Integrating the Healthcare Enterprise

IHE

IHE IT Infrastructure
Technical Framework Supplement

Non-patient File Sharing
(NPFS)

FHIR® STU3

Using Resources at FMM Level 3-5

Draft for Public Comment

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework V13.0. Each supplement
30   undergoes a process of public comment and trial implementation before being incorporated into
the volumes of the Technical Frameworks.

This supplement is published on May 17, 2017 for public comment. Comments are invited and
can be submitted at http://www.ihe.net/ITI_Public_Comments. In order to be considered in
development of the trial implementation version of the supplement, comments must be received
35   by June 16, 2017.

This supplement describes changes to the existing technical framework documents.

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

Amend Section X.X by the following:

40   Where the amendment adds text, make the added text **bold underline**. Where the amendment
removes text, make the removed text **bold strikethrough**. When entire new sections are added,
introduce with editor's instructions to "add new text" or similar, which for readability are not
bolded or underlined.

45   General information about IHE can be found at http://ihe.net.

Information about the IHE IT Infrastructure domain can be found at http://ihe.net/IHE_Domains.

Information about the organization of IHE Technical Frameworks and Supplements and the
process used to create them can be found at http://ihe.net/IHE_Process and http://ihe.net/Profiles.

The current version of the IHE IT Infrastructure Technical Framework can be found at
50   http://ihe.net/Technical_Frameworks.

CONTENTS

Introduction to this Supplement

This supplement defines how to enable the sharing of non-patient files.

150   Those files can be created, consumed and updated by many different systems involved in a wide variety of data sharing workflows (clinical workflow definition, domain policies sharing, stylesheets management, etc.). This supplement identifies three actors: File Manager, File Consumer, and File Source. In order to fulfill use-cases requirements, this profile defines three new transactions (Submit File transaction, Search File transaction and Update

155   DocumentReference transaction) and re-use an MHD transaction: Retrieve Document [ITI-68].

The goal of this supplement is to identify protocol requirements for the sharing of files, primary focusing on three types of file:

- Workflow Definitions: structured or unstructured documents that define the processing rules for a specific clinical/administrative workflow (see ITI TF-1: 30.4.1.1 "XDW
160   Workflow Architecture" for additional information).

- Privacy Domain Policies: structured or unstructured documents that describe a specific privacy policy that can be subscribed to by the patient (see ITI TF-1: 19.2 "Creating Patient Privacy Policies" for further details).

- Stylesheets: structured documents used by user-agents (e.g., Web Browsers) to render the
165   content of an XML document.

Local policies could extend the list of documents that can be shared using NPFS and that can be classified using the metadata model described in this profile.

Open Issues and Questions

NPFS_001: This version of the NPFS supplement does not define metadata elements that can
170   *be used to identify or classify targets for the publication of the file (e.g., IntendedRecipients or intended classes of recipients). Readers during PC period are asked to provide feedback on this topic. Should we address this use-cases? Should we cover the requirements to identify targets with both identifiers and classes (e.g., This doc is intended for user 12345, or this document is intended for GP's)?*

175   *NPFS_003: What are the metadata that can be used to classify those files?*

- *https://docs.google.com/spreadsheets/d/1F-6uEurFM-fI15wIiqPPCEIZj9csw1rdFny_alO0G5Y/edit?usp=sharing*

- *periodValidity metadata does to have a mandatory start and an optional end submeta?*

This issue could be addressed valuating the context.period.start and context.period.end element
180   *of the DocumentReference resource.*

- *interestedPartiesIdentification metadata has to be a code or an identifier?*

This use-case has not been addressed. Check OI NPFS_001

- *Should we let the status metadata be modified by the File Manager such we had the most recent status in order to accomplish the release management?*

185 *The Update DocumentReference transaction has been added to fulfill this issue*

NPFS_005: FHIR STU3 doesn't support, for the DocumentReference resource, the mime-type search parameter. How can we search for mime-types?

- *The use-case for which this issue was opened no longer exists. So the File Consumer can search for the format of the file and that is sufficient.*

190 **NPFS_006: This version of NPFS supplement define three new actors and three new transactions. Readers during PC period are asked to provide feedback on this topic. Actor and transaction names needs to be changed?**

NPFS_010: This document begins the definition of a value set for the class element. How do we complete the value set for this profile. Suggestions are requested. How do we coordinate
195 **this value set with other Document Sharing profiles. Suggestions are requested.**

Closed Issues

NPFS_002: Confirm the scope, because I just received again requests to cover such other documents (public health report in particular…). We are going to draft 3 use-cases: Policy
200 **Documents, Workflow Definitions, stylesheets.**

- *This supplement targets specific use cases selected as representative of wider classes of use. Feedback on non-patient document sharing uses not addressed through the supplement is requested.*

NPFS_004: How can I know if there is an updated version of the file or my file is deprecated?

205 - *Using a specific metadata it's possible to search, through the replacement association, the latest version of the file. The status of the replaced file needs to be changed by the File Source with the Update DocumentReference transaction.*

NPFS_007: We will follow the FHIR approach, should we align this work-item with MHD? (Option in MHD…)

210 - *Keep them separate for many reasons. Although we've decided to profile the Document Reference resource, there are some different requirements. It' is more safe to keep the two work-items separate for security requirements and to decrease the implementation effort on server side.*

NPFS_008: Is the word "document" the right one? Should we speak about "Files"?

215 - *This profile introduces the concept of "File" in order to mark a clear separation with DS* profiles defined by IHE IT Infrastructure domain. A "File" represents a collection of information from the web that is stored on a computer as one unit under one specific name. IHE IT Infrastructure domain has already defined a suite of profiles aimed to*

220   *share (using different sharing paradigms) documents related to patients, so another characteristic of a file (as it is described in this profile) is to be non-patient related.*

NPFS_009: Should we address the Consume process as a fetch?

- *This profile defines the usage of two distinct transaction to consume the file, because in one of our use-case the consumer could just be interested to retrieve DocumentReference resource and not the file itself.*

225 **General Introduction**

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

Appendix A – Actor Summary Definitions

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

230

Actor	Definition
File Manager	This actor stores files provided by the File Source and maintains related metadata. The File Manager responds to search and retrieve requests initiated by the File Consumer. The File Manager responds to metadata update requests initiated by the File Source.
File Source	The File Source publishes and updates files produced by either the File Source or by other systems. It is responsible for sending files and related metadata to a File Manager.
File Consumer	The File Consumer queries a File Manager for file's metadata meeting certain criteria, and may retrieve selected files.

Appendix B – transaction Summary Definitions

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

transaction	Definition
Submit File [ITI-YY]	This transaction allows a File Source to publish a file and related metadata or to update a file already existing.
Search File [ITI-XX]	This transaction allows a File Consumer to query for a file's metadata which meets certain criteria
Update DocumentReference [ITI-ZZ]	This transaction allows a File Source to update file's metadata.

235 **Glossary**

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

Glossary Term	Definition
File	A collection of non-patient health information (non-PHI) data that can be shared among different systems (e.g., stylesheets, Patient Privacy Policies, Workflow Definitions, etc.)

