Integrating the Healthcare Enterprise

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IHE IT Infrastructure
Technical Framework Supplement

10

Non-patient File Sharing
(NPFSm)

HL7® FHIR® STU 3

Using Resources at FMM Level 3-5

15

Rev. 1.1 – Trial Implementation

Date: August 4, 2017

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Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework V14.0. Each supplement undergoes a process of public comment and trial implementation before being incorporated into the volumes of the Technical Frameworks.

This supplement is published on August 4, 2017 for trial implementation and may be available for testing at subsequent IHE Connectathons. The supplement may be amended based on the results of testing. Following successful testing it will be incorporated into the IT Infrastructure Technical Framework. Comments are invited and can be submitted at http://www.ihe.net/ITI_Public_Comments.

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:

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.

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 http://ihe.net/Technical_Frameworks.

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Introduction to this Supplement

Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE committee determines that an emerging standard offers significant benefits for the use cases it is attempting to address and has a high likelihood of industry adoption, it may develop IHE profiles and related specifications based on such a standard.

The IHE committee will take care to update and republish the IHE profile in question as the underlying standard evolves. Updates to the profile or its underlying standards may necessitate changes to product implementations and site deployments in order for them to remain interoperable and conformant with the profile in question.

This NPFSm Profile uses the emerging HL7[®1] FHIR[®2] specification. The FHIR release profiled in this supplement is STU 3. HL7 describes the STU (Standard for Trial Use) standardization state at https://www.hl7.org/fhir/versions.html.

In addition, HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through 5 (normative ballot ready). The FHIR Maturity Model is described at http://hl7.org/fhir/versions.html#maturity.

Key FHIR STU 3 content, such as Resources or ValueSets, used in this profile, and their FMM levels are:

FHIR Resource Name	FMM Level
DocumentReference	3
Bundle	5
OperationOutcome	5

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[1] HL7 is the registered trademark of Health Level Seven International.
[2] FHIR is the registered trademark of Health Level Seven International.

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

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. To fulfill use-cases requirements, this profile defines three new

160 transactions (Submit File transaction, Search File transaction and Update DocumentReference transaction) and re-uses an MHD transaction: Retrieve Document [ITI-68].

There are IHE Profiles that manage documents that are not patient-related; this profile does not require that the actors be able to process the contents of the files being shared. Understanding this profile does not require the knowledge of the files shared.

165 The NPFSm Profile specifies transactions for the sharing of files. Any file type can be shared using this profile; however, specific guidance is given for three types of files:

- Workflow Definitions: files which define the processing rules for a specific clinical/administrative workflow (see ITI TF-1: 30.4.1.1 "XDW Workflow Architecture" for additional information).

170 - Privacy Domain Policies: files which describe a specific privacy policy that applies to, or may be agreed 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 content of an XML document.

175 Local policies may extend the types of files shared using NPFSm and that can be classified using the metadata model described in this profile.

Open Issues and Questions

NPFSm_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

180 *this value set with other Document Sharing profiles? Suggestions are requested.*

NPFSm_012: This document does not require the use of profile tags to identify compliant resources. Use of profile tags will also allow the File Consumer to search just for resources that matches this profile in a FHIR Server that store different types of resources. Readers are required to provide feedback on this topic.

185

Closed Issues

NPFSm_001: This supplement does not define metadata elements identify or classify targets for the publication of the file (e.g., intended recipients or classes of recipients). Readers are asked to provide feedback on whether this is needed. Should the profile cover the requirements

190 *to identify targets with both identifiers and classes (e.g., This "document is intended for user 12345," or "this document is intended for GPs.")?*

- *We choose to not address this issue because the use of the context.related.ref could open the user to reference any type of resource also ones with patient information in it*

NPFSm_002: Confirm the scope, because as requests were received to cover other documents, in particular, public health report. We are going to draft three use-cases: Policy 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.*

NPFSm_003: What are the metadata that can be used to classify those files?

- *ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr15-2017-2018/Technical_Cmte/Workitems/Non-Patient%20Document%20Sharing%20(NPDS)/NPFS%20-%20Technical%20Needs.xlsx*

- *periodValidity metadata: Should it have mandatory start, but optional end elements?*

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

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

This use-case has not been addressed. Check OI NPFSm_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?*

The Update DocumentReference transaction has been added to fulfill this issue

NPFSm_004: How can I know if there is an updated version of the file or my file is deprecated?

- *Using a specific metadata, it is 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.*

NPFSm_005: FHIR STU3 doesn't support the "mime-type" search parameter for the DocumentReference Resource. 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.*

NPFSm_006: This version of NPFSm supplement define three new actors and three new transactions. Readers during PC period are asked to provide feedback on this topic. and transaction names needs to be changed?

No particular feedback received during PC, so the committee decided to maintain the names defined.

NPFSm_007: We will follow the FHIR approach, should we align this work-item with MHD? (Option in MHD…)

- *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 decrease the implementation effort on server side.*

230

NPFSm_008: Is the word "document" the right one? Should we speak about "Files"?

- *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 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.*

235

NPFSm_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.*

240

NPFSm_011: Which is the right standard to use?

