supported document types and publication policies.

A.8.1 Global Architecture

355 The XDS Affinity Domain global architecture diagram should be offered in this section indicating the stakeholders and system actors. If the XDS-I Profile is to be supported then this section must define whether the long term archives for the images will be on individual site specific Image Manager/Image Archives, on regional Image Manager/Image Archives supporting multiple imaging sites, or a combination of both.

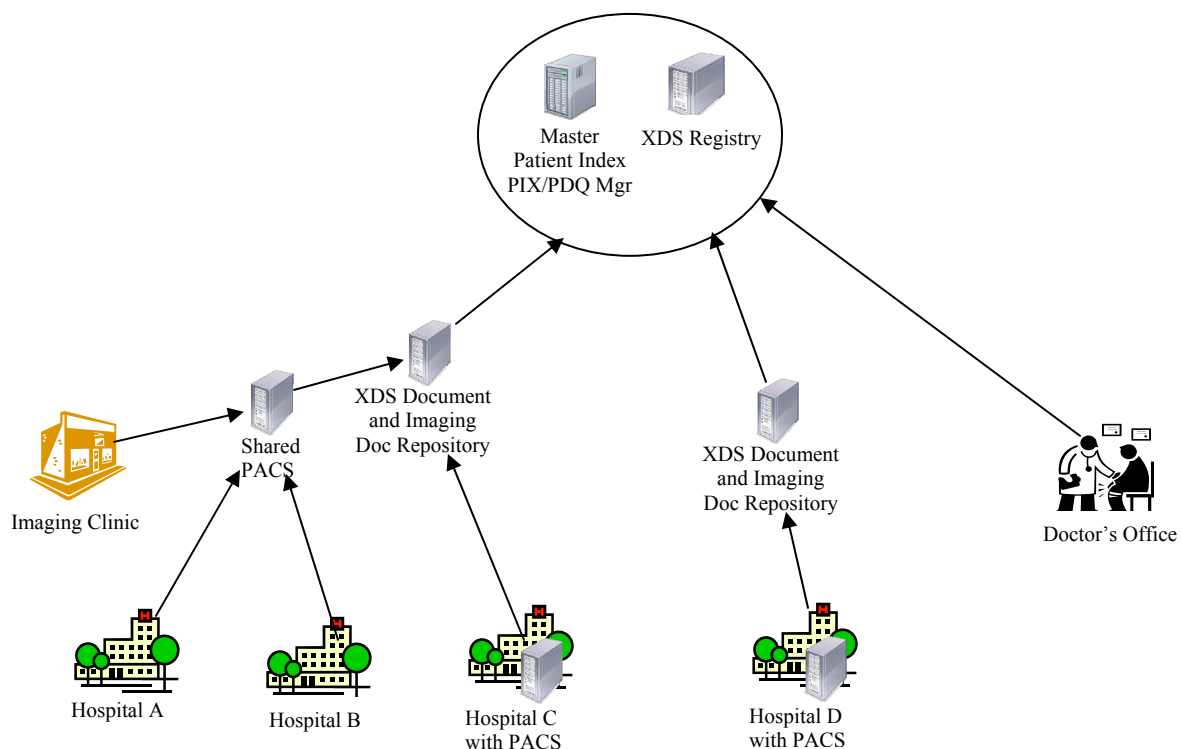


Figure A.8.1-1 Example XDS Affinity Domain Architecture

360 If there are general overall policies regarding such things as Folder Management policies then
 365 define these here. Profile Actor specific details should be defined in the sub-sections of the
 A.8.2.2.3 XDS Document Source Technical Actor Specifications below.

A.8.2 Affinity Domain Actors

365 The system architecture for the XDS Affinity Domain shall provide details of how systems shall
 support specific IHE Actors for the IHE Profiles to be supported within the XDS Affinity
 Domain. It shall identify any Business Actors defined for the Affinity Domain along with the
 specific IHE Actor Profiles that these shall support.

A.8.2.1 Business Actors

370 Specify the details of business role actors for the XDS Affinity Domain. The following table
 provides some examples of such business actors and should be used as a template for defining
 the Affinity Domains Business Actors.

375 Use the Actor Optionality Column to specify whether each Technical Actor is required (labeled
 “R”), optional (labeled “O”), or conditional (labeled “C”). If the Technical Actor is conditional
 then define the requirements in the Comments column. The Comments column should provide
 references to relevant sections concerning the Technical Actor that appear in the remainder of the
 document, particularly to the more detailed requirements specified in a sub-section of A.8.2.2
 Technical Actor Specifications.

380 Note that it could be necessary to define differences in the requirements for a particular
 Technical Actor, depending upon which Business Actor it is fulfilling. For example, the
 technical requirements for support of the XDS-I Consumer could vary depending upon whether
 it is being specified for use by regional agencies, referring general practitioners, or radiologists,
 etc. Any such differences should be noted in the Comments section, and the details provided in
 the sub-section of A.8.2.2 Technical Actor Specifications for the specific Technical Actor.

Table A.8.2.1-1. Business Actors

Business Actor	Definition	Technical Actors	Actor Optionality	Comments
'Regional' (State/Provincial, Regional, or Local) HIE	Shared service provider for Patient ID Cross- Referencing Manager, Policy Repository, Consent Repository, Audit Repository, Possibly Registry	PIX Manager	R/O/C	If the Actor is Conditional then provide the requirements here. Provide references to relevant sections in the remainder of the document, particularly to the more detailed requirements specified in a sub-section of A.8.2.2 Technical Actor Specifications.
		PDQ Supplier	R/O/C	
		ATNA Audit Repository	R/O/C	
		XDS Registry	R/O/C	

Business Actor	Definition	Technical Actors	Actor Optionality	Comments
		XUA X-Service Provider	R/O/C	
		...		
'Regional' Document Repository	Repository servicing the regional health care providers; may include the document registry, or documents may be registered with a separate registry.	XDS-MS for document transport and sharing	R/O/C	
		XDS-I for imaging information.		
		ATNA for audit trail and network security	R/O/C	
'Regional' agencies retrieving records (Document Consumer)	Provide list of regional agencies that are authorized to query and retrieve records (provide the list here or a link to an Annex listing the details).	XDS Document Consumer	R/O/C	
		XDS-I Imaging Document Consumer	R/O/C	
		ATNA Secure Node	R/O/C	
		PIX Consumer	R/O/C	
		PDQ Consumer	R/O/C	
		...		
Health care Providers Retrieving Records (Document Consumer)	Provide list of HIE member health care providers that are authorized to query and retrieve records (provide the list here or a link to an Annex listing the details).	XDS Document Consumer	R/O/C	
		XDS-I Imaging Document Consumer	R/O/C	
		XDS Document Source	R/O/C	
		XDS-I Imaging Document Source	R/O/C	
		ATNA Secure Node	R/O/C	
		PIX Consumer	R/O/C	
		PDQ Consumer	R/O/C	
		...		

Business Actor	Definition	Technical Actors	Actor Optionality	Comments
Health care Providers Publishing Records (Document Source)	Provide list of health care providers that are authorized to publish records (provide the list here or a link to an Annex listing the details).	XDS Document Source	R/O/C	
		XDS-I Imaging Document Source	R/O/C	
		ATNA Secure Node	R/O/C	
		...		
'Regional' Agencies Publishing Records (Document Source)	Provide list of state agencies that are authorized to publish records (provide the list here or a link to an Annex listing the details).	XDS Document Source	R/O/C	
		XDS-I Imaging Document Source	R/O/C	
		ATNA Secure Node	R/O/C	
		...		
etc...				

A.8.2.2 Technical Actor Specifications

385 This section provides the details for the transactions/messaging that need to be supported by the technical actors required by the listed business actors. For the most part these technical actors will correspond to particular IHE Profile Actors. A number of systems implementing IHE Actors defined in the XDS Integration Profile need to be identified and configured to communicate. In addition, there will be systems in the XDS Affinity Domain that must conform to other IHE Actor Profiles. This section should identify the requirements for all IHE Actor/Profiles that are not fully specified or mandated by the IHE Technical Framework.

390 For example, it should specify whether any Optional Transactions for specific Actor/Profiles will be required to be supported in the XDS Affinity Domain, and how certain error/exception cases should be handled.

395 In addition, there may be required technical actors that are not defined in IHE Profiles. If so then such technical actors should also be defined in this section. Such documentation will need to provide precise use cases, policies, actor interaction, and implementation details, or a reference to another document that does this.