Volume 1 – Profiles

240 ## Copyright Licenses

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

NA

Domain-specific additions

245 NA

Add Section X
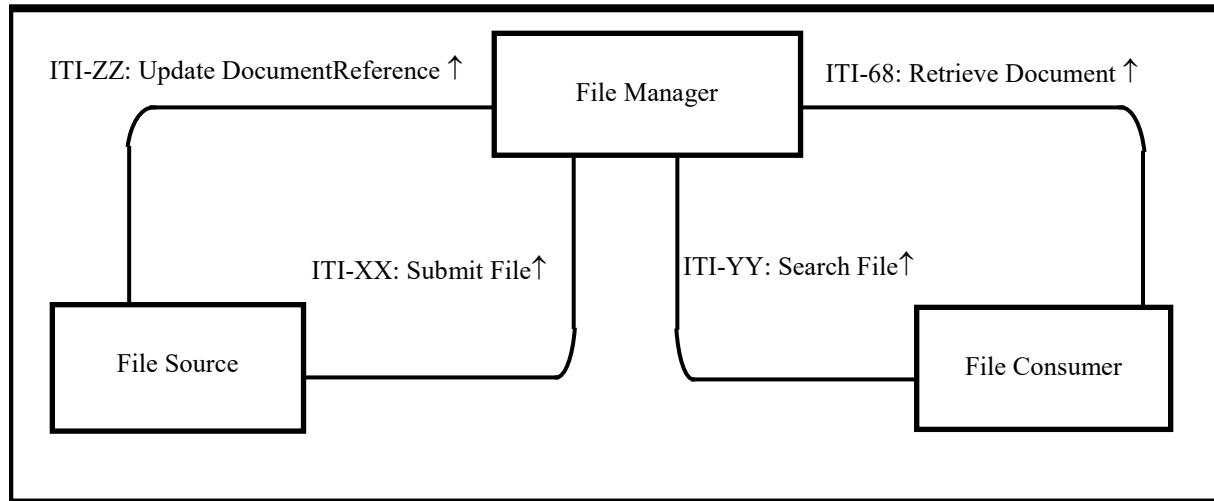
X Non-Patient File Sharing (NPFS) Profile

250　The Non-Patient File Sharing Profile defines how to enable sharing of non-patient files such as clinical workflow definitions, domain policies, and stylesheets. Those files can be created and consumed by many different systems involved in a wide variety of data sharing workflow. NPFS specifies transactions for the sharing of files, primarily focusing on three types of files:

255
- Workflow Definitions: structured or unstructured documents that define the processing rules for a specific clinical/administrative workflow (see ITI TF-1: 30.4.1.1 "XDW Workflow Architecture")

- Privacy Domain Policies: structured or unstructured documents that describe a specific privacy policy that the patient can subscribe to (see ITI TF-1: 19.2 "Creating Patient Privacy Policies")

260
- Stylesheets: structured documents that can be used by user-agents to render the content of an XML document.

Local policies could extend the list of documents that can be shared using NPFS and that can be classified using the metadata model described in this profile.

X.1 NPFS Actors, Transactions, and Content Modules

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

Figure X.1-1 shows the actors directly involved in NPFS Profile and the relevant transactions between them. If needed for context, other actors that may be indirectly involved due to their
270　participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

Figure X.1-1: NPFS Actor Diagram

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

Table X.1-1: NPFS Profile - Actors and transactions

Actors	Transactions	Optionality	Reference
File Manager	Submit File [ITI-XX]	R	ITI TF-2c: 3.XX
	Search File [ITI-YY]	R	ITI TF-2c: 3.YY
	Retrieve Document [ITI-68]	R	ITI TF-2c: 3.68 (Note)
	Update DocumentReference [ITI-ZZ]	R	ITI TF-2c: 3.ZZ
File Consumer	Search File [ITI-YY]	R	ITI TF-2c: 3.YY
	Retrieve Document [ITI-68]	O	ITI TF-2c: 3.68 (Note)
File Source	Submit File [ITI-XX]	R	ITI TF-2c: 3.XX
	Update DocumentReference [ITI-ZZ]	R	ITI TF-2c: 3.ZZ

Note: This transaction is currently specified in the MHD Trial Implementation Supplement.

280

X.1.1 Actor Descriptions and Actor Profile Requirements

Most requirements are documented in transactions (Volume 2) and Content Modules (Volume 3). This section documents any additional requirements on profile's actors.

X.1.1.1 File Manager

The File Manager stores files provided by the File Source and maintains related metadata. The File Manager responds to search and retrieve requests initiated by the File Consumer. The File Manager responds to metadata update requests initiated by the File Source.

X.1.1.2 File Consumer

The File Consumer queries for files' metadata meeting certain criteria, and may retrieve selected files.

X.1.1.3 File Source

The File Source publishes and updates files produced by either the File Source or by other systems. It is responsible for sending files and related metadata to a File Manager. The File Source can send metadata update requests to the File Manager.

X.2 NPFS Actor Options

Options that may be selected for each actor in this profile, if any, are listed in Table X.2-1. Dependencies between options when applicable are specified in notes.

Table X.2-1: Not Patient-centric Document Sharing - Actors and Options

Actor	Option Name	Reference
File Manager	No options defined	--
File Consumer	File Retrieve Option	Section X.2.1
File Source	No options defined	--

X.2.1 File Retrieve Option

The File Retrieve Option enables a File Consumer to retrieve the targeted file stored/managed by the File Manager.
A File Consumer that supports the File Retrieve Option shall support the Retrieve Document [ITI-68] transaction.

X.3 NPFS Required Actor Groupings

This profile does not mandate the grouping with other actors.

X.4 NPFS Overview

X.4.1 Concepts

The NPFS Profile introduces the concept of "file" in order to mark a clear separation with IHE Document Sharing profiles defined by IT Infrastructure domain. A file represents a collection of information that is stored on a computer as one unit under one specific name.

The IT Infrastructure domain has already defined a suite of profiles aimed to share (using different sharing paradigms) documents related to patients, so another characteristic of a file, as described in this profile, is to be non-patient related. In the NPFS Profile, a file does not contain
315   PHI, and does not expose sensible data related to a specific patient.

X.4.2 Use Cases

X.4.2.1 Use Case #1: Stylesheet Management

A technician using the Hospital Information System (HIS) creates a stylesheet to render the XML of CDA®[1] Laboratory Reports produced in all the Laboratory Information System (LIS)
320   involved in the Healthcare Information Exchange (HIE). The technician wants to make the stylesheet available to all the LIS involved in the HIE so that they can search for the stylesheet and reference it as a transformation in the XML digital signature of the Laboratory Report.