- *For this profile, we had a standard selection process between several healthcare standards, such FHIR and infoButton, and non-healthcare standards such NPI storage and OData. The selection was made starting from which metadata shall be addressed by the standard and by IHE implementers efforts. The result of this selection was HL7 FHIR. See ftp://ftp.ihe.net/IT_Infrastructure/iheitiyr15-2017-2018/Technical_Cmte/Workitems/Non-Patient%20Document%20Sharing%20(NPDS)/NPFS%20-%20Technical%20Needs.xlsx.*

245

250 # 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:

255

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 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-88]	This transaction allows a File Source to publish a file and related metadata, or to update an existing file.
Search File [ITI-87]	This transaction allows a File Consumer to query for a file metadata that meets certain criteria
Update DocumentReference [ITI-89]	This transaction allows a File Source to update file metadata.

260 # Glossary

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

No new glossary terms.

Volume 1 – Profiles

265 **Copyright Licenses**

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

NA

Domain-specific additions

270 NA

Add Section 47

47 Non-Patient File Sharing (NPFSm) Profile

275   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 workflows.

The NPFSm Profile describes a mechanism for sharing non-patient files; it does not require that the actors be able to process the contents of the files being shared.

280   The NPFSm Profile specifies transactions for the sharing of files. Any file type can be shared using this profile; however, specific guidance is given for three types of files:

- Workflow Definitions: files which define the processing rules for a specific clinical/administrative workflow (see ITI TF-1: 30.4.1.1 "XDW Workflow Architecture")

285
- Privacy Domain Policies: files which describe a specific privacy policy that applies to, or may be agreed to, by a patient (see ITI TF-1: 19.2 "Creating Patient Privacy Policies")

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

Local policies may extend the types of files that are being shared using NPFSm and that can be classified using the metadata model described in this profile.

290   47.1 NPFSm Actors, Transactions, and Content Modules

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 47.1-1 shows the actors directly involved in NPFSm Profile and the relevant transactions
295   between them. If needed for context, other actors that may be indirectly involved due to their participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.
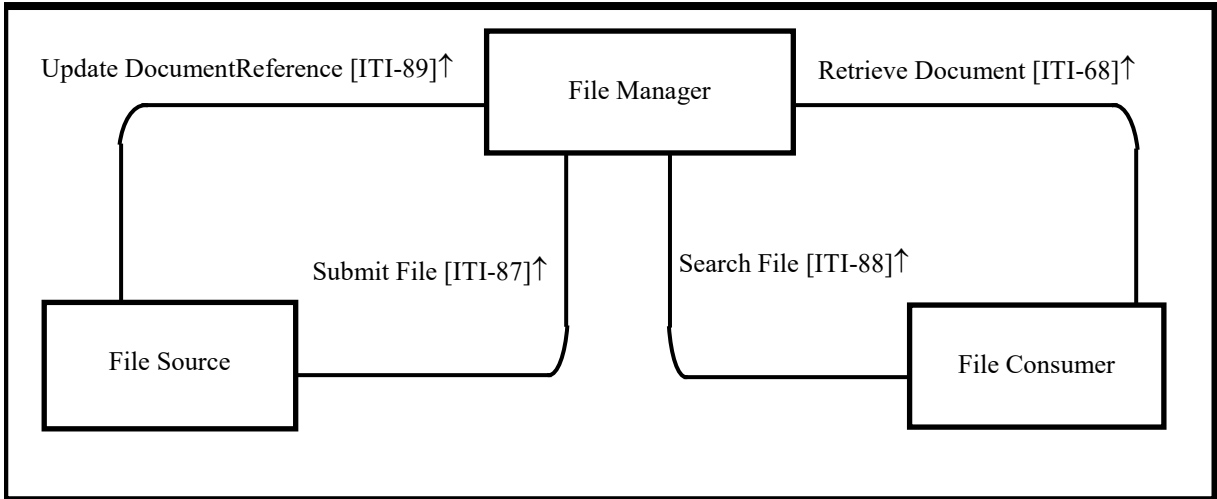
300

Figure 47.1-1: NPFSm Actor Diagram

Table 47.1-1 lists the transactions for each actor directly involved in the NPFSm 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 47.1-1: NPFSm Profile - Actors and transactions

Actors	Transactions	Optionality	Reference
File Manager	Submit File [ITI-87]	R	ITI TF-2c: 3.87
	Search File [ITI-88]	R	ITI TF-2c: 3.88
	Retrieve Document [ITI-68]	R	ITI TF-2c: 3.68 (Note)
	Update DocumentReference [ITI-89]	R	ITI TF-2c: 3.89
File Consumer	Search File [ITI-88]	R	ITI TF-2c: 3.88
	Retrieve Document [ITI-68]	O	ITI TF-2c: 3.68 (Note)
File Source	Submit File [ITI-87]	R	ITI TF-2c: 3.87
	Update DocumentReference [ITI-89]	O	ITI TF-2c: 3.89

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

47.1.1 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.

47.1.1.1 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.

47.1.1.2 File Consumer

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

47.1.1.3 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.

47.2 NPFSm Actor Options

Options that may be selected for each actor in this profile, if any, are listed in Table 47.2-1. Dependencies between options when applicable are specified in notes.

Table 47.2-1: Not-patient File Sharing - Actors and Options

Actor	Option Name	Reference
File Manager	No options defined	--
File Consumer	File Retrieve Option	Section 47.2.1
File Source	Update File Metadata Option	Section 47.2.2

47.2.1 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.

47.2.2 Update File Metadata Option

The Update File Metadata Option enables a File Source to update file's metadata stored/managed by the File Manager.