A.8.2.2.1 XDS Document Registry

400 Identify any specific requirements for a Registry Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. For example, it should specify how a Registry should behave if it receives registration requests containing terminology it does not understand (i.e. define whether it should be 'strict' or 'relaxed' when it comes to handling such cases). Specify whether XDS.a, XDS.b, or both of these messaging Profiles must be

405 supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

Table A.8.2.2.1-1. XDS.a Document Registry Transactions

Actor	Transactions	Optionality	Comments
Document Registry	Register Document Set [ITI-14]	R	Define any extended requirements for this Transaction. Note that specifications for attribute content should be defined in A.9 Terminology and Content, rather than being defined for each Transaction that can be used to convey or modify such content.
	Query Registry [ITI-16]	R	
	Registry Stored Query [ITI-18]	O/R	
	Patient Identity Feed [ITI-8]	O/R	
	Patient Identity Feed HL7v3 [ITI-44]	O/R	

Table A.8.2.2.1-2. XDS.b Document Registry Transactions

Actor	Transactions	Optionality	Comments
Document Registry	Register Document Set-b [ITI-42]	R	
	Registry Stored Query [ITI-18]	R	
	Patient Identity Feed [ITI-8]	O/R	
	Patient Identity Feed HL7v3 [ITI-44]	O/R	

410 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS Document Registry in the Affinity Domain, or a reference to another document that does this.

415 **Table A.8.2.2.1-3. Additional XDS Document Registry Messaging**

Actor	Messaging	Optionality	Comments
Document Registry		O/R/C	

A.8.2.2.2 XDS Document Repository

420 Identify any specific requirements for a Repository Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether XDS.a, XDS.b, or both of these messaging Profiles must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them. Also list any of the Optional Document Repository Transactions that must be supported for the XDS Affinity Domain, or have particular requirements regarding their implementation.

Table A.8.2.2.2-1. XDS.a Document Repository Transactions

Actor	Transactions	Optionality	Comments
Document Repository	Provide and Register Document Set [ITI-15]	R	
	Register Document Set [ITI-14]	R	
	Retrieve Document [ITI-17]	R	

425

Table A.8.2.2.2-2. XDS.b Document Repository Transactions

Actor	Transactions	Optionality	Comments
Document Repository	Provide and Register Document Set-b [ITI-41]	R	
	Register Document Set-b [ITI-42]	R	
	Retrieve Document [ITI-17]	R	

430

Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS Document Repository in the Affinity Domain, or a reference to another document that does this.

435

As an example, the Affinity Domain might require that an XDS Document Repository support acting as a gateway for receiving HL7 v2.5 Lab messages and translating these into XDS Lab Content that it then registers. The following table would have to provide a reference to the relevant sections of HL7 v2.5, and then provide the specific implementation details of the receipt, conversion, and registration of lab content.

Table A.8.2.2.2-3. Additional XDS Document Repository Messaging

Actor	Messaging	Optionality	Comments
Document Repository		O/R/C	

A.8.2.2.3 XDS Document Source

440

Identify any specific requirements for a Document Source Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Identify any specific Content Profiles that must be supported. Specify whether XDS.a, XDS.b, or both of these messaging Profiles must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

445

List any of the Optional Document Source Transactions that must be supported for the XDS Affinity Domain, or have particular requirements regarding their implementation. For example define whether XDS Document Sources must support the otherwise Optional Folder

Management Transaction. If so then specify the reasoning for this as well as any particular requirements regarding this Transaction, such as a particular semantic meaning associated with a Folder within this XDS Affinity Domain.

450 Use the following table to convey any Transaction related details.

Table A.8.2.2.3-1. XDS.a Document Source Transactions

Actor	Transactions	Optionality	Comments
Document Source	Provide and Register Document Set [ITI-15]	R	In addition to comments for this Transaction, also provide a reference to the Content Options table below that defines the optionality of the Content Options for this Transaction. At least one of these must be supported.
	Off-Line Transaction mode	O/R	
	Multiple Documents Submission [ITI-15.5]	O/R	
	Document Life Cycle Management [ITI-15.5]	O/R	
	Folder Management [ITI-15.5]	O/R	

Table A.8.2.2.3-2. XDS.b Document Source Transactions

Actor	Transactions	Optionality	Comments
Document Source	Provide and Register Document Set-b [ITI-41]	R	In addition to comments for this Transaction, also provide a reference to the Content Options table below that defines the optionality of the Content Options for this Transaction. At least one of these must be supported.
	Off-Line Transaction mode	O/R	
	Multiple Documents Submission [ITI-15.5]	O/R	
	Document Life Cycle Management [ITI-15.5]	O/R	
	Folder Management [ITI-15.5]	O/R	

Table A.8.2.2.3-3. Provide and Register Document Set Content Options

Content Options	Optionality	Comments
Medical Summary in HL7 CDA Format [XDS-MS]	R/O	
Scanned Document as HL7 CDA with PDF or plain text content [XDS-SD]	R/O	
...		

455 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments

should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS Document Source in the Affinity Domain, or a reference to another document that does this.

460

Table A.8.2.2.3-4. Additional XDS Document Source Messaging

Actor	Messaging	Optionality	Comments
Document Source		O/R	

A.8.2.2.4 XDS-I Imaging Document Source

Identify any specific requirements for an Imaging Document Consumer Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework.

Use the following table to convey any Transaction related details.

465

Table A.8.2.2.4-1. XDS-I Imaging Document Source Transactions

Actor	Transactions	Optionality	Comments
Imaging Document Source	Provide and Register Imaging Document Set [RAD-54]	R	In addition to comments for this Transaction, also provide a reference to the Content Options table below that defines the optionality of the Content Options for this Transaction. At least one of these must be supported.
	Retrieve Images [RAD-16]	R	
	Retrieve Presentation States [RAD-17]	R	
	Retrieve Reports [RAD-27]	R	
	Retrieve Key Image Note [RAD-31],	R	
	Retrieve Evidence Documents [RAD-45]	R	
	WADO Retrieve [RAD-55]	R	

Table A.8.2.2.4-2. Provide and Register Imaging Document Set Content Options

Content Options	Optionality	Comments
Set of DICOM Instances [RAD-18.2.1]	R/O	
PDF Report [RAD-18.2.2]	R/O	
Text Report [CDA]	R/O	

470

Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS-I Imaging Document Source in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.4-3. Additional XDS-I Imaging Document Source Messaging

Actor	Messaging	Optionality	Comments
Imaging Document Source		O/R	

A.8.2.2.5 XDS Document Consumer

475 Identify any specific requirements for a Document Consumer Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether XDS.a, XDS.b, or both of these messaging Profiles must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

480 **Table A.8.2.2.5-1. XDS.a Document Consumer Transactions**

Actor	Transactions	Optionality	Comments
Document Consumer	Query Registry [ITI-16]	R	
	Retrieve Document [ITI-17]	R	
	Registry Stored Query [ITI-18]	R	

Table A.8.2.2.5-2. XDS.b Document Consumer Transactions

Actor	Transactions	Optionality	Comments
Document Consumer	Retrieve Document Set [ITI-43]	R	
	Registry Stored Query [ITI-18]	R	

Define any requirements regarding display, integration in application, content options, and workflow context management for the types of retrieved Content in the following table.

Table A.8.2.2.5-3. Document Consumer Content Support

Content Options	Optionality	Comments
Medical Summary in HL7 CDA Format [XDS-MS]	R/O	
Scanned Document as HL7 CDA with PDF or plain text content [XDS-SD]	R/O	
...		

485 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS Document Consumer in the Affinity Domain, or

490 a reference to another document that does this.

Table A.8.2.2.5-4. Additional XDS Document Consumer Messaging

Actor	Messaging	Optionality	Comments
Document Consumer		O/R	

A.8.2.2.6 XDS-I Imaging Document Consumer

495 Identify any specific requirements for an Imaging Document Consumer Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether XDS.a, XDS.b, or both of these messaging Profiles must be supported.

List the Optional Document Source Transactions that must be supported for the XDS Affinity Domain, or have particular requirements regarding their implementation.

Use the following table to convey any Transaction related details.

Table A.8.2.2.6-1. XDS-I Imaging Document Consumer Transactions

Actor	Transactions	Optionality	Comments
Imaging Document Consumer	Retrieve Images [RAD-16]	O/R	
	Retrieve Presentation States [RAD-17]	O/R	
	Retrieve Reports [RAD-27]	O/R	
	Retrieve Key Image Note [RAD-31]	O/R	
	Retrieve Evidence Documents [RAD-45]	O/R	
	WADO Retrieve [RAD-55]	O/R	

500 Define any requirements regarding display, integration in application, content options, and workflow context management for the types of retrieved Content in the following table.