X.4.2.1.1 Stylesheet Management Use Case Description

A Healthcare Organization desires uniform rendering of XML Laboratory Reports produced
325   within the organization, so it creates a stylesheet document. Mr. Black, a technician of the Healthcare Organization, uses an HIS create the stylesheet. Then the HIS, acting as a File Source, publishes the file into a system that manage non-patient files (File Manager) using a Submit File [ITI-XX] transaction. Now the stylesheet will be available to all the LIS involved in the organization.
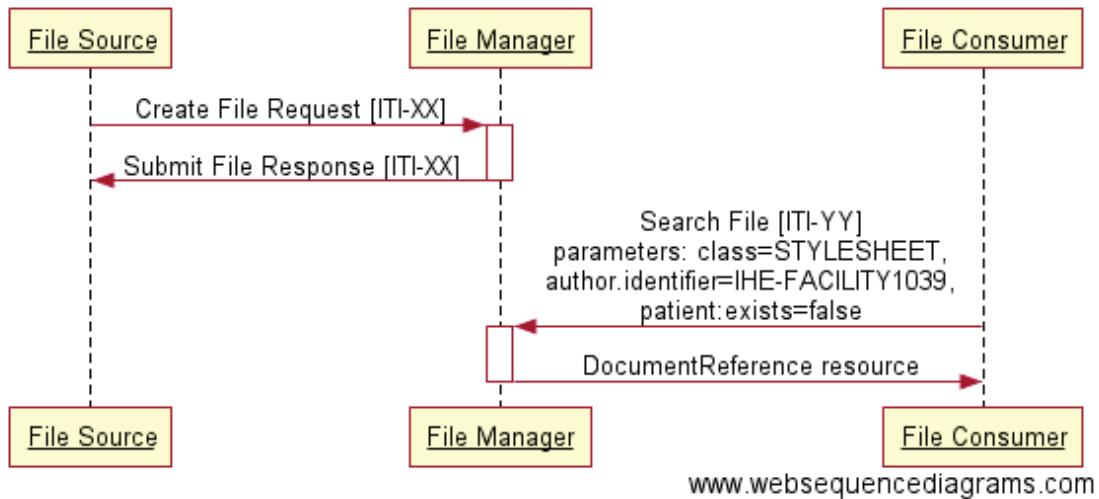
330   A Laboratory Information System, according to the HIE policy, should be able to identify the stylesheet that can be used to render the CDA document.

Mrs. White uses the LIS to retrieve a CDA Lab Report issued by Goodcare Labs from the HIE. The LIS also issues a query using a Search File [ITI-YY] transaction, to search for a stylesheet published by the HIE Organization, in order to discover the resource URL of the stylesheet
335   applicable to the Laboratory Reports. This URL is used to reference it as a XSL transformation of the CDA R2 Laboratory Reports produced.

X.4.2.1.2 Stylesheet's Management Process Flow

- The Health Information System acting as a File Source issues a Submit File [ITI-XX] transaction to the File Manager to submit the stylesheet

340
- The LIS acting as a File Consumer issues a Search File [ITI-YY] transaction to the File Manager, using the class parameter to search for stylesheets, and the author.identifier parameter to search for the organization that submitted the file. The query response contains the URL of the stylesheet.

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[1] CDA is the registered trademark of Health Level Seven International.

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345   **Figure X.4.2.2-1: Basic Process Flow in NPFS Profile for Stylesheets management**

File Source->+File Manager: Create File Request [ITI-XX]

File Manager->-File Source: Submit File Response [ITI-XX]

File Consumer->+File Manager: Search File [ITI-YY]\nparameters: class=STYLESHEET,\nauthor.identifier=IHE-FACILITY1039,\npatient:exists=false

File Manager->-File Consumer:DocumentReference resource

X.4.2.2 Use Case #2: Workflow Definitions

A technician at Goodcare Hospital uses the Hospital Information System to create a BPMN ("Business Process Model and Notation" see http://www.bpmn.org/ for further details)
350   Workflow Definition file to design and then publish an eReferral Process. Later, a specialist, who does not regularly work with Goodcare Hospital can use his to review the particular workflow before referring a patient.

X.4.2.2.1 Workflow Definitions Use Case Description

An HIE decides to design the eReferral Process for all the participants involved in that workflow.
355   Mr. Smith, an administrator with Goodcare Hospital, records the process in a BPMN Workflow Definition file[2], and makes it available, using a Submit File [ITI-XX] transaction.

Dr. Jones, a specialist, uses her HIS to query for the BPMN Workflow Definition file produced by Goodcare Hospital related to eReferral workflow, using a Search File [ITI-YY] transaction.

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[2] "Workflow Definition Document" is BPMN terminology, and does not suggest that this file is an IHE Document Sharing patient document.

360 The previously submitted Workflow Definition file is identified and retrieved, and Dr. Jones can identify what next steps in the eReferral process will be.

The HIE decides that the Workflow Definition file submitted is no longer valid and should be deprecated. Mr. Smith searches for that Workflow Definition to discover the id of its metadata (FHIR[®3] resources id) and then, using an Update DocumentReference [ITI-ZZ], sends the new metadata to update the status of the document.

365 X.4.2.2.2 Workflow Definitions Process Flow

- The Health Information System acting as a File Source issues a Submit File [ITI-XX] transaction to the File Manager to submit the Workflow Definition file.

370
- The HIS acting as a File Consumer issues a Search File [ITI-YY] transaction to the File Manager using the class parameter, to search for Workflow Definition file, and the type parameter, to search for Workflow Definitions related to eReferral workflow, and once the resource it's found issue a Retrieve Document [ITI-68] transaction to the File Manager to retrieve it.

375
- The Health Information System acting as a File Source issues an Update DocumentReference [ITI-ZZ] transaction to the File Manger to update the status of the Workflow Definition

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[3] FHIR is the registered trademark of Health Level Seven International.
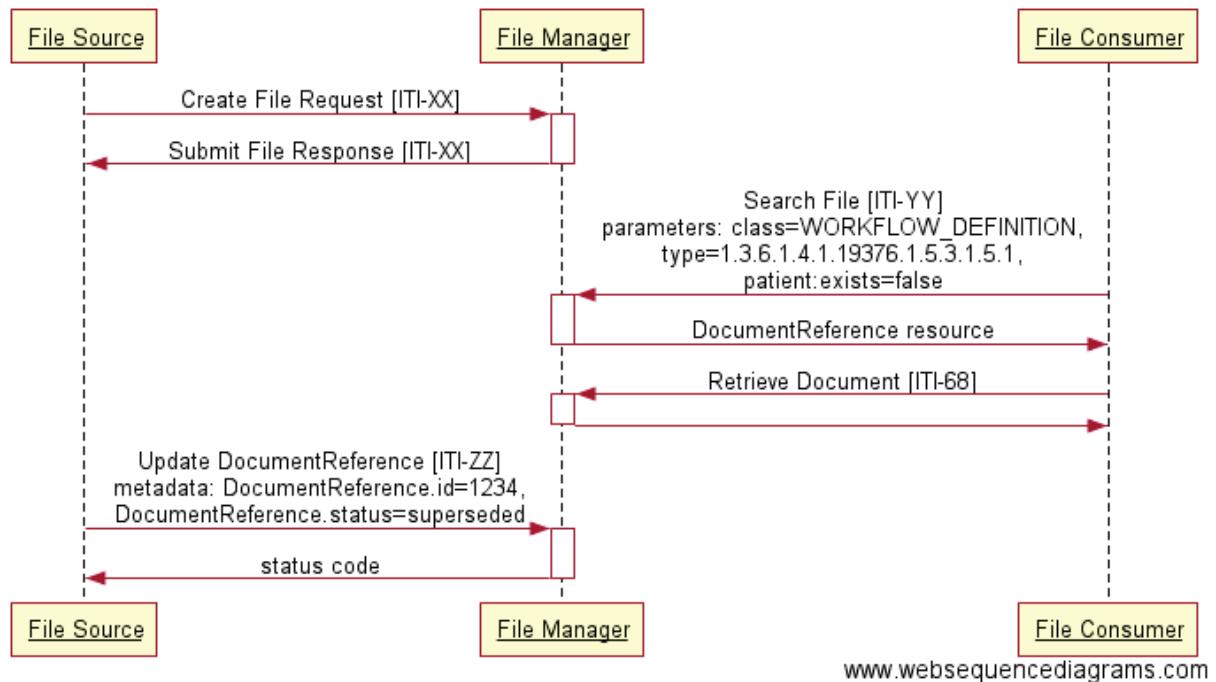
Figure X.4.2.2.2-1: Basic Process Flow in NPFS Profile for Workflow Definition Documents management