A File Source that supports the Update File Metadata Option shall support the Update DocumentReference [ITI-89] transaction.

47.3 NPFSm Required Actor Groupings

340   This profile does not mandate the grouping with other actors.

47.4 NPFSm Overview

47.4.1 Concepts

The NPFSm Profile uses the term "file" to mark a clear distinction from the IHE Document Sharing profiles.

345   A file represents a collection of information stored on a computer as one unit. For the purposes of this profile, a file is not patient-related, as it does not contain patient health identifying information. It may contain other sensitive information.

Other IHE profiles are used to share (using different sharing paradigms) information related to patients. In IHE terminology, such patient-specific content is a "document."

350   ### 47.4.2 Use Cases

47.4.2.1 Use Case #1: Stylesheet Management

A technician creates a stylesheet to render the XML of CDA[®3] Laboratory Reports produced in all the Laboratory Information System (LIS) involved in the Healthcare Information Exchange (HIE). The technician wants to make the stylesheet available to all the LIS involved in the HIE
355   so that they can search for the stylesheet and reference it as an XSL transformation of the Laboratory Report.

47.4.2.1.1 Stylesheet Management Use Case Description

A Healthcare Organization desires uniform rendering of XML Laboratory Reports produced within the organization, so it creates a stylesheet file. Mr. Black, a technician of the Healthcare
360   Organization, creates the stylesheet. Then Mr. Black uses his File Source to publish the stylesheet file into a system that manages non-patient files (File Manager) using the Submit File [ITI-87] transaction. Now the stylesheet will be available to all the LIS involved in the organization.

A Laboratory Information System, according to the HIE policy, should be able to identify the
365   stylesheet that can be used to render the CDA document.

Mrs. White uses the LIS to retrieve a CDA Lab Report from the HIE. The LIS also issues a query using the Search File [ITI-88] transaction, to search for a stylesheet published by the HIE Organization, in order to discover the resource URL of the stylesheet applicable to the Laboratory Reports. This URL is used to reference it as an XSL transformation of the CDA R2
370   Laboratory Reports produced.

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

47.4.2.1.2 Stylesheet's Management Process Flow

- The Health Information System acting as a File Source issues a Submit File [ITI-87] transaction to the File Manager to submit the stylesheet

- The LIS acting as a File Consumer issues a Search File [ITI-88] 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.
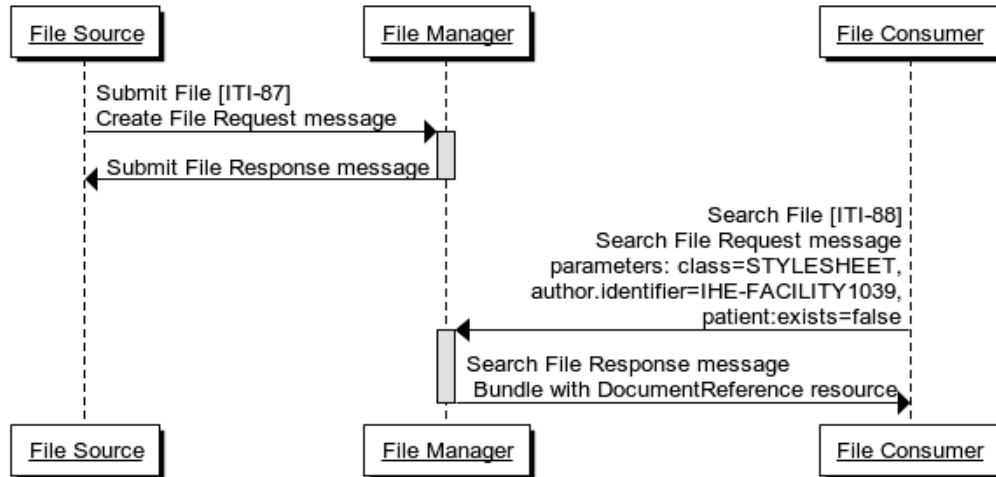
Figure 47.4.2.1.2-1: Basic Process Flow in NPFSm Profile for Stylesheets management

The text in Figure 47.4.2.1.2-2 was used to generate the diagram in Figure 47.4.2.1.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

File Source->+File Manager: Submit File [ITI-87]\nCreate File Request message

File Manager->-File Source: Submit File Response message

File Consumer->+File Manager: Search File [ITI-88]\nSearch File Request message\nparameters: class=STYLESHEET,\nauthor.identifier=IHE-FACILITY1039,\npatient:exists=false

File Manager->-File Consumer:Search File Response message\n Bundle with DocumentReference resource

---

Figure 47.4.2.1.2-2: Pseudocode for Process Flow Diagram

47.4.2.2 Use Case #2: Workflow Definitions submission and update

A technician at Goodcare Hospital uses the Hospital Information System to create and later update a BPMN ("Business Process Model and Notation;" see http://www.bpmn.org/ for further details) Workflow Definition file to design an eReferral Process. This file is published using a File Source. Later, a specialist, who does not regularly work with Goodcare Hospital can access this Workflow Definition to review the workflow steps before referring a patient.

47.4.2.2.1 Workflow Definitions submission and update Use Case Description

An HIE decides to design the eReferral Process for all the participants involved in that workflow. Mr. Smith, a technician at Goodcare Hospital, records the process in a BPMN Workflow Definition file, and makes it available using the Submit File [ITI-87] 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-88] transaction. The previously submitted Workflow Definition file is found and retrieved, and Dr. Jones can identify what next steps in the eReferral process will be.