Table A.8.2.2.6-2. XDS-I Imaging Document Consumer Content Support

Content Options	Optionality	Comments
Set of DICOM Instances [RAD-18.2.1]	R/O	
PDF Report [RAD-18.2.2]	R/O	
Text Report [CDA]	R/O	

505 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS-I Imaging Document Consumer in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.6-3. Additional XDS-I Imaging Document Consumer Messaging

Actor	Messaging	Optionality	Comments
Imaging Document Consumer		O/R	

510 A.8.2.2.7 XDS Patient Identity Source

Identify any specific requirements for a Patient Identity Source in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether HL7 v2.3.1, v3, or both must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

515 Table A.8.2.2.7-1. XDS Patient Identity Source Transactions

Actor	Transactions	Optionality	Comments
Patient Identity Source	Patient Identity Feed [ITI-8]	R	

Table A.8.2.2.7-2. XDS HL7v3 Patient Identity Source Transactions

Actor	Transactions	Optionality	Comments
Patient Identity Source	Patient Identity Feed HL7v3 [ITI-44]	R	

Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS Patient Identity Source in the Affinity Domain, or a reference to another document that does this.

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Table A.8.2.2.7-3. Additional XDS Patient Identity Source Messaging

Actor	Messaging	Optionality	Comments
Patient Identity Source		O/R	

A.8.2.2.8 PIX Patient Identity Source

525 Identify any specific requirements for a PIX Patient Identity Source Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether HL7 v2.x, v3, or both must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

Table A.8.2.2.8-1. PIX Patient Identity Source Transactions

Actor	Transactions	Optionality	Comments
Patient Identity Source	Patient Identity Feed [ITI-8]	R	

530 **Table A.8.2.2.8-2. PIX HL7v3 Patient Identity Source Transactions**

Actor	Transactions	Optionality	Comments
Patient Identity Source	Patient Identity Feed HL7v3 [ITI-44]	R	

535 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by a PIX Patient Identity Source in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.8-3. Additional PIX Patient Identity Source Messaging

Actor	Messaging	Optionality	Comments
Patient Identity Source		O/R	

A.8.2.2.9 PIX Manager

540 Identify any specific requirements for a PIX Manager Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether HL7 v2.3.1, v3, or both must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

Table A.8.2.2.9-1. PIX Manager Transactions

Actor	Transactions	Optionality	Comments
Patient Identifier Cross-reference Manager	Patient Identity Feed[ITI-8]	R	
	PIX Query[ITI-9]	R	
	PIX Update Notification[ITI-10]	R	

Table A.8.2.2.9-2. PIX HL7v3 Manager Transactions

Actor	Transactions	Optionality	Comments
Patient Identifier Cross-reference Manager	Patient Identity Feed HL7v3 [ITI-44]	R	
	PIXV3 Query[ITI-45]	R	
	PIXV3 Update Notification[ITI-46]	R	

545 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by a PIX Manager in the Affinity Domain, or a reference to another document that does this.

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Table A.8.2.2.9-3. Additional PIX Manager Messaging

Actor	Messaging	Optionality	Comments
Patient Identifier Cross-reference Manager		O/R	

A.8.2.2.10 PIX Consumer

555 Identify any specific requirements for a PIX Consumer Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether HL7 v2.3.1, v3, or both must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

In addition, specify whether or not the Optional PIX Update Notification Transaction must be supported by PIX Consumers for the XDS Affinity Domain, or have particular requirements regarding their implementation.

560 Use the following tables to convey any Transaction related details.

Table A.8.2.2.10-1. PIX Consumer Transactions

Actor	Transactions	Optionality	Comments
Patient Identifier Cross-reference Consumer	PIX Query [ITI-9]	R	
	PIX Update Notification [ITI-10]	O/R	

Table A.8.2.2.10-2. PIX HL7v3 Consumer Transactions

Actor	Transactions	Optionality	Comments
Patient Identifier Cross-reference Consumer	PIXV3 Query [ITI-45]	R	
	PIXV3 Update Notification [ITI-46]	O/R	

565 Define any additional messaging that must be supported, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by a PIX Consumer in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.10-3. Additional PIX Consumer Messaging

Actor	Messaging	Optionality	Comments
Patient Identifier Cross-reference Consumer		O/R	

A.8.2.2.11 PDQ Patient Demographics Supplier

570 Identify any specific requirements for a PDQ Patient Demographics Supplier Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether HL7 v2.3.1, v3, or both must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

575 If HL7 v2.3.1 must be supported then also specify whether or not the Optional Patient Demographics and Visit Query Transaction must be supported by PDQ Suppliers for the XDS Affinity Domain, or have particular requirements regarding their implementation.

Use the following tables to convey any Transaction related details.

Table A.8.2.2.11-1. PDQ Patient Demographics Supplier Transactions

Actor	Transactions	Optionality	Comments
Patient Demographics Supplier	Patient Demographics Query [ITI-21]	R	
	Patient Demographics and Visit Query [ITI-22]	O/R	

580 **Table A.8.2.2.11-2. PDQ HL7v3 Patient Demographics Supplier Transactions**

Actor	Transactions	Optionality	Comments
Patient Demographics Supplier	Patient Demographics Query HL7 V3[ITI-47]	R	

585 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by a PDQ Patient Demographics Supplier in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.11-3. Additional PDQ Patient Demographics Supplier Messaging

Actor	Messaging	Optionality	Comments
Patient Demographics Supplier		O/R	

A.8.2.2.12 PDQ Patient Demographics Consumer

590 Identify any specific requirements for a PDQ Patient Demographics Consumer Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify whether HL7 v2.3.1, v3, or both must be supported. If only one of these must be supported then include only one of the following tables. If both must be supported then include both of them.

595 If HL7 v2.3.1 must be supported then also specify whether or not the Optional Patient Demographics and Visit Query Transaction must be supported for the XDS Affinity Domain, or have particular requirements regarding their implementation.

Use the following tables to convey any Transaction related details.

Table A.8.2.2.12-1. PDQ Patient Demographics Consumer Transactions

Actor	Transactions	Optionality	Comments
Patient Demographics Consumer	Patient Demographics Query [ITI-21]	R	
	Patient Demographics and Visit Query [ITI-22]	O/R	

Table A.8.2.2.12-2. PDQ HL7v3 Patient Demographics Consumer Transactions

Actor	Transactions	Optionality	Comments
Patient Demographics Consumer	Patient Demographics Query HL7 V3[ITI-47]	R	

600 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an PDQ Patient Demographics Consumer in the Affinity Domain, or a reference to another document that does this. .

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Table A.8.2.2.12-3. Additional PDQ Patient Demographics Consumer Messaging

Actor	Messaging	Optionality	Comments
Patient Demographics Consumer		O/R	

A.8.2.2.13 ATNA Audit Record Repository

610 Identify any specific requirements for an Audit Record Repository Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify any requirements for security audit logs that go beyond those specified in the ATNA Profile.

Use the following table to convey any Transaction related details.

Table A.8.2.2.13-1. ATNA Audit Record Repository Transactions

Actor	Transactions	Optionality	Comments
Audit Record Repository	Record Audit Event [ITI-20]	R	

615 Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments should define the precise use cases, policies, actor interaction, and implementation details

regarding support of this messaging by an XDS Document Registry in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.13-2. Additional ATNA Audit Record Repository Messaging

Actor	Messaging	Optionality	Comments
Audit Record Repository		O/R	

620 **A.8.2.2.14 ATNA Secure Node**

Identify any specific requirements for an ATNA Secure Node Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework.

Use the following table to convey any Transaction related details.

Table A.8.2.2.14-1. ATNA Secure Node Transactions

Actor	Transactions	Optionality	Comments
Secure Node	Authenticate Node [ITI-19]	R	
	Maintain Time [ITI-7]	R	
	Record Audit Event [ITI-20]	R	

625 Identify the types of systems, such as those supporting specific Profile Actors or specific roles in the defined architecture, that must act as ATNA Secure Nodes, and whether or not it is permitted for certain types of systems to act as ATNA Secure Applications rather than as Secure Nodes.

Table A.8.2.2.14-2. ATNA Secure Nodes

System Description	Profile-Actor	Comments
Audit Record Repository	ATNA AuditRecord Repository	Example system that must act as a Secure Node.
Etc.		

A.8.2.2.15 Secure Application

630 Identify any specific requirements for an ATNA Secure Application Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework. Specify which of the Optional ATNA Secure Application Transactions must be supported by ATNA Secure Applications for the XDS Affinity Domain, or have particular requirements regarding their implementation.