380

File Source->+File Manager: Create File Request [ITI-XX]

File Manager->-File Source: Submit File Response [ITI-XX]

File Consumer->+File Manager: Search File [ITI-YY]\nparameters: class=WORKFLOW_DEFINITION,\ntype=1.3.6.1.4.1.19376.1.5.3.1.5.1,\npatient:exists=false

File Manager->-File Consumer:DocumentReference resource

File Consumer->+File Manager: Retrieve Document [ITI-68]

File Manager->-File Consumer:

File Source->+File Manager: Update DocumentReference [ITI-ZZ]\nmetadata: DocumentReference.id=1234,\nDocumentReference.status=superseded

File Manager->-File Source:status code

X.4.2.3 Use Case #3: Privacy Policies

In this use case, the hospital's privacy office creates a structured or unstructured document describing the Privacy Policies that the patient can subscribe to. When a patient is admitted, the
385   admitting nurse uses a Basic Patient Privacy Consent (BPPC) Content Creator in the admitting area to show the patient this policy document, which the patient then consents to and a BPPC is created.

X.4.2.3.1 Privacy Policies Use Case Description

390 A hospital's privacy office defines a set of Privacy Domain Policies that a patient can subscribe to. Mr. Blue, Security/ Privacy Officer of the hospital, using an HIS creates the file and, using a Submit File [ITI-XX] transaction, makes it available to all the systems involved in his organization.

When a patient is admitted at the Goodcare Hospital, Mrs. Black, a nurse in the hospital, uses a BPPC Content Creator as a File Source to issue a query, a Search File [ITI-YY] transaction, to
395 search for the current valid Privacy Policies that the admitting patient can subscribe. Once they are found she can retrieve them to create the consent for the patient.

A legal health officer informs the Goodcare Hospital that it needs to update one of the current Privacy Domain Policies, because it has changed. Mr. Blue searches for the Privacy Policy that needs to be updated to discover the ids of the Policy and its related metadata (FHIR resource
400 ids), once they are found he uses an HIS perform the Submit File [ITI-XX] to update the targeted Privacy Policy and related metadata with the new ones.

X.4.2.3.2 Privacy Domain Policies Process Flow

- The Health Information System, acting as a File Source, issues a Submit File [ITI-XX] transaction to the File Manager to submit the Privacy Policy Document.

405 - The EHR acting as a File Consumer, issues a Search File [ITI-YY] transaction to the File Manager using the class parameter to search for Privacy Policy Document and the status parameter to search for valid Privacy Policy, and once the resource is found, issues a Retrieve Document [ITI-68] transaction to the File Manager to retrieve it.

- The HIS, acting as a File Source, issues a Submit File [ITI-XX] transaction to the File
410 Manager to update the existing Privacy Policy and its related metadata.
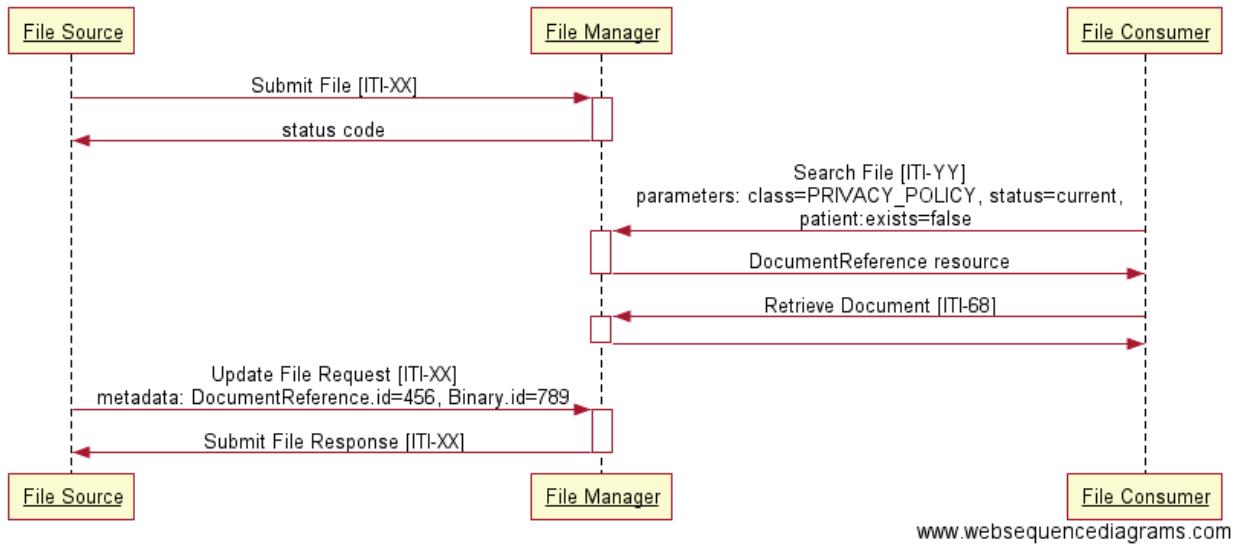
Figure X.4.2.3.2-1: Basic Process Flow in NPFS Profile for Privacy Policies management

File Source->+File Manager: Submit File [ITI-XX]

File Manager->-File Source: status code

File Consumer->+File Manager: Search File [ITI-YY]\nparameters: class=PRIVACY_POLICY, status=current,\n patient:exists=false

File Manager->-File Consumer: DocumentReference resource

File Consumer->+File Manager: Retrieve Document [ITI-68]

File Manager->-File Consumer:

File Source->+File Manager: Submit File [ITI-XX]\nmetadata: DocumentReference.id=456, Binary.id=789

File Manager->-File Source: status code

415

X.5 NPFS Security Considerations

Non-patient files do not convey Patient Health Information (PHI) or other sensitive information. However, those files can be used in conjunction with patient related documents in order to satisfy clinical data consuming/sharing workflows.

420 This profile does not require actors involved to send audit messages to an Audit Record Repository because non-patient files do not convey PHI. However, the grouping with an ATNA Secure Node or Secure Application is strongly encouraged in order to track creation/update operation executed.

425 User authentication/authorization represents another important factor to consider in order to avoid malicious creation/updating of files. Grouping NPFS actors with actors in the Internet User Authorization (IUA) Profile enables deployments to mitigate these security issues.

X.6 NPFS Cross Profile Considerations

None.

Volume 2c – Transactions (cont.)

430 | *Add Section 3.XX*

3.XX Submit File [ITI-XX]

3.XX.1 Scope

This transaction allows a File Source to publish one or more new files and related metadata or to update one or more existing file and metadata by publishing a new version.