Later the HIE decides that the Workflow Definition file submitted is no longer valid and should be replaced. Mr. Smith, according to the Goodcare Hospital replacement policy, issue a Submit File [ITI-87] (using a create interaction) to make the new BPMN Workflow Definition file available (linked to the previous version via a replacement association, using the `relatesTo` parameter). After that the File Consumer searches the previous version of the Workflow Definition that needs to be deprecated to discover the `id` of its metadata (FHIR resource id) and then, the File Source issue an Update DocumentReference [ITI-89], in order to sends the new metadata and to update the status of the previous file (from current to superseded).

47.4.2.2.2 Workflow Definitions Process Flow

- The Health Information System acting as a File Source issues a Submit File [ITI-87] transaction to the File Manager to submit the Workflow Definition file.

- The HIS acting as a File Consumer issues a Search File [ITI-88] 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. Once the resource is found, the HIS issues a Retrieve Document [ITI-68] transaction to the File Manager to retrieve it.

- The Health Information System acting as a File Source issues a Submit File [ITI-87] to the File Manager to make available the new Workflow Definition file.

- The Health Information System acting as a File Consumer issues a Search File [ITI-88] in order to discover the `id` of the file's metadata that need to be updated.

- The Health Information System acting as a File Source issues an Update DocumentReference [ITI-89] transaction to the File Manager to update the status of the previous Workflow Definition.

Figure 47.4.2.2.2-1: Basic Process Flow in NPFSm Profile for Workflow Definition Documents management

425

The text in Figure 47.4.2.2.2-2 was used to generate the diagram in Figure 47.4.2.2.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

File Source->+File Manager: Submit File [ITI-87]\nCreate File Request message

File Manager->-File Source: Submit File Response message

File Consumer->+File Manager: Search File [ITI-88]\nSearch File Request message\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:Search File Response message\n Bundle with DocumentReference resources

File Consumer->+File Manager: Retrieve Document [ITI-68]\nRetrieve Document Request message

File Manager->-File Consumer:Retrieve Document Response message

File Source->+File Manager: Submit File [ITI-87]\nCreate File Request message

File Manager->-File Source: Submit File Response message

```
File Consumer->+File Manager: Search File [ITI-88]\nSearch File Request message\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:Search File Response message\n Bundle with DocumentReference
resource

File Source->+File Manager: Update DocumentReference [ITI-89]\nUpdate DocumentReference
Request message\nmetadata:
DocumentReference.id=1234,\nDocumentReference.status=superceded

File Manager->-File Source: Update DocumentReference Response message
```

Figure 47.4.2.2.2-2: Pseudocode for Process Flow Diagram

47.4.2.3 Use Case #3: Privacy Policies

In this use case, the hospital's privacy office creates a file that describes the Privacy Policies that the patient can agree to. When a patient is admitted, the admitting nurse uses a File Consumer to search for the current Privacy Policy available. The nurse uses a Basic Patient Privacy Consent (BPPC) Content Creator (see ITI TF-1: 19) to create a consent document with the Privacy policy selected by the patient.

47.4.2.3.1 Privacy Policies Use Case Description

A hospital's privacy office defines a set of Privacy Policies that a patient can agree to. Mr. Blue, a hospital privacy office employee, creates the policy file using the HIS. Using a Submit File [ITI-87] transaction, the application makes it available to all the systems involved in his organization.

Mrs. Black, a nurse of the Goodcare Hospital, wants to search for the current valid BPPC Privacy Policy files that the admitting patient can agree to. She uses a combined BPPC Content Creator and NPFSm File Consumer to issue a query, a Search File [ITI-88] transaction, to search for the current valid Privacy Policy files. Once policies are found, she can retrieve them. The retrieved Privacy Policy files are used, by the Content Creator, in the creation of the consent document that the patient can read and agree to.

A legal health officer informs the Goodcare Hospital that one of the Privacy Policy files changed. Mr. Blue searches to discover the Privacy Policy and its related metadata (including FHIR resource ids), once they are found he uses an HIS to perform the Submit File [ITI-87] to update the targeted Privacy Policy and related metadata.

47.4.2.3.2 Privacy Domain Policies Process Flow

- The Health Information System, acting as a File Source, issues a Submit File [ITI-87] transaction to the File Manager to submit the Privacy Policy file.

- The EHR acting as a File Consumer, issues a Search File [ITI-88] transaction to the File Manager. The File Consumer uses the `class` parameter to search for Privacy Policy Documents and the `status` parameter to search for valid Privacy Policy files. Once the resource is found, the File Consumer issues a Retrieve Document [ITI-68] transaction to the File Manager to retrieve it.