635 Use the following table to convey any Transaction related details.

Table A.8.2.2.15-1. ATNA Secure Application Transactions

Actor	Transactions	Optionality	Comments
Secure Application	Authenticate Node [ITI-19]	O/R	
	Maintain Time [ITI-7]	O/R	

Actor	Transactions	Optionality	Comments
	Record Audit Event [ITI-20]	O/R	

Identify the types of systems, such as those supporting specific Profile Actors or specific roles in the defined architecture, that must act as ATNA Secure Applications.

Table A.8.2.2.15-2. ATNA Secure Applications

System Description	Profile-Actor	Comments
Image Display systems	XDS-I Imaging Document Consumer	Example system that must act as a Secure Application.
Etc.		

640 **A.8.2.2.16 CT Time Server**

Identify any specific requirements for a CT Time Server Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework.

Use the following table to convey any Transaction related details.

Table A.8.2.2.16-1. CT Time Server Transactions

Actor	Transactions	Optionality	Comments
Time Server	Maintain Time [ITI-1]	R	

645 **A.8.2.2.17 CT Time Client**

Identify any specific requirements for a CT Time Client Actor in the XDS Affinity Domain that are not fully specified or mandated by the IHE Technical Framework.

Use the following table to convey any Transaction related details.

Table A.8.2.2.17-1. CT Time Client Transactions

Actor	Transactions	Optionality	Comments
Time Client	Maintain Time [ITI-1]	R	

650 **A.8.2.2.18 Any Additional IHE Actor Systems...**

Provide further sub-sections that identify any specific requirements for any additional IHE Actor systems. These should include any specific functionality required by systems supporting IHE Actor/Profiles from Domains other than ITI (Radiology, Cardiology, etc.)

Use the following table templates to convey any Transaction related details.

655 **Table A.8.2.2.18-1. <Profile Actor>Transactions**

Actor	Transactions	Optionality	Comments
		O/R	

Define any additional messaging that must be supported that is not defined as a Transaction for this Profile Actor in the IHE Technical Framework, such as additional HL7 messaging. The Messaging section should provide reference(s) to the technical specifications. The Comments

660 should define the precise use cases, policies, actor interaction, and implementation details regarding support of this messaging by an XDS Document Registry in the Affinity Domain, or a reference to another document that does this.

Table A.8.2.2.18-2. Additional <Profile Actor> Messaging

Actor	Messaging	Optionality	Comments
		O/R	

A.8.2.2.19 Additional Affinity Domain Specific Recognized Technical Actors

665 Provide further sub-sections that define the specific requirements of any other Affinity Domain specific ‘actors’ which are not actually defined by existing IHE Technical Framework Profiles. For instance, national or regional standards organizations may develop profile-like constructs that are not defined in IHE, but which will need to be supported by some systems in the XDS Affinity Domain. These requirements should be specified in the same document as the IHE related refinements, as the document should serve as an agreement for all types of systems
670 exchanging information within the Affinity Domain. Provide a reference to the appropriate documentation if the technical details of the profile-like construct are defined in another document.

Use the following table templates to convey any messaging related details.

Table A.8.2.2.19-1. Additional Technical Actor Messaging

Actor	Transactions	Optionality	Comments
		O/R	

675 A.8.2.3 XDS Affinity Domain Transaction Diagram

Define the transaction diagram for the XDS Affinity Domain. In particular, it is important to detail any optional transactions that the XDS Affinity Domain extensions now define as being mandatory.

680 The following transaction diagram is offered in this section indicating the stakeholders, business actors, system actors and transactions.

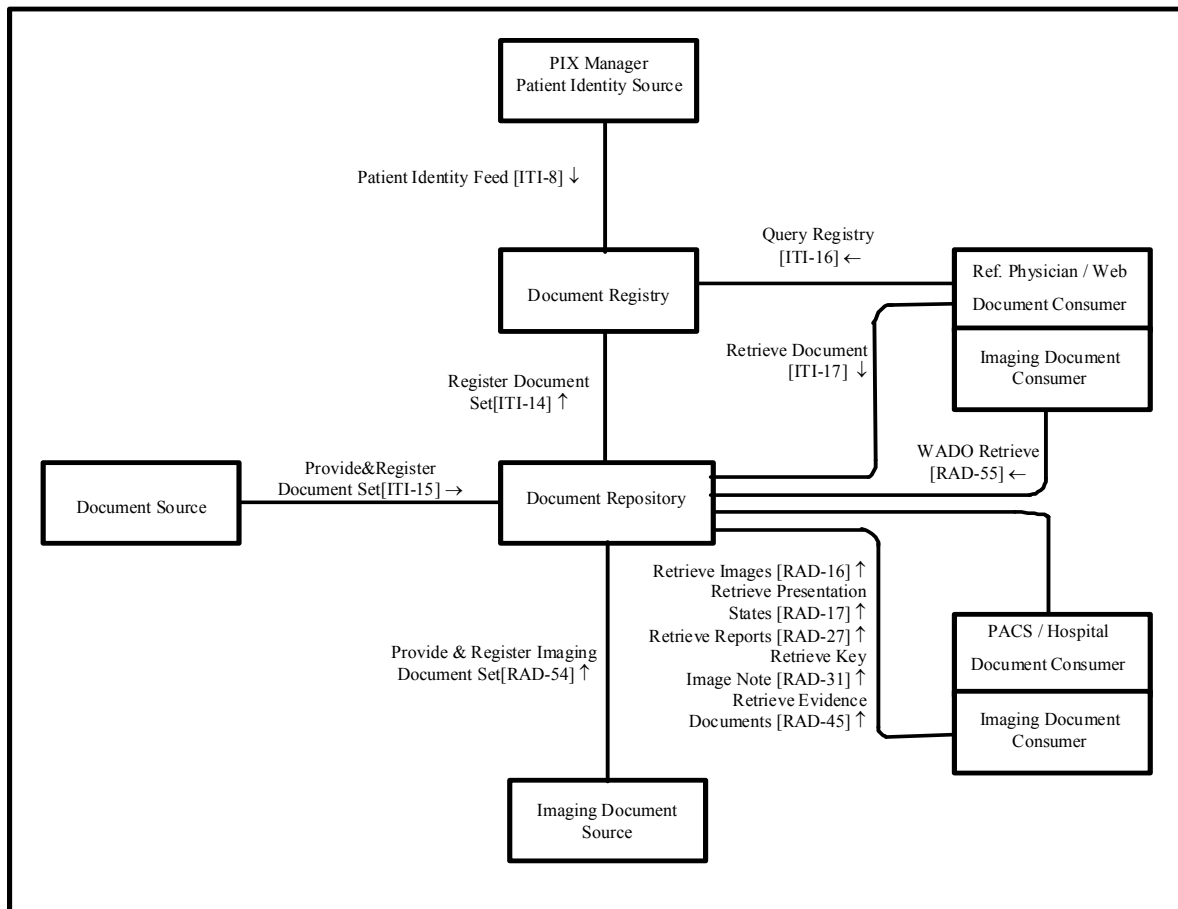


Figure A.8.2.3-1 Example XDS Affinity Domain Transaction Diagram

NOTE: This transaction diagram should depict the transactions associated with publishing and retrieving of health information, and not include the audit transactions specified in section A.11.6 Secure Audit Trail.

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A.8.2.4 Cross XDS Affinity Domain Transaction Support

Specify whether or not the IHE XCA Profile will be used for communication across XDS Affinity Domains. If it supported then specify the details of its support. If there are plans for it to be supported in the future then detail any policies in place for supporting cross domain communication until XCA support is enabled. Specify any details required for transactions from this XDS Affinity Domain to any components of another XDS Affinity Domain. Explain procedures for dealing with the use of different code sets if any exist. Also explain how to deal with the validity of assigning authorities for identifiers from external systems.

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If instead access will only ever be granted to systems that become part of this XDS Affinity Domain then specify this here, along with any differences between the procedures that must be followed if a system or user will be outside of the normal boundaries (geographic, governmental, etc.) of the XDS Affinity Domain.

695

A.9 Terminology and Content

A.9.1 Introduction

700 If the IHE XDS Profile or XDS Content Profiles are refined in any way then describe this here. Typically the following types of refinements are made:

- 705 • XDS Affinity Domains can refine the use of many attributes of XDS Profile Transactions and attributes of the contents of the supported XDS Content Profiles. Frequently this involves restricting attributes to using certain defined sets of values, or mandating the manner in which the fields of an attribute's data type are used. In the case of Metadata attributes, their values are explicitly defined as being "XDS Affinity Domain specific" by the XDS Profile itself.
- 710 • In addition, XDS Affinity Domains can refine the attributes of XDS Transactions or Content so they are required to be supported rather than optional as stated in the XDS Profile or the definition of the Content for the XDS Content Profile.