435 This transaction uses the create message either when there is no prior file or when the prior needs to be preserved.

This transaction uses the update message when there is a prior file that doesn't need to be preserved (The File Manager is not required to support FHIR resource versioning https://www.hl7.org/fhir/STU3/http.html#history).

440 ### 3.XX.2 Actor Roles

File Source   File Manager

Submit File
[ITI-XX]
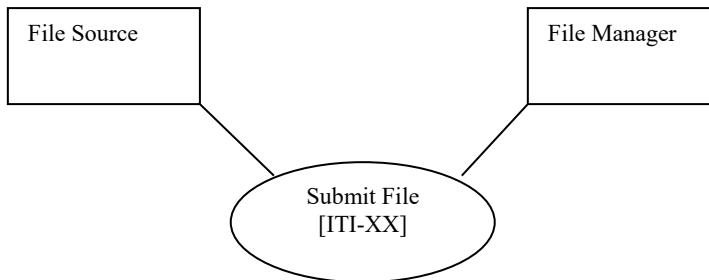
Figure 3.XX.2-1: Use Case Diagram

Table 3.XX.2-1: Actor Roles
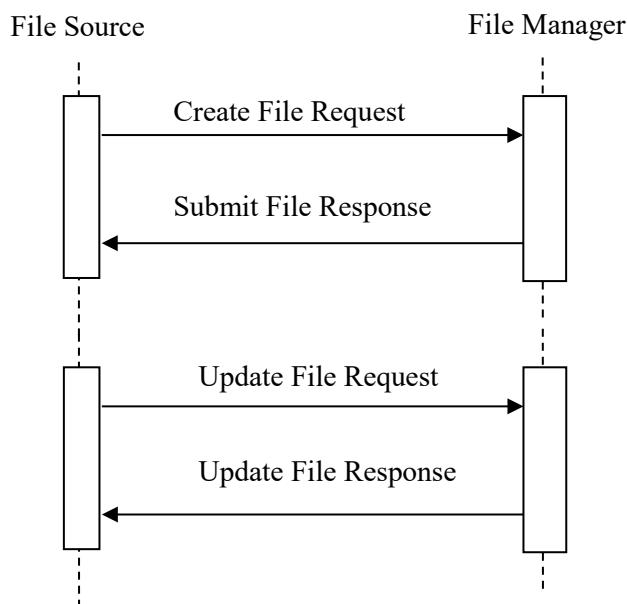
Actor:	File Source
Role:	Sends files and related metadata to a File Manager.
Actor:	File Manager
Role:	Stores received non-patient files and maintains related metadata

445

3.XX.3 Referenced Standards

HL7®[4] FHIR	HL7 FHIR standard STU3 http://hl7.org/fhir/STU3/index.html
RFC2616	Hypertext Transfer Protocol – HTTP/1.1
RFC7540	Hypertext Transfer Protocol – HTTP/2
RFC3986	Uniform Resource Identifier (URI): Generic Syntax
RFC6585	Additional HTTP Status Codes

3.XX.4 Interaction Diagram

3.XX.4.1 Create File Request Message

450   This message is used to submit a new file and related metadata to a target File Manager using FHIR transaction.

3.XX.4.1.1 Trigger Events

This message is sent when the File Source needs to submit one or more new files to a File
455   Manager. The file may have been created by the File Source itself or by another content creator.

This message is used when there is no prior file or when the prior needs to be preserved.

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[4] HL7 is the registered trademark of Health Level Seven International.

3.XX.4.1.2 Message Semantics

The File Manager shall issue an HTTP request according to requirements defined in FHIR specification for "`create`" transactions (http://hl7.org/fhir/STU3/http.html#create). The
460   message uses an HTTP POST method to submit a FHIR Bundle resource.

The FHIR Bundle resource shall contain one FHIR Binary resource (https://www.hl7.org/fhir/STU3/binary.html), representing the file, and one FHIR DocumentReference (https://www.hl7.org/fhir/STU3/documentreference.html) resource with the file's metadata.

465   The Binary resource shall contain the base64-encoded file in the content element and the mime-type of the file in the contentType element.

Additional constraints on the DocumentReference resource are listed in Table 3.XX.4.1.2-1.

The File Source shall submit FHIR resources in either XML format or JSON format. Values for media-type of the request message are defined in the ITI TF-2x: Appendix Z.6.

470   ### 3.XX.4.1.2.1 DocumentReference constraints

The following table lists the constraints defined for a DocumentReference resource.

Table 3.XX.4.1.2.1-1: Elements of the DocumentReference Resource

Element Name	Description	Constraints	OPT (note)
id	Contains the logical identifier of the resource		R+
status	Contains the file's status	The value of this element shall be "current"	R
type	Contains the type of the file	See Section 3.XX.4.1.2.1.2	R
class	Contains the file's class (e.g., WD, stylesheet, Privacy Policy)	See Section 3.XX.4.1.2.1.1	R+
subject	Contains Who or what the file is about	This element SHALL NOT reference a Patient resource	O
created	Contains the time when the file was created		R2
indexed	Contains the time when the file was submitted		R
author	Contains the reference to the author of the submission	The author element SHALL be valued with a reference to an Organization resource	R+
relatesTo	Identifies other DocumentReference resources that have a relationship with the submitted version of the DocumentReference resource.	See Section 3.XX.4.1.2.1.3	O
content/attachment/contentType	Contains the Mime-type of the file		R+
content/attachment/language	Contains the language of the file		R2
content/attachment/url	Contains the url of the resource, that can be		R+

Element Name	Description	Constraints	OPT (note)
	used to retrieve the file using the [ITI-68] transaction		
content/attachment/size	Contains the file's size		R+
content/attachment/hash	Contains the file's hash		R+
content/format	Contains the format of the file. The values of this metadata should be defined by local domain policies.		R+
context/sourcePatientInfo	This element is forbidden.		X

Note: See ITI TF-2x: Appendix Z.10 for definitions of values in the OPT column.

475   An example of Bundle created is presented below.

```
{
    "resourceType": "Bundle",
    "entry": [
        {"resource": {
            "resourceType": "DocumentReference",
            "id": "112345",
            "contained": [
                {
                    "resourceType": "Organization",
                    "id": "org1",
                    "identifier": [{
                        "system": "1.12.234.56",
                        "value": "IHE FACILITY1039"
                    }]
                }
            ],
            "status": "current",
            "type": {"coding": [{
                "code": "1.3.6.1.4.1.19376.1.5.3.1.5. ",

                "display": "eReferral workflow "
            }]},
            "class": {"coding": [{
                "system": "urn:ihe:iti:npfs:2017:class-codes",
                "code": "WORKFLOW_DEFINITION"
            }]},
            "created": "2017-04-17T10:30:00",
            "indexed": "2017-04-17T11:00:00",
            "author": [{"reference": "#org1"}],
            "content": [{
                "attachment": {
                    "contentType": "application/pdf",
                    "language": "en-US",
                    "url": "http://ihe-npfs.com/214",
                    "size": "3456",
                    "hash":
```

```
"07ae8b27c7596b3314601736f32d5f0ed17fc8c0e27a0475e8ea2d8b2c788436"
            },
            "format": [{"code": "application/pdf"}]
        }]
    }},
    {
        "fullUrl": "http://ihe-npfs.com/214",
        "resource": {
            "resourceType": "Binary",
            "id": "214",
            "contentType": "application/pdf",
            "content":
"PD94bWwgdmVyc2ldHRwOi8vd3d3LncKPC9DbGluaWNhbERvY3VtZW50Pgo="
        }
    }
    ]
}
```

3.XX.4.1.2.1.1 Class element

To be conformant, codes in this element shall be from Table 3.XX.4.1.2.1.1-1 if any of the codes within the value set can apply to the concept being communicated. If the table does not cover the concept (based on human review), an alternate code may be used instead.