460
- The HIS, acting as a File Source, issues a Submit File [ITI-87] transaction to the File Manager to update the existing Privacy Policy file and its related metadata.
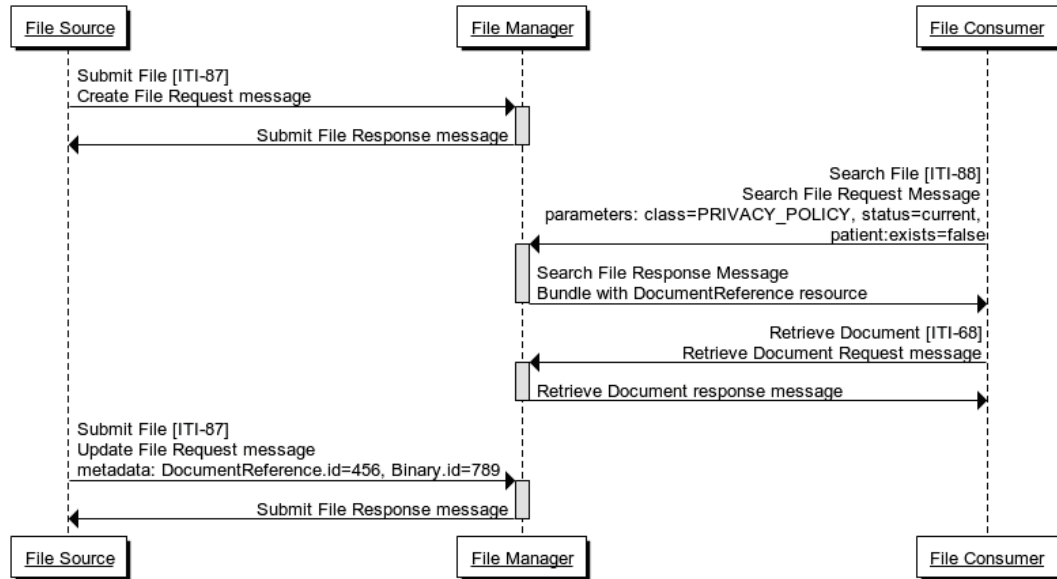
Figure 47.4.2.3.2-1: Basic Process Flow in NPFSm Profile for Privacy Policies management

465   The text in Figure 47.4.2.3.2-2 was used to generate the diagram in Figure 47.4.2.3.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

File Source->+File Manager: Submit File [ITI-87]\nCreate File Request message

File Manager->-File Source: Submit File Response message

File Consumer->+File Manager: Search File [ITI-88]\nSearch File Request Message\nparameters: class=PRIVACY_POLICY, status=current,\n patient:exists=false

File Manager->-File Consumer: Search File Response Message\nBundle with DocumentReference resource

File Consumer->+File Manager: Retrieve Document [ITI-68]\nRetrieve Document Request message

File Manager->-File Consumer: Retrieve Document response message

File Source->+File Manager: Submit File [ITI-87]\nUpdate File Request message\nmetadata: DocumentReference.id=456, Binary.id=789

File Manager->-File Source: Submit File Response message

Figure 47.4.2.3.2-1: Pseudocode for Process Flow Diagram

47.5 NPFSm Security Considerations

470 Non-patient files do not contain Patient Health Information (PHI), but they may contain other sensitive information such as physician reviews, work schedules, etc. However, those files can be used in conjunction with patient related documents in order to satisfy clinical data consuming/sharing workflows. The reader should know that mistakes will be made and these file may convey private information.

475 Although this profile does not require actors to audit the transactions that exchange non-patient files, grouping with an ATNA Secure Node or Secure Application is strongly encouraged in order to track file and metadata creation and update.

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

47.6 NPFSm Cross Profile Considerations

None.

Volume 2c – Transactions (cont.)

Add Section 3.87 – 3.89

3.87 Submit File [ITI-87]

3.87.1 Scope

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

This transaction uses the Create File Request message either when there is no prior file, or when the prior needs to be preserved.

This transaction uses the Update File Request 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 (see https://www.hl7.org/fhir/STU3/http.html#history).
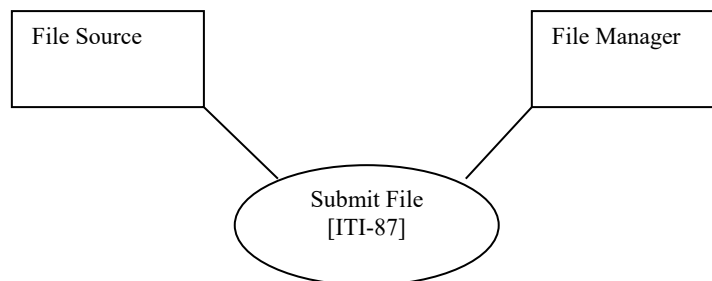
3.87.2 Actor Roles

Figure 3.87.2-1: Use Case Diagram

Table 3.87.2-1: Actor Roles

Actor:	File Source
Role:	Sends non-patient files and related metadata to a File Manager.
Actor:	File Manager
Role:	Stores received non-patient files and maintains related metadata

3.87.3 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

500

3.87.4 Interaction Diagram
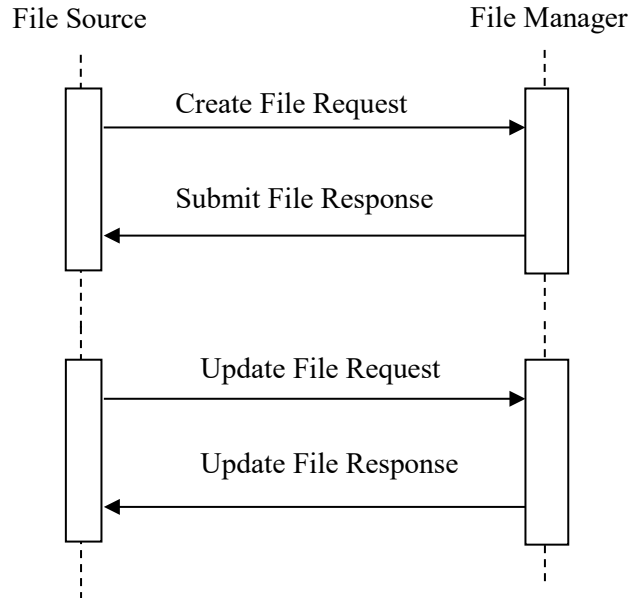
3.87.4.1 Create File Request Message

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

3.87.4.1.1 Trigger Events

This message is sent when the File Source needs to submit one or more new files to a File
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.