Such refinements must not break conformance with the XDS Profile or to the defined Content of the XDS Content Profiles being supported. For example, it is not acceptable to lower the requirement of an attribute to be optional when it is defined to be required for XDS Metadata or Content.

715 This introductory section explains any principle areas of terminology and content that are refined by the XDS Affinity Domain. In addition, if there is any overall philosophy followed in defining these then this should also be explained here.

720 For example if there is some overall way in which any object identifier value (i.e. for patient ids, practitioner id, etc.) must be created then this should be specified as part of the introduction to this terminology section.

A.9.1.1 Common Rules for Identifier Construction (example)

This terminology sub-section serves as an example of where general rules for constructing any identifiers for this XDS Affinity Domain should be specified. For example, this sub-section could specify rules for creating OIDs to be used in this XDS Affinity Domain.

725 A.9.2 Data Content Rules and Restrictions

The XDS Affinity Domain may wish to define general rules and restrictions regarding the usage of certain general types of data, such as patient demographic information. This section should be used to convey such information.

A.9.2.1 Example of Rules and Restrictions for Patient Demographic Data

730 As an example, the following table could be used to convey restrictions on the usage of patient demographic attributes for specific Transactions. Some patient demographic attributes may be required for matching and thus specified as required, whereas the collection and processing of others may be prohibited by jurisdiction, law, or policy. There also may be some contradiction in

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requirements specified by different regulatory bodies. It is important that such policies be documented along with the final guidelines established for the XDS Affinity Domain so that the implementation rules are clearly established.

Table A.9.2.1-1. Example of Patient Demographic Data Restrictions

Data Element	Transactions	
	Patient Identity Feed (Regulatory Restrictions – i.e. HITSP)	Patient Identity Feed (XDS Affinity Domain - HIE)
Set ID - Patient ID	R ('1')	R ('1')
Patient ID	O	O
Patient Identifier List	R	R
Medical Record Number/Patient_ID Assigning Authority	R	R
Medical Record Number/Patient_ID Assigning Authority Universal ID	R	R
Medical Record Number/Patient_ID Assigning Authority Universal ID Type	R ('ISO')	R ('ISO')
Medical Record Number/Patient_ID	R	R
Alternate Patient ID	O	O
Patient Name	R	R (Must use Full Legal Name)
Patient First Name	C (Required if known)	R (Must use Full legal name)
Patient Middle Name	C (Required if known)	C (Required if known) (Must use Full Legal Name)
Patient Last Name	R	R (Must use Full legal name)
Patient Family Name	R	R (Must use Full Legal Name)
Patient Suffix	C (Required if known)	C (Required if known) (Must use Full legal name)
Name Prefix/Title	C (Required if known)	C (Required if known) (Must use Full legal name)
Name Type Code	R	R
Mother's Maiden Name	C (Required if known)	C (Required if known)
Mother's Maiden Name Family Name	C (Required if known)	C (Required if known)
Mother's Maiden Name Surname	C (Required if known)	C (Required if known)
Patient DOB	R	R
Gender	C (Required if known)	C (Required if known)
Patient Previous Names	O	O
Race	O	N (Not Permitted)
Patient Address	O	C (Required if known)
Patient Home Street Address	O	C (Required if known)
Patient home Street or mailing Address	O	C (Required if known)
Street Name	O	C (Required if known)

Data Element	Transactions	
	Patient Identity Feed (Regulatory Restrictions – i.e. HITSP)	Patient Identity Feed (XDS Affinity Domain - HIE)
Dwelling Number	O	C (Required if known)
Other Designation (second line of street address)	O	C (Required if known)
Patient Home City	O	C (Required if known)
Patient Home State/Province	O	C (Required if known)
Patient Zip	O	C (Required if known)
Country	O	C (Required if known)
Address type	O	O
County Code	O	O
Patient Daytime Phone	O	O
Patient Daytime Phone country code	O	O
Patient Daytime Phone Area/City Code	O	O
Patient Daytime Phone Local Number	O	O
Patient Daytime Phone Extension	O	O
Patient Daytime Phone Any other text	O	O
Work Telephone	R2	R2
Primary Language[11]	O	C (Required if known)
Marital Status	O	O
Religion	O	O
Patient Account Number	O	O
Patient SSN[12]	O	O
Patient Driver License	O	O
Mother's Identifier	O	O
Patient Ethnicity	O	N (Not Permitted)
Birth Place	O	O
Multiple Birth Indicator	O	O
Birth Order	O	O
Citizenship	O	O
Veteran's Military Status[13]	O	O
Nationality	O	O
Deceased Data/Time	O	O
Deceased Indicator	O	O

A.9.3 XDS Registry Metadata

740 Define all ways in which the XDS Affinity Domain refines Metadata attributes of an XDS Document Entry, XDS Submission Set, or an XDS Folder. It must specify any refinements to the way these attributes are used or to the sets of values that can be assigned to them. In addition, if

745 the language used in the XDS Affinity Domain is not english and a translation of the entire IHE ITI Technical Framework has not been done then translations should be provided. If more than one language exists in the XDS Affinity Domain then this entire section and its sub-sections should be repeated for each of these languages.

A.9.3.1 XDS Document Entry Metadata

750 If the language used in the XDS Affinity Domain is not english and a translation of the entire IHE ITI Technical Framework has not been done then this section should provide a translation of the ITI TF-2: Table 4.1-5 Document Metadata Attribute Definitions, to one of the languages. If more than one language exists in the XDS Affinity Domain then this entire section and its sub-sections should be repeated for each of these languages.

If a translation is not provided here then the following table should list all of the Document Metadata Attributes from ITI TF-2: Table 4.1-5 whose use is refined in any way for this XDS Affinity Domain.

755 Indicate if the use of each listed XDS Document Metadata Attribute is refined in any way for the XDS Affinity Domain. If so then the comments must indicate how this is done. Unless this can be explained very briefly then it should provide a link to a following sub-section that includes text describing how the attribute's use is refined. For example, if the XDS Affinity Domain restricts an attribute so that it can only use a set of values that is not already specified in the XDS Profile, then this set should be specified in the sub-section for this attribute.

760

Table A.9.3.1-1. Document Metadata Attribute Definition

XSDocument Entry Attribute	Refinement of Attribute	Source/Query (Bold and Underline if refined)	Data Type
authorInstitution	Provide a translation if necessary. Define whether or not the XDS Affinity Domain refines the use of this Attribute in any way. If not then it is not mandatory to list the attribute here. Otherwise, point to the sub-section of A.9.3.1XDS Document Entry Metadata that explains the refinement of this Attribute for the extension. If the Attribute is refined by defining a Source or Query value that is different from the Technical Framework (i.e. by requiring a value whereas it is optional in the Framework) then bold and underline the altered value and provide an explanation in the sub-section. Same applies for the remaining Attributes.	R2/R	Provide a reference to the sub-section of A.9.3.1 that specifies the list of permitted XON data type authorInstitution values for the of this attribute. For this example, "Refer to A.9.3.1.1 for the XDS Affinity Domain specification of this Attribute".
etc...			

Create a sub-section for each Document Entry Metadata Attribute that is refined for the XDS Affinity Domain.

A.9.3.1.1 Refinement of authorInstitution (example)

765 This sub-section for the authorInstitution Metadata Attribute should state how the values for this attribute are specified for this XDS Affinity Domain.

For example, authorInstitution, has an HL7 Data Type of XON so the authorInstitution sub-section could specify the sets of permitted values for each field of the XON Data Type for authorInstitution.

770 **Table A.9.3.1.1-1. HL7 V2.5 Component Table - XON – for authorInstitution**

SEQ	D T	O P T	Component Name	Comments
1	ST	O	Organization Name	Specify whether or not the XDS Affinity Domain refines this component in any way for authorInstitution. If not then the comment “No Refinement” will suffice. Otherwise, point to the sub-section of A.9.3.1.1 that specifies how values for this component should be specified. If only a defined set of values should be used then this list should be specified. Same applies for each of the following XON components.
2	IS	O	Organization Name Type Code	
3	N M	B	ID Number	
4	N M	O	Identifier Check Digit	
5	ID	O	Check Digit Scheme	
6	H D	O	Assigning Authority	
7	ID	O	Identifier Type Code	
8	H D	O	Assigning Facility	
9	ID	O	Name Representation Code	
10	ST	O	Organization Identifier	

A.9.3.1.1.1 Refinement of Organization Name component (example)

This sub-section for the authorInstitution Metadata Attribute should state how the Organization Name component is specified for this XDS Affinity Domain.