480

Table 3.XX.4.1.2.1.1-1: Coded values the class element

Value for code	Description	codeSystem
STYLESHEET	Code for Stylesheets	`urn:ihe:iti:npfs:2017:class-codes`
WORKFLOW_DEFINITION	Code for Workflow Definition templates	`urn:ihe:iti:npfs:2017:class-codes`
57017-6	Code for Privacy Policies	`http://www.loinc.org`

3.XX.4.1.2.1.2 Type element

This section identifies specific requirements for the type element which depends on the "class" of the file:

- If the file submitted is a Workflow Definition template, the type metadata shall be valued
485 with the workflow definition reference associated to the Workflow Definition profile (as defined by the XDW Profile).

- If the file submitted is a Privacy Policy, the type metadata shall be valued with the Policy Privacy Identifier associated (as defined by the BPPC Profile).

- If the File submitted is a Stylesheet, the type element should be valued with an oid that
490 classifies the type of the stylesheet.

3.XX.4.1.2.1.3 File relationships

This transaction does not mandate specific requirements for the creation of relationships between DocumentReference resources.

The DocumentReference.relatesTo element allows for the creation of those relationships (e.g., replacement, sign, etc.). Unlike XDS, a replaced file is not deprecated by creating a replacement relationship.

3.XX.4.1.3 Expected Actions

The File Manager SHALL support all the media-types defined in ITI TF-2x: Appendix Z.6.

On receipt of the Create File Request, the File Manager shall validate the resources and respond with one of the HTTP codes defined in Section 3.XX.4.3.2 Message Semantics.

The File Manager shall process the bundle atomically.

The File Manager shall support Create File request message that contains one Binary resource and one DocumentReference resource. The File Manager shall store these resources and make them available for further search [ITI-YY] and retrieve [ITI-68].

3.XX.4.2 Update File Request Message

The File Source uses this message is to update a file and related metadata already stored by the File Manager

3.XX.4.2.1 Trigger Events

The File Source needs to submit a new version of an already existing file. Prior to sending the update, the File Source shall discover the resource ids related to the DocumentReference resource and to the Binary resource already submitted.

This message is used when there is a prior file that does not need to be preserved (The File Manager is not required to support fhir resource versioning (https://www.hl7.org/fhir/STU3/versions.html)).

3.XX.4.2.2 Message Semantics

The File Source shall issue an HTTP request according to requirements defined in the FHIR specification for "update" transactions (http://hl7.org/fhir/STU3/http.html#update).

The message uses an HTTP PUT method to submit a FHIR Bundle that contains the updated Binary and DocumentReference resources.

The FHIR Bundle resource shall contain one FHIR Binary resource (https://www.hl7.org/fhir/STU3/binary.html) representing the file to update, and one FHIR DocumentReference (https://www.hl7.org/fhir/STU3/documentreference.html) resource with the updated set of metadata.

The File Source shall set the bundle.entry.fullurl element with the target url of the resource being updated.

The File Source shall submit FHIR resources in either XML format or JSON format. Values for media-type of the request message are defined in the ITI TF-2x: Appendix Z.6.

This message define constraints for the structure of the DocumentReference resources exchanged. These constraints are defined in Section 3.XX.4.1.2.1.

3.XX.4.2.3 Expected Actions

The File Manager SHALL support all the media-type defined in ITI TF-2x: Appendix Z.6.

On receipt of the Update File Request, the File Manager shall validate the resources and respond with one of the HTTP codes defined in Section 3.XX.4.2.2 Message Semantics.

The File Manager shall process the bundle atomically.

The File Manager shall support Update File Request messages that contains one Binary resource and one DocumentReference resource. The File Manager shall store these resources and make them available for further search [ITI-YY] and retrieve [ITI-68].

3.XX.4.3 Submit File Response Message

The File Manager sends a Submit File Response message in response to either a Submit File Request or and Update File Request Message.

3.XX.4.3.1 Trigger Events

When the file has been created or updated by the File Manager, the File Manager sends this message to the File Source acknowledging the result of the create or update request.

3.XX.4.3.2 Message Semantics

The File Manager returns a HTTP Status code appropriate to the processing, conforming to the transaction specification requirements as specified in http://hl7.org/fhir/STU3/http.html#transaction.

When the File Manager has successfully processed the request, then the File Manager shall return an HTTP response with an overall status code.

In order to allow the File Source to know the outcomes of processing the transaction, and the identities assigned to the resources by the File Manager, the File Manager shall return a Bundle, with type set to transaction-response, that contains one entry for each entry in the request, in the same order, with the outcome of processing the entry. Each entry element shall contain a response element which details the outcome of processing of the entry with an HTTP Status Code.

If the outcome is a success, the File Manager shall return the 200 - OK HTTP status code

If the outcome is a failure, the File Manager shall return one of the following status codes:

- 400 – Bad Request: if the resource could not be parsed or failed basic FHIR validation rules

- 404 - Not Found: if the resource type is not supported.

Below is an example of the Submit File response:

```
{
  "resourceType":"Bundle",
  "type":"transaction-response",
  "entry":[
    {
      "response":
        {
          "status":"201"
        }
    },
    {
      "response":
        {
          "status":"201"
        }
    }
  ]
}
```

3.XX.4.3.3 Expected Actions

565   The File Source processes the results according to application-defined rules.

3.XX.5 Security Considerations

This transaction does not define specific Security Considerations. See ITI TF-2x: Appendix Z.8.

3.XX.5.1 Security Audit Considerations

This transaction does not require the actors involved to send audit messages to an Audit Record
570   Repository because it does not convey PHI. However the auditing of the submit operation is
suggested in order to avoid malicious creation/updating of files of interest for the care of the
patient. The structure of the Audit message generated shall comply with DICOM[5] PS3.15
Annex A.5.3.5 Data Import.
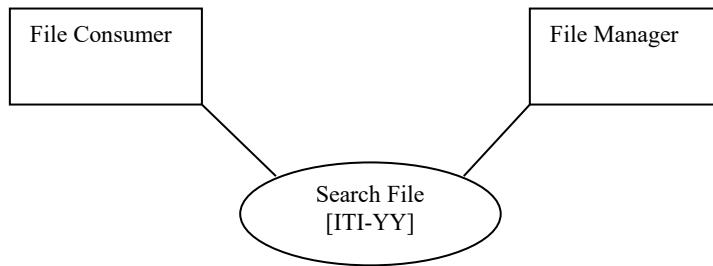
3.YY Search File [ITI-YY]

575   ### 3.YY.1 Scope

This transaction is used by the File Consumer to find DocumentReference resources that are not
associated with a patient that are stored and managed by a File Manager.