510   ### 3.87.4.1.2 Message Semantics

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

The File Source shall submit FHIR resources in either XML format or JSON format. Values for
515   media-type of the request message are defined in the ITI TF-2x: Appendix Z.6 (currently in the
Appendix Z on HL7 FHIR Trial Implementation Supplement).

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 Resource (https://www.hl7.org/fhir/STU3/documentreference.html) with
520 the file's metadata and may contain other resources that are referenced by the DocumentReference Resource.

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 3.87.4.1.2.1-1.

525 **3.87.4.1.2.1 DocumentReference constraints**

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

Table 3.87.4.1.2.1-1: Elements of the DocumentReference Resource

Element Name	Description	Constraints	OPT (note)
id	Logical identifier of the DocumentReference Resource	The id element shall be provided if the File source needs to update an existing file	C
masterIdentifier	MasterIdentifier of the file	See Section 3.87.4.1.2.1.5	O
status	File's status	For this transaction the value of this element shall be "current"	R
type	File's type	See Section 3.87.4.1.2.1.2	R
class	File's class (e.g., Workflow Definition, Stylesheet, Privacy Policy)	See Section 3.87.4.1.2.1.1	R+
subject	Contains Who or what the file is about		X
created	Time when the file was created		R2
indexed	Time when the file was submitted		R
author	Reference to the author of the submission	The author element shall be valued with at least 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 3.87.4.1.2.1.3	O
content.attachment.contentType	Mime-type of the file		R+
content.attachment.language	Language of the file		R2
content.attachement.data	Data inline base64ed		X
content.attachment.url	URL of the Binary Resource. The file can be retrieved at this location using the Retrieve Document [ITI-68] transaction		R+
content.attachment.size	File's size		R+

Element Name	Description	Constraints	OPT (note)
content.attachment.hash	File's hash		R+
content.format	File's format. The values of this metadata should be defined by local domain policies.		R+
context.sourcePatientInfo	Reference to a Patient Resource.		X
context.encounter	Reference an Encounter Resource		X
context.related	Reference a related resource or identifier		X

Note: See ITI TF-2x: Appendix Z.10 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement) for definitions of values in the OPT column.

530   See ITI TF-2x: Appendix W for informative implementation material for this transaction.

Sections below provide specific guidance about how handle metadata for the types of files submitted by this transaction. If other files types will be managed local policy should establish values for `type`, `class`, `format`, `mime-type` and `masterIdentifier` elements.

3.87.4.1.2.1.1 class element

535   Codes in the `class` element shall be from Table 3.87.4.1.2.1.1-1 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.

Table 3.87.4.1.2.1.1-1: 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 Definitions	`urn:ihe:iti:npfs:2017:class-codes`
57017-6	Code for Privacy Policies	`http://www.loinc.org`

3.87.4.1.2.1.2 type element

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

- If the file submitted is a Workflow Definition template, the `type` element could be valued with the workflow definition reference of the Workflow Definition profile (see `workflowDefinitionReference` as defined by the XDW Profile; see ITI TF-3: 5.4.2.2).

545   • If the file submitted is a Privacy Policy, the `type` element could be valued with the Patient Privacy Policy Identifier associated as defined by the BPPC Profile; see ITI TF-3: 5.1.2.1.1.2.

    • If the file submitted is a Stylesheet, the `type` element will be valued with a codeable concept defined by local policy that classifies the type of the stylesheet. The codeable
550   concept of the `type` element shall be defined by both a `code` and a `system` (e.g., code= "laboratory" system="http://localdomain.org/stylesheetstype").

3.87.4.1.2.1.3 File relationships

The `relatesTo` element holds relationships that the file has with other non-patient files. The `DocumentReference.relatesTo` element allows for the creation of those relationships (e.g.,
555 replacement, sign, etc.).

This transaction does not require the File Manager to manage the status of the related file's metadata. For example, a replaced file is not deprecated when creating a replacement relationship. If the file needs to be deprecated the File Source shall issue an Update DocumentReference [ITI-89] transaction to modify the status of the existing DocumentReference
560 Resource.