A.9.3.1.1.2 Etc.

775 Sub-section for specification of each remaining XON Data Type component for authorInstitution.

A.9.3.1.2 Refinement of Further XDS Document Entry Attributes(example)

780 Define a sub-section for each remaining XDS Document Metadata Attribute that the XDS Affinity Domain refines the use of. Explain how the value for each of these attributes must be specified. If a defined set of values should be used and this is not defined in the XDS Profile itself, then this list of values should be specified here.

A.9.3.2 XDS Submission Set Metadata

785 If the language used in the XDS Affinity Domain is not english and a translation of the entire IHE ITI Technical Framework has not been done then this section should provide a translation of the ITI TF-2: Table 4.1-6 Submission Set Metadata Attribute Definitions, to one of the languages. If more than one language exists in the XDS Affinity Domain then this entire section and its sub-sections should be repeated for each of these languages.

790 If a translation is not provided here then the following table should list all of the Submission Set Metadata Attributes from ITI TF-2: Table 4.1-6 whose use is refined in any way for this XDS Affinity Domain.

795 Indicate if the use of each listed XDS Submission Set Metadata Attribute is refined in any way for the XDS Affinity Domain. If so then the comments must indicate how this is done. Unless this can be explained very briefly then it should provide a link to a following sub-section that includes text describing how the attribute's use is refined. For example, if the XDS Affinity Domain restricts an attribute so that it can only use a set of values that is not already specified in the XDS Profile, then this set should be specified in the sub-section for this attribute. Refer to prior sections for those Attributes that have already been refined for Document Entry Metadata and thus will have same rules apply for Submission Set Metadata..

800

Table A.9.3.2-1. Submission Set Metadata Attribute Definitions

XDS Document Entry Attribute	Refinement of Attribute	Source/Query (Bold and Underline if refined)	Data Type
authorInstitution	<p>If the refinement of an attribute is already specified for the XDS Document Metadata then just refer to that section rather than repeating the entire text. For this example, “Refer to A.9.3.1.1 for the refinement of this Submission Set Metadata Attribute”</p> <p>Otherwise, provide a translation if necessary.</p> <p>Then define whether or not the XDS Affinity Domain refines the use of this Attribute in any way. If not then it is not mandatory to list the attribute here. Otherwise, point to the sub-section of A.9.3.2 XDS Submission Set Metadata that explains the refinement of this Attribute for the extension. If the Attribute is refined by defining a Source or Query value that is different from the Technical Framework (i.e. by requiring a value whereas it is optional in the Framework) then bold and underline the altered value and provide an explanation in the sub-section.</p> <p>Same applies for the remaining Attributes.</p>	R2/R	<p>If the refinement of an attribute is already specified for the XDS Document Metadata then just refer to that section rather than repeating the entire text. For this example, “Refer to A.9.3.1.1 for the refinement of this Submission Set Metadata Attribute”</p> <p>Otherwise, provide a reference to the sub-section of A.9.3.2 that specifies the list of permitted XON data type authorInstitution values for the of this attribute.</p>
etc...			

Create a sub-section for each Submission Set Metadata Attribute that is refined for the XDS Affinity Domain.

A.9.3.2.1 Refinement of Submission Set Metadata Attributes (example)

805 Define a sub-section for each remaining Submission Set Metadata Attribute that the XDS Affinity Domain refines the use of. Explain how the value for each of these attributes must be specified. If a defined set of values should be used and this is not defined in the XDS Profile itself, then this list of values should be specified here.

A.9.3.3 Folder Metadata

810 If the language used in the XDS Affinity Domain is not english and a translation of the entire IHE ITI Technical Framework has not been done then this section should provide a translation of the ITI TF-2: Table 3.14.4.1-7 Folder Metadata Attribute Definitions, to one of the languages. If more than one language exists in the XDS Affinity Domain then this entire section and its sub-sections should be repeated for each of these languages.

815 If a translation is not provided here then the following table should list all of the Folder Metadata Attributes from ITI TF-2: Table 3.14.4.1-7 whose use is refined in any way for this XDS Affinity Domain.

820 In either case, there should be a comment for each listed attribute indicating if the use of the attribute is refined in any way for the XDS Affinity Domain. If so then the comments must indicate how this is done. Unless this can be explained very briefly then it should provide a link to a following sub-section that includes text describing how the attribute's use is refined. For example, this could require defining the set of possible values that can be used for the attribute.

Table A.9.3.3-1. Folder Metadata Attribute Definitions

XDSFolder Attribute	Refinement of Attribute	Source/Query (Bold and Underline if refined)	Data Type
codeList	Provide a translation if necessary. Define whether or not the XDS Affinity Domain refines the use of this Attribute in any way. . If not, then it is not mandatory to list the attribute here. If it is, then point to the sub-section of A.9.3.3 Folder Metadata that explains the refinement of this Attribute. If the Attribute is refined by defining a Source or Query value that is different from the Technical Framework (i.e. by requiring a value whereas it is optional in the Framework) then bold and underline the altered value and provide an explanation in the sub-section. Same applies for the remaining Attributes.	R/R	Provide a reference to the sub-section of 0 Create a sub-section for each Folder Metadata Attribute that is refined for the XDS Affinity Domain. that specifies the list of codes that can be used to specify the type of clinical activity that resulted in placing the XDS Documents in an XDSFolder. For this example, "Refer to A.9.3.3.1 for the XDS Affinity Domain refinement of this Attribute".
etc...			

Create a sub-section for each Folder Metadata Attribute that is refined for the XDS Affinity Domain.

825 **A.9.3.3.1 Refinement of codeList (example)**

This sub-section for the codeList Folder Metadata Attribute should state how the values for this attribute are specified for this XDS Affinity Domain.

For example, the codeList sub-section could specify the set of permitted values (Code Value, Display Name, and Coding Scheme Designator):

830 **Table A.9.3.3.1-1. Permitted Clinical Activity codeList Values**

Coding Scheme Designator	Display Name	Code Value

A.9.4 Supported Content

A.9.4.1 Supported Content Profiles

Table A.9.4.1-1. Supported XDS Content Profiles

Code	Comment
XDS-MS	Comment explaining if the XDS Affinity Domain has any guidelines or rules for this type of content beyond those defined in the ITI Technical Framework. If there are then a reference to a following sub-section explaining these, or to another document that does this must be provided. Same applies for all listed XDS Content Profiles.
XDS-SD	
XDS-I	
XDS-BPPC	
XDS-*	An XDS Affinity Domain may choose to support certain types of content for which an XDS Content Profile does not currently exist. All such content should be listed here. Further details about this content, and rules for its use should be specified in sub-sections following this table.
Etc.	

835 The following sections should specify any refinement of attributes and terminology to be used in content of each of the XDS Content Profiles listed in the above Table.

A.9.4.1.1 XDS-MS Document Content Refinement (Example)

840 This section should specify any specialization of attributes and terminology to be used in published content of the XDS-MS Content Profile. This should be only for those attributes that are not defined as being part of the Metadata.

A.10 Patient Privacy and Consent

A.10.1 General Guidelines Regarding Document Access and Use

845 Specify the general guidelines to be followed regarding the access and use of medical information in the XDS Affinity Domain. The Privacy Access Policies (Informative) section of the IHE BPPC Profile provides several examples of the ways this can be expressed, such as the example table below:

Table A.10.1-1. Access Control Policies

Privacy Consent Policy	Description
Billing Information	May be accessed by administrative staff and the patient or their legal representative.
Administrative Information	May be accessed by administrative or dietary staff or general, direct emergency care providers, the patient or their legal representative.
Dietary Restrictions	May be accessed by dietary staff, general, direct or emergency care providers, the patient or their legal representative.
Etc.	

850 If access control policies are tied to specific user roles then an access control matrix should be specified here that links specific user roles to the types of documents that these users are permitted to access. The means for actually defining, and assigning these user roles should be specified in the A.11.1.1 Role Management section

A.10.2 Patient consent

855 The rules for patient consent have to be harmonized or agreements have to be defined on how differences shall be bridged when harmonization is not possible. Both parties shall agree to this in the Policy Agreement.

Patient privacy is a key issue in trans-border information exchange.