---

[5] DICOM is the registered trademark of the National Electrical Manufacturers Association for its standards
publications relating to digital communications of medical information.

3.YY.2 Actor Roles

580
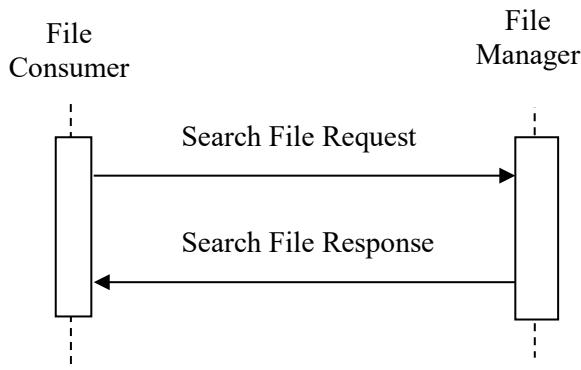
Figure 3.YY.2-1: Use Case Diagram

Table 3.YY.2-1: Actor Roles

Actor:	File Consumer
Role:	Searches for a list of files (DocumentReference resources) based on a set of search parameters
Actor:	File Manager
Role:	Returns a list of files (DocumentReference resources) that match the search parameters provided

3.YY.3 Referenced Standards

HL7 FHIR	HL7 FHIR standard STU3 http://hl7.org/fhir/STU3/index.html
RFC2616	Hypertext Transfer Protocol – HTTP/1.1
RFC7540	Hypertext Transfer Protocol – HTTP/2
RFC3986	Uniform Resource Identifier (URI): Generic Syntax
RFC6585	Additional HTTP Status Codes

3.YY.4 Interaction Diagram

585

3.YY.4.1 Search File Request Message

This message is a parametrized HTTP GET that allows a File Consumer to search for a list of the FHIR DocumentReference resources, managed by the File Manager, based on a set of search parameters.

590 **3.YY.4.1.1 Trigger Events**

A File Consumer sends this message to the File Manager when it needs to discover DocumentReference resources related to non-patient related files.

3.YY.4.1.2 Message Semantics

The File Search request is a parametrized HTTP GET request to the File Manager. This request
595 shall comply with requirements specified in the FHIR specification
http://hl7.org/fhir/STU3/http.html#search.

The search target URL of the File Manager needs to follow the FHIR http specification.

The target URL shall be structured as follows:

```
[base]/DocumentReference?[Parameters]
```

600 The `[Parameters]` element represents a series of encoded name-value pairs representing the filter for the query.

3.YY.4.1.2.1 Query Search Parameters

The File Consumer may supply and the File Manager shall support all the query parameters listed below:

605   • **created**

This parameter, of type `date`, specifies the time when the file, to which the DocumentReference refers, has been created. The File Consumer shall use the date and interval mechanism described in HL7 FHIR (http://hl7.org/fhir/STU3/search.html#date) to indicate a specific date or a date that lies within the range specified by the parameter

610   • **indexed**

This parameter, of type `date`, specifies the time when the file, to which the DocumentReference refers, has been submitted. The File Consumer shall use the date and interval mechanism described in HL7 FHIR (http://hl7.org/fhir/STU3/search.html#date) to indicate a specific date or a date that lies within the range specified by the parameter

615   • **author.identifier**

This parameters, of type `token`, specifies the identifier of the organization that has submitted the file. See ITI TF-2x: Appendix Z.2.2 for use of the `token` data type.

    • **format**

This parameter, of type `token`, specifies the mime-type of the file. See ITI TF-2x: Appendix
620   Z.2.2 for use of the `token` data type.

    • **language**

This parameter, of type `token`, specifies the language of the file. See ITI TF-2x: Appendix Z.2.2 for use of the `token` data type.

    • **location**

625 This parameter, of type `uri`, specifies the uri where the data can be found.

    • **status**

This parameter, of type `token`, specifies the status of the file. See ITI TF-2x: Appendix Z.2.2 for use of the `token` data type.

    • **relatesto**

630 This parameter, of type `reference`, specifies one or more resource that have been replaced by this version of the file.

    • **relation**

This parameter, of type `token`, specifies the type of relation that this file has with the targeted file. See ITI TF-2x: Appendix Z.2.2 for use of the `token` data type.

635   • **relationship**

This parameter, of type `composite`, is the combination of the relatesTo and relation search parameter.

- **patient**

640 This parameter SHALL always be used in this transaction. It is used to find resources that do not have the patient element valued. To achieve that, this parameter shall be used with the exists modifier (e.g., patient:exists=false).

The File Consumer SHALL NOT use the query parameters listed below:

- **subject** with a reference to a patient resource

3.YY.4.1.2.2 Populating Expected Response Format

645 See ITI TF-2x: Appendix Z.6 for details.

3.YY.4.1.3 Expected Actions

The File Manager shall process the query to discover only DocumentReference resources that are not associated to any patient and that match the search parameters given and shall send back the matching results.

650 ### 3.YY.4.2 Search File Response Message

The File Manager returns a HTTP Status code appropriate to the processing as well as a list of the matching DocumentReference resources

3.YY.4.2.1 Trigger Events

The File Manager has completed the processing of the Search File Request message.

655 ### 3.YY.4.2.2 Message Semantics

Based on the query results, the File Manager shall either return an error or success.

Guidance on handling Access Denied related to use of 200, 403 and 404 can be found in ITI TF-2x: Appendix Z.7

When the File Manager needs to report an error, it shall use HTTP error response codes and 660 should include a FHIR OperationOutcome with more details on the failure. See FHIR http://hl7.org/fhir/STU3/http.html and http://hl7.org/fhir/STU3/operationoutcome.html.

If the Search File Request message is processed successfully, whether or not any DocumentReference Resources are found, the HTTP status code shall be 200.

The Search File Response message shall be a Bundle Resource containing zero or more 665 DocumentReference Resources. If the File Manager is responding with warnings, the Bundle Resource shall also contain an OperationOutcome Resource that contains those warnings.

The response shall adhere to the FHIR Bundle constraints specified in ITI TF-2x: Appendix Z.1.

3.YY.4.2.3 Expected Actions

The File Consumer shall process the results according to application-defined rules.

670 If a File Consumer cannot automatically recover from an error condition, it should, at a minimum, display the error to the user.

3.YY.5 Security Considerations

This transaction does not define specific Security Considerations. See ITI TF-2x: Appendix Z.8.

3.YY.5.1 Security Audit Considerations
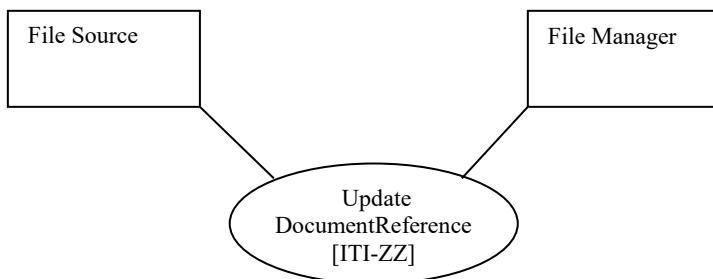
675 This transaction does not require the actor involved to send audit messages to an Audit Record Repository because does not convey PHI. However, the auditing of the search operation is suggested in order track unusual access to. The structure of the Audit message generated shall comply with DICOM PS3.15 Annex A.5.3.10 Query.