3.87.4.1.2.1.4 Create File request message example

An example of a Create File Request Bundle is presented below.

```
{
    "resourceType": "Bundle",
    "type": "transaction",
    "entry": [
        {
            "resource": {
                "resourceType": "DocumentReference",
                "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": "urn:uuid:9f146027-bbab-467e-b8f7-
5b695c4c6891"}],
                "content": [{
                    "attachment": {
                        "contentType": "application/pdf",
                        "language": "en-US",
                        "url": "urn:uuid:d3e62cb3-7be5-4971-a765-471669688f33",
                        "size": "3456",
                        "hash":
"07ae8b27c7596b3314601736f32d5f0ed17fc8c0e27a0475e8ea2d8b2c788436"
                    },
                    "format": [{"code": "application/pdf"}]
                }]
```

```
            },
            "request": {
                "method": "POST",
                "url": "http://ihe-npfs.com/DocumentReference"
            }
        },
        {
            "fullUrl": "urn:uuid:d3e62cb3-7be5-4971-a765-471669688f33",
            "resource": {
                "resourceType": "Binary",
                "contentType": "application/pdf",
                "content":
"PD94bWwgdmVyc2ldHRwOi8vd3d3LncKPC9DbGluaWNhbERvY3VtZW50Pgo=",
            },
            "request": {
                "method": "POST",
                "url": "http://ihe-npfs.com/Binary"
            }
        },
        {
            "fullUrl": "urn:uuid:9f146027-bbab-467e-b8f7-5b695c4c6891",
            "resource": {
                "resourceType": "Organization",
                "identifier": [{
                    "system": "1.12.234.56",
                    "value": "IHE FACILITY1039"
                }]
            },
            "request": {
                "method": "POST",
                "url": "http://ihe-npfs.com/Organization"
            }
        }
    ]
}
```

Figure 47.4.2.1.2-1: Create File Request example

3.87.4.1.2.1.5 MasterIdentifier element

565 This section identifies specific requirements for the `masterIdentifier` element, if used:

- If the file submitted is a Workflow Definition template, the `masterIdentifier` element shall be valued with the workflow definition reference of the Workflow Definition profile (see `workflowDefinitionReference` as defined by the XDW Profile; see ITI TF-3: 5.4.2.2).

570 - If the file submitted is a Privacy Policy, the `masterIdentifier` element shall be valued with the Patient Privacy Policy Identifier associated as defined by the BPPC Profile; see ITI TF-3: 5.1.2.1.1.2.

Local policies should define how to handle this parameter in case of file's revision, update or replacement.

3.87.4.1.3 Expected Actions

The File Manager shall support all the media-types defined in ITI TF-2x: Appendix Z.6 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

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 3.87.4.3.2 Message Semantics.

The File Manager shall process the Bundle atomically.

The File Manager shall support Create File Request messages that contain one Binary Resource and one DocumentReference Resource. The File Manager shall store these resources and make them available for further search [ITI-88] and retrieve [ITI-68].

If the File Manager receives a Create File Request message that contains resources other than the required ones may respond to the File Consumer with a failure (see Section 3.87.4.3.2).

3.87.4.2 Update File Request Message

The File Source uses this message to update the Binary and the DocumentReference Resources already stored by the File Manager.

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.)

3.87.4.2.1 Trigger Events

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

3.87.4.2.2 Message Semantics

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

The message uses an overall HTTP POST to submit a FHIR Bundle that contains the updated Binary and DocumentReference Resources and for each resource, the bundle.entry.request.method shall be valued with the HTTP PUT Method.

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 Resource (https://www.hl7.org/fhir/STU3/documentreference.html) with the updated set of metadata.

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 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

This message defines constraints for the structure of the DocumentReference Resources exchanged. These constraints are defined in Section 3.87.4.1.2.1.

In addition, for each `entry.resource`, the `bundle.entry.fullUrl` element shall be set to the target URL used to retrieve the resource being updated.

3.87.4.2.3 Expected Actions

The File Manager shall support all the media-type defined in ITI TF-2x: Appendix Z.6 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

On receipt of the Update File Request, the File Manager shall respond with one of the HTTP codes defined in Section 3.87.4.2.3.2 Message Semantics.

The File Manager shall process the Bundle atomically.

The updated file will be no longer accessible and the new version of the file will be retrieved using the same `bundle.entry.fullUrl` of the previous version of the file.

The File Manager shall support Update File Request messages that contain one Binary Resource and one DocumentReference Resource. The File Manager shall store these resources and make them available for further search [ITI-88] and retrieve [ITI-68].

3.87.4.3 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.

3.87.4.3.1 Trigger Events

When the File Manager has finished creating or updating the file and metadata received from the File Source, the File Manager sends this message to the File Source acknowledging the result of the create or update request.

3.87.4.3.2 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-response.

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

To allow the File Source to know the outcome 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 as received, with the outcome of processing the entry. Each entry element shall contain a response element with an HTTP Status Code which details the outcome of processing of the request entry.

If the outcome is a success, the http status code of the response shall be a 2xx code.

If the outcome is a failure, the File Manager shall be capable of returning the following status codes:

- 422 - Unprocessable Entity:

    - When the FHIR Resource `documentReference.type` is not supported by the File Manager.

    - If the Bundle Resource contains resources other than Binary, DocumentReference Resources and the resources referenced by the Document Reference Resource.

650

The File Manager can return other status codes 4xx or 5xx in accordance to internal business rules that are out of scope for this transaction.

Below is an example of the Submit File response:

```
{
  "resourceType":"Bundle",
  "type":"transaction-response",
  "entry":[
    {
      "response":
        {
          "status":"201"
          "location":"http://www.ihe.org/DocumentReference/453"
          "etag":"npfs-docRef"
        }
    },
    {
      "response":
        {
          "status":"201"
          "location":"http://www.ihe.org/Binary/123"
          "etag":"npfs-binary"
        }
    },
    {
      "response":
        {
          "status":"201"
          "location":"http://www.ihe.org/Organization/789"
          "etag":"npfs-organization"
        }
    }
  ]
}
```

655

3.87.4.3.3 Expected Actions

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

3.87.5 Security Considerations

Actors involved in this transaction should be aware that even if the files exchanged does not
660 contain PHI or other private information, action such revision, update and replace of those files

could compromise patient care or have other legal ramification. For general security
considerations, see ITI TF-2x: Appendix Z.8 (currently in the Appendix Z on HL7 FHIR Trial
Implementation Supplement).