In order to gain a patient's full confidence with the information transactions it is of utmost importance that the rules are clear and easily understood by the patients.

A.10.2.1 BPPC

860 Specify whether or not support of the IHE XDS Basic Patient Privacy Consents Content Profile is mandatory or not for systems connecting to this XDS Affinity Domain.

Define the rules for the use of BPPC in the XDS Affinity Domain. Refer to the IHE ITI BPPC Profile for a thorough discussion of these rules. Some examples of the rules to define are:

- Location where the set of common consent agreements are to be published.
- 865 • Manner in which the Policy OIDs are going to be distributed to and used by systems in the XDS Affinity Domain.
 - The configuration of the Document Consumers and Sources on the appropriate behaviors when specific consent OIDs are used or referenced.
 - 870 • Document Sources should select the appropriate OIDs when documents are published.
 - Document Consumers should enforce the policies associated with the OIDs when documents are queried and retrieved.
- Specify if on a patient-by-patient basis Consent documents will be published into the XDS Affinity Domain.
 - 875 • If Consent documents are published then specify whether “wet” signatures (thus requiring support for XDS Scanned Documents), or electronic patient consents will be used.
 - If “wet” signatures are used then specify whether or not the Scanned Documents must be digitally signed or not.
 - 880 • If electronic patient consents are used then define how the certificates are obtained for the patient digital signatures.
 - Note that in XDS Affinity Domains where implied consent is used, Consent documents are not likely to be published.
- 885 • Define all the conditions that can be used for defining a patient’s privacy consent (type of data, type of access, etc.).

A.10.3 Privacy Override Guidelines

890 This section should specify those conditions (emergency mode, break-glass, system failure mode, etc) under which privacy restrictions can be over-ridden. This should specify any special procedures that must be followed and how such cases of privacy override must be documented and reviewed.

A.11 Technical Security

This section details the technical aspects of security for the XDS Affinity Domain.

895 It is most likely that each domain will have its own security rules. It would be ideal of course if the involved domains can commit themselves to one and the same security model. This is the primary goal and the security standards defined in both CEN and ISO shall be the primary tools to achieve this.

If this is not possible it shall be specified in the Agreement which security level in one domain corresponds with which security level in another domain and authority for the users has to be designed for the various levels in both domains.

900 Refer to the “HIE Security and Privacy through IHE White Paper” for further details on the issues that should be considered when implementing an XDS Affinity Domain.

905 Implementers are also encouraged to review the health sector standard, ISO 27799. This has reached 'final approval' stage within its development cycle (Technical Committee ISO/TC 215). It has a proposed title of 'Health Informatics - Security management in health using ISO/IEC 17799'.

This standard provides guidance to health organizations and other holders of personal health information on how to protect such information via implementation of ISO17799/ISO27002. It specifically covers the security management needs in this sector, with respect to the particular nature of the data involved.

910 A.11.1 Authorisation

The authorization process shall be defined in the Policy Agreement both internally in the domain and externally in the other jurisdiction domains.

A.11.1.1 Role Management

915 Specify the Roles defined for users in the XDS Affinity Domain. Both functional and structural roles may need to be defined.

A.11.1.1.1 Functional Roles

The following table lists some examples of possible Functional Roles for the Affinity Domain:

Table A.11.1.1.1-1. Affinity Domain Functional Roles

Functional Role	Description
Subject of care	The principal data subject of the electronic health record
Subject of care agent	E.g. parent, guardian, carer, or other legal representative
Personal health care professional	The health care professional or professionals with the closest relationship to the patient, often the patient's GP.
Privileged health care professional	Nominated by the subject of care OR Nominated by the health care facility of care (if there is a nomination by

	regulation, practice, etc. such as an emergency over-ride)
Health care professional	Party involved in providing direct care to the patient
Health-related professional	Party indirectly involved in patient care, teaching, research, etc.)
Administrator	Any other parties supporting service provision to the patient

A.11.1.1.2 Structural Roles

920 It is highly recommended that Affinity Domains utilize the following International Standard
 Classification of Occupations (ISCO-08) codes when there is a need to convey a health care
 provider's specialty (both in the document metadata and in local policy expression). While the
 jurisdiction's implementation of these may be distinct, the clinical roots of the specialties are
 global. Their use will facilitate role based access when trying to access data across regional or
 925 national Affinity Domains.

Table A.11.1.1.2-1. Sample Affinity Domain Structural Role Mapping to ISCO-08 Classification

Regional Description	Regional Role Code	ISCO-08 Role Description	ISCO-08 Role
Licensed Acupuncturist		Traditional and complementary medicine practitioners	3238
Athletic Trainer		Fitness and recreation instructors and program leaders	3433
Audiologist		Audiologists and speech therapists	2246
Audiology Assistant		Health care assistants	5133
Chiropractic Physician		Health associate professionals not elsewhere classified	3239
Registered Chiropractic Assistant		Physiotherapy technicians and assistants	3235
Clinical Lab Director		Managing directors and chief executives	1120
Clinical Lab Technician		Medical laboratory technicians	3142
Clinical Lab Technologist		Medical laboratory technicians	3142
Clinical Social Worker		Social work and counselling professionals	2636
Dentist		Dentists	2241
Dental Hygienist		Dental assistants and therapists	3231
Dental Radiographer		Medical equipment technicians	3236

Regional Description	Regional Role Code	ISCO-08 Role Description	ISCO-08 Role
Dietetics/Nutritionist		Dieticians and nutritionists	2245
Nutrition Counselors		Dieticians and nutritionists	2245
Electrologist		Health associate professionals not elsewhere classified	3239
Hearing Aid Specialists		Medical and dental prosthetic and related technicians	7314
Massage Therapist		Physiotherapy technicians and assistants	3235
Medical Doctor		2211 Generalist medical practitioners, 2212 Specialist medical practitioners	2211, 2212
Medical Doctor Public Psychiatry Certificate		Specialist medical practitioners	2212
Medical Doctor Public Health Certificate		Specialist medical practitioners	2212
Medical Doctor Area Critical Need		Specialist medical practitioners	2212
Diagnostic Radiological Physicist		Medical equipment technicians	3236
Therapeutic Radiological Physicist		Medical equipment technicians	3236
Medical Nuclear Radio Physicist		Medical equipment technicians	3236
Medical Health Physicist		Physicists and astronomers	2111
Mental Health Counselor		Social work and counselling professionals	2636
Midwife		Midwifery professionals	2222
Naturopathic Physician		Traditional and complementary medicine practitioners	3238
Advanced Registered Nurse Practitioner		Nursing professionals	2221
Registered Nurse		Nursing professionals	2221
Licensed Practical Nurse		Nursing associate professionals	3221
Nursing Home Administrator		Aged care service managers	1343

Regional Description	Regional Role Code	ISCO-08 Role Description	ISCO-08 Role
Ancillary Service Providers - Occupational Therapy		Health professionals not elsewhere classified	2249
Occupational Therapy Assistant		Physiotherapy technicians and assistants	3235
Dispensing Optician		Optometrists and opticians	3234
Optometrist		Optometrists and opticians	3234
Orthotist		Medical and dental prosthetic and related technicians	7314
Orthotic Fitter		Medical and dental prosthetic and related technicians	7314
Orthotic Fitter Assistant		Medical and dental prosthetic and related technicians	7314
Prosthetist-Orthotist		Medical and dental prosthetic and related technicians	7314
Osteopathic Physician		Specialist medical practitioners	2212
Pharmacist		Pharmacists	2242
Nuclear Pharmacist		Pharmacists	2242
Ancillary Service Providers - Physical Therapist		Physiotherapists	2244
Physical Therapist Assistant		Physiotherapy technicians and assistants	3235
Physician Assistant		Doctor's assistants	3211
Podiatric Physician		Specialist medical practitioners	2212
Prosthetist		Medical and dental prosthetic and related technicians	7314
Respiratory Care		Physiotherapists	2244
Certified R. T. Technician		Physiotherapy technicians and assistants	3235
Respiratory Care Practitioner Critical Care		Physiotherapists	2244
Respiratory Care Practitioner Non-Critical Care		Physiotherapists	2244

Regional Description	Regional Role Code	ISCO-08 Role Description	ISCO-08 Role
School Psychologist		Psychologists	2635
Speech-Language Pathology		Audiologists and speech therapists	2246
Audiologist		Audiologists and speech therapists	2246
Speech-Language Pathology Assistant		Physiotherapy technicians and assistants	3235
Audiology Assistant		Physiotherapy technicians and assistants	3235
Homeopath		Traditional and complementary medicine practitioners	3238

A.11.1.2 Authentication of Users/Role

930 Specify the minimal user and role authentication strength (password rules, 2-factor, certificates, etc)

A.11.1.2.1 User/Role Certificates Management

935 Specify how user authentication security certificates will be managed for the XDS Affinity Domain. For example, it should state which certificate provider(s) will be allowed and how the certificates can be obtained. It should also specify whether or not user certificates will also incorporate information regarding their role, etc.