3.ZZ Update DocumentReference [ITI-ZZ]

680 ### 3.ZZ.1 Scope

This transaction allows a File Source to update a DocumentReference resource already submitted.

3.ZZ.2 Actor Roles

685

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

Table 3.ZZ.2-1: Actor Roles
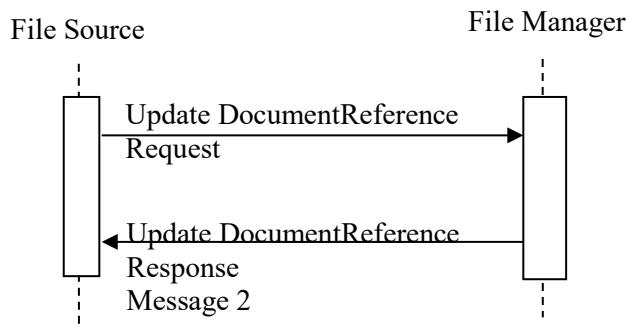
Actor:	File Source
Role:	Sends to a File Manager a new DocumentReference resource that replaces the previous one.
Actor:	File Manager
Role:	Updates and maintains related metadata.

3.ZZ.3 Referenced Standards

HL7 FHIR	HL7 FHIR standard STU3 http://hl7.org/fhir/STU3/index.html
RFC2616	Hypertext Transfer Protocol – HTTP/1.1
RFC7540	Hypertext Transfer Protocol – HTTP/2
RFC3986	Uniform Resource Identifier (URI): Generic Syntax
RFC6585	Additional HTTP Status Codes

690

3.ZZ.4 Interaction Diagram

3.ZZ.4.1 Update DocumentReference Request Message

695 The File Source uses this message to update a DocumentReference resource already stored by the File Manager

3.ZZ.4.1.1 Trigger Events

The File Source needs to update one DocumentReference resource managed in the File Manager. Prior to sending the update, the File Source shall discover the resource ids related to the 700 DocumentReference resource and to the Binary resource already submitted.

3.ZZ.4.1.2 Message Semantics

The File Source shall issue an HTTP request according to requirements defined in FHIR specification for "update" transactions.

The File Source shall use an HTTP PUT method to submit to the File Manager a FHIR 705 DocumentReference resource. The FHIR DocumentReference resource conveys to the File Manager the update to the file's metadata.

This message shall convey one DocumentReference resource. The id of the DocumentReference resource shall be valued with the id of the DocumentReference resource to be updated.

710   The FHIR DocumentReference resource can be submitted to the File Manager in XML format or JSON format. Values admitted for media-type of the request message are defined in the ITI TF-2x: Appendix Z.6

Below is an example of the body for the DocumentReference update request:

715

720

725

730

```
{
            "resourceType": "DocumentReference",
            "id": "112345",
            "contained": [
                {
                    "resourceType": "Organization",
                    "id": "org1",
                    "identifier": [{
                        "system": "1.12.234.56",
                        "value": "IHE Facility"
                    }]
                }
            ],
            "status": "current",
            "type": {"coding": [{
                "system": "1.3.6.1.4.1.19376.1.5.3.1.5.1",
                "code": "eReferral workflow"
            }]},
            "class": {"coding": [{
                "system": "urn:ihe:iti:npfs:2017:class-codes",
                "code": "WORKFLOW_DEFINITION"
            }]},
            "created": "2017-04-17T10:30:00",
            "indexed": "2017-04-17T11:00:00",
            "author": [{"reference": "#org1"}],
            "content": [{
                "attachment": {
                    "contentType": "application/pdf",
                    "language": "en-US",
                    "url": "http://ihe-npfs.com/214",
                    "size": "3456",
                    "hash":
"07ae8b27c7596b3314601736f32d5f0ed17fc8c0e27a0475e8ea2d8b2c788436"
                },
                "format": [{"code": "application/pdf"}]
            }]
        }
```

3.ZZ.4.1.3 Expected Actions

The File Manager shall support all the media-type listed in ITI TF-2x: Appendix Z.6.

735   On receipt of the DocumentReference Update Request, the File Manager shall validate and update the resources and respond with one of the HTTP codes defined in Section 3.ZZ.4.2.2 Message Semantics.

3.ZZ.4.2 Update DocumentReference Response Message

The File Manager returns a HTTP Status code appropriate to the processing.

3.ZZ.4.2.1 Trigger Events

When the file it has been processed and updated by the File Manager, the File Manager sends this message to the File Source acknowledging the result of the submission

3.ZZ.4.2.2 Message Semantics

The response message shall conform to the transaction specification requirements as specified in http://hl7.org/fhir/STU3/http.html#transaction.

When the File Manager has successfully processed the PUT transaction, then the File Manager shall return an HTTP response with an overall status code.

If the operation is a success, the File Manager shall return the 200 - OK HTTP status code

If the operation is a failure, the File Manager shall return one of the following status codes:

- 400 – Bad Request: if the resource could not be parsed or failed basic FHIR validation rules

- 404 - Not Found: if the resource type is not supported.

3.ZZ.4.2.3 Expected Actions

The File Source processes the results according to application-defined rules.

3.ZZ.5 Security Considerations

This transaction does not define specific Security Considerations. See ITI TF-2x: Appendix Z.8.
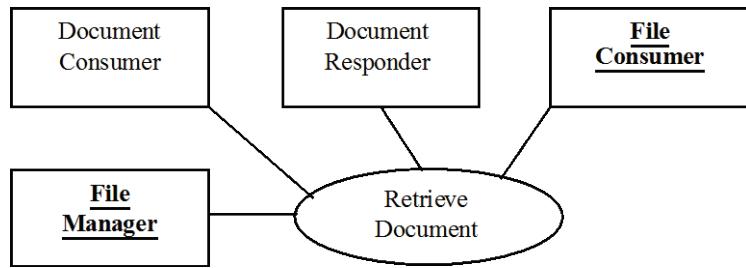
3.ZZ.5.1 Security Audit Considerations

This transaction does not require the actor involved to send audit messages to an Audit Record Repository because does not convey PHI. However the auditing of the submit operation is suggested in order to avoid malicious creation/updating of files of interest for the care of the patient. The structure of the Audit message generated shall comply with DICOM PS3.15 Annex A.5.3.5 Data Import.

Volume 2c – Transactions (cont.)

765 | *Editor: Update Volume 2c-Section 3.68.2 Use Case Roles to add File Manager and File Consumer to both text and diagram as shown.*

Note: Section 3.68.2 is currently in the MHD Trial Implementation Supplement

3.68.2 Use Case Roles

770

Actor: Document Consumer

Role: Requests a document from the Document Responder

Actor: Document Responder

775   **Role:** Serves the document to the Document Consumer

Actor: File Consumer
Role: Requests a file from the File Manager

For the purposes of this transaction, there is no behavioral distinction between a Document Consumer and File Consumer. The File Consumer will follow all requirements described
780   **for the Document Consumer.**

Actor: File Manager
Role: Serves the file to the File Consumer

For the purposes of this transaction, there is no behavioral distinction between a Document
785   **Responder and File Manager. The File Manager will follow all requirements described for the Document Responder.**