A.11.1.3 Attestation rights

940 The Policy Agreement shall name the individuals in the organization who have the right to assign roles and attestation authority to employees. An employee with attestation authority has the right to attest medical information.

A.11.1.4 Delegation rights

Delegation is often necessary in daily operation. In order to be able to keep this under control delegation rights have to be specified in the Agreement since it is particularly difficult to know who has which rights inside and between the domains.

A.11.1.5 Validity time

945 Authorization, roles, attestation rights, delegation rights shall have a well defined and specified time period for the access rights to information both within the domain and across domain borders. These time periods shall be notified in the Agreement.

A.11.2 Node Authentication

950 Specify whether or not the ATNA Secure Node and/or Secure Application Profiles must be supported for Node Authentication.

A.11.2.1 Node Certificates Management

955 Specify how node security certificates will be managed for the XDS Affinity Domain. For example, it should state which certificate provider(s) will be allowed and how the certificates can be obtained.

A.11.3 Information Access

How access to the information should be controlled in the XDS Affinity Domain, depending upon whether it is contained on a computer system, removable media, or being transferred over a network.

A.11.3.1 Security Audit Log Access

960 Specify how access to the security audit logs will be managed.

A.11.3.2 Network Communication Access Security Requirements

965 Specify the network access security requirements for the XDS Affinity Domain. Specify the means by which network communication security will be ensured (will all Transactions have to be secured by

A.11.3.3 Node Access Security Requirements

Specify the system node access security requirements. For example, whether or not all nodes must conform to the IHE ATNA Secure Node Actor/Profile.

A.11.3.4 Removable Media Access Security Requirements

970 Whether or not media transfer of XDS content is permitted as part of the XDS Affinity Domain, and if so what media security is required if any. For example, must the media itself be encrypted, or the individual files?

A.11.3.5 Agreement validity period

975 The time period for which an access Agreement is valid shall be specified in the Agreement. The Agreement shall also include a clause defining the procedure for termination of the Agreement both at the end of the Agreement period and within the Agreement period. Legitimate reasons for cancellation of the Agreement shall be defined. Economic compensations for extra costs if the Agreement is cancelled between the agreed time periods shall also be defined in the Agreement.

A.11.4 Information Integrity

980 The integrity of the data shall be checked in order to detect corruption of data during transfer between the domains. The rules and techniques for this shall be agreed upon and specified in the Policy Agreement.

A.11.4.1 Network Communication Integrity Requirements

985 How will integrity of data transmitted over a (cable or wireless) network within the XDS Affinity Domain be managed? What methods for checking this integrity should be used and whether it is mandatory or not for systems acting as specific Actor/Profiles.

A.11.4.2 Document Digital Signature Requirements/Policy

990 Is it necessary to digitally sign any of the content in order to ensure the lifetime integrity of the data, or to allow authentication of the identity entity that created, authorized, or modified the content.

A.11.4.3 Document Update and Maintenance Policies

Detail policies regarding the modification, reading, and deletion of documents in the following sub-sections:

A.11.4.3.1 Document Correction Policy

995 **A.11.4.3.2 Document Update Policy**

A.11.4.3.3 Document Read Policy

A.11.4.3.4 Document Deletion Policy

A.11.4.4 Folder Update and Maintenance Policies

Detail policies regarding the modification, reading, and deletion of folders

1000 **A.11.4.4.1 Folder Correction Policy**

A.11.4.4.2 Folder Update Policy

A.11.4.4.3 Folder Read Policy

A.11.4.4.4 Folder Deletion Policy

A.11.5 Ethics

1005 The rules and regulations will never cover all possible situations. Therefore ethics have to be taken into consideration and a memorandum has to be formulated to give everybody a good understanding about the framework for responsibility that everyone has to work within.

A.11.6 Secure Audit Trail

1010 As mentioned above, all transactions shall be logged. This section shall define the use of the ATNA Audit Logging feature.

Specify whether or not ATNA Audit Record Repositories will be centralized or distributed. In addition, state whether or not they will be expected to support the following, and if so how:

- Filtering
- Reporting
- 1015 • Alerting
- Alarming
- Forwarding to other Audit Record Repositories

A.11.7 Consistent Time

1020 In order to be able to ensure high quality logging, time stamping is necessary. All information transactions shall have a time stamp. Specify how support for the IHE Consistent Time Profile will be implemented, and who will be responsible for providing Consistent Time servers. This may require substantial reprogramming of older system and therefore may not possible for economical reasons. In this case the parties signing the Agreement shall decide what can be done under existing circumstances and what measures shall be taken for improving the situation. An implementation plan is part of the Agreement.

1025

Add cross-referencing

A.11.8 Audit check

The agreement shall stipulate when, by whom and how the log files shall be checked and appropriate action taken.

A.11.9 Risk analysis

1030 If risks are observed all parties have jointly to evaluate them and decide whether the risks can be accepted or not. The risks have to be documented in the Policy Agreement. If the risks can be accepted all parties shall approve it. If the risks are not acceptable a plan detailing resource requirements for risk reduction shall be included in the Policy Agreement.

1035 Specify the frequency of risk assessments. It is recommended that they be done at least on an annual basis.

1040 Be aware that IHE has not analysed local or national regulations to make sure there are not additional requirements beyond those IHE has addressed. There could be local rules and regulations that IHE has not considered. For example, patient privacy versus employee related privacy considerations usually require local analysis.

A.11.9.1 General Mitigations

Discuss any overall mitigation mechanisms and policies used for addressing systemic risks:

- Identity Management policies used in order to mitigate the potential risk of identity theft and masquerade.
- 1045
- Digital Signature policies used to mitigate the risk of data modification and masquerade.

A.11.9.1.1 Common Criteria (ISO/IEC 15408)

Policy makers are encouraged to make use of the security framework defined in the Common Criteria for Information Technology Security Evaluation (abbreviated as Common Criteria or CC). Common Criteria is an international standard (ISO/IEC 15408) for computer security.

- 1050 Common Criteria is based upon a framework in which computer system users can specify their security requirements, vendors can then implement and/or make claims about the security attributes of their products, and testing laboratories can evaluate the products to determine if they actually meet the claims. In other words, Common Criteria provides assurance that the process of specification, implementation and evaluation of a computer security product has been conducted
- 1055 in a rigorous and standard manner.

- The framework can thus be used to translate the security requirements for the XDS Affinity Domain into specific requirements that must be met in order for systems to connect to others within the Affinity Domain. Demonstrating that these requirements are met then allows some proof that organizations are maintaining technical security before a user in that organization
- 1060 connects to the XDS Affinity Domain.

A.11.9.2 Identified Risks

The following table lists examples of some potential risks along with possible mitigation mechanisms:

Table A.11.9.2-1. Table of Risks and Mitigations

Risk	Description	Risk Level	IHE Mitigation	Other Mitigation

Risk	Description	Risk Level	IHE Mitigation	Other Mitigation
‘Masquerade by insiders (including masquerade by health professionals and support staff)	Masquerade by insiders consists of system use by those who make use of accounts that are not their own. As such, it constitutes a breakdown in secure user authentication. Many cases of masquerade by insiders are committed simply because it makes it easier for people to do their work. For example, when one health professional may replace another at a workstation and continues to work on an already active patient record, there is a strong temptation to skip the inconvenience of the first user logging out and the second user logging in. Nevertheless, masquerade by insiders is also the source of serious breaches in confidentiality. Indeed, the majority of breaches of confidentiality are committed by organizational insiders. Masquerade by insiders can also be carried out with the intention to cover up cases where harm has been caused.	High	Cross Enterprise User Assertion , ATNA TLS Communication, ATNA Secure Node, ATNA Audit Trail, Consistent Time	Identity Management Policy
...				

1065 **A.11.10 Future system developments**

The Policy Agreement shall commit all parties to develop their future system according to this and other accepted standards in order to facilitate future co-operation for information transfer between their systems.

1070 All these functions shall be specified in the Policy Agreement. The standardized layout of the Policy Agreement is described in Annex B of this document and shall be used as a guide when Policy Agreements are established.

All information exchange functions have shall be specified in the Policy Agreement.