3.87.5.1 Security Audit Considerations

665 This transaction does not require the actors involved to send audit messages to an Audit Record
Repository because it does not convey PHI. However, the auditing of the Submit File transaction
is suggested in order to avoid malicious creation/updating of files of interest for the care of the
patient. The audit message for the Submit File transaction shall comply with the structure
defined in DICOM[4] PS3.15 Annex A.5.1.

670 # 3.88 Search File [ITI-88]

3.88.1 Scope

The transaction is used by the File Consumer to find DocumentReference Resources that are
stored and managed by a File Manager. Those DocumentReference Resources are not associated
with a Patient Resource.

675 ## 3.88.2 Actor Roles
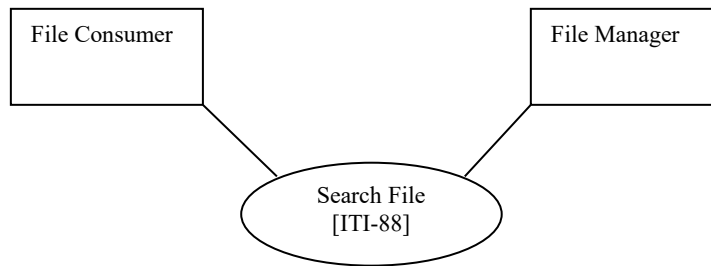
Figure 3.88.2-1: Use Case Diagram

Table 3.88.2-1: Actor Roles

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

---

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

3.88.3 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

680 ### 3.88.4 Interaction Diagram
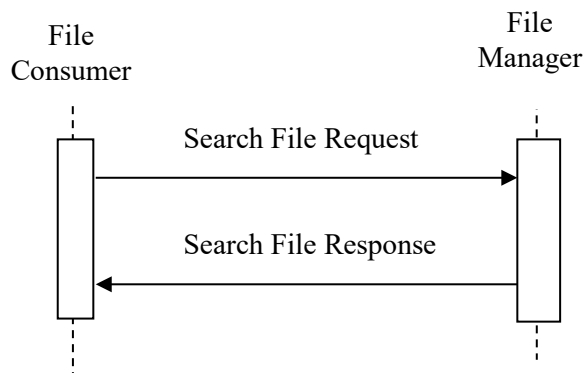
3.88.4.1 Search File Request Message

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
685 parameters.

3.88.4.1.1 Trigger Events

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

3.88.4.1.2 Message Semantics

690 The File Consumer executes an HTTP GET against the File Manager. This request shall comply with requirements specified in the FHIR specification http://hl7.org/fhir/STU3/http.html#search.

The search target URL follows the FHIR HTTP specification, addressing the DocumentReference Resource http://hl7.org/fhir/STU3/http.html:

        [base]/DocumentReference?[Parameters]

695 The [Parameters] element represents a series of encoded name-value pairs representing the filter for the query, as specified in Section 3.88.4.1.2.1, as well as control parameters to modify the behavior of the Document Responder such as response format, or pagination.

3.88.4.1.2.1 Query Search Parameters

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

- **patient**

This parameter shall always be used in this transaction 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).

705 The File Consumer shall not use the query parameter **subject** with a reference to a Patient Resource.

- **created**

This parameter, of type `date`, specifies the time when the file to which the DocumentReference refers was created. The File Consumer shall use the date and interval mechanism described in 710 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.

- **indexed**

This parameter, of type `date`, specifies the time when the file, to which the DocumentReference refers, was submitted. The File Consumer shall use the date and interval mechanism described in 715 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.

- **author.identifier**

This parameter, of type `token`, specifies the identifier of the organization that has submitted the file. See ITI TF-2x: Appendix Z.2.2 (currently in the Appendix Z on HL7 FHIR Trial 720 Implementation Supplement) 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 Z.2.2 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement) for use of the `token` data type.

725 - **language**

This parameter, of type `token`, specifies the language of the file. See ITI TF-2x: Appendix Z.2.2 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement) for use of the `token` data type.

- **location**

730 This parameter, of type `uri`, specifies the URI where the file can be found.

- **status**

This parameter, of type `token`, specifies the status of the file. See ITI TF-2x: Appendix Z.2.2 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement) for use of the `token` data type.

735
- **relatesTo**

This parameter, of type `reference`, specifies one or more existing DocumentReference Resources that have been replaced by the submitted DocumentReference Resource.

- **relation**

740
This parameter, of type `token`, specifies the type of relation that the file being searched has with the targeted file specified in the relatesTo parameter, see http://hl7.org/fhir/STU3/valueset-document-relationship-type.html for the type of relation allowed. See ITI TF-2x: Appendix Z.2.2 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement) for use of the `token` data type.

- **relationship**

745
This parameter, of type `composite`, is the combination of the relatesTo and relation search parameter.

- **identifier**

This parameter, of type `token`, allows the File Consumer to search on the logical identifier of the file.

750
3.88.4.1.2.2 Populating Expected Response Format

See ITI TF-2x: Appendix Z.6 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement) for details.

3.88.4.1.3 Expected Actions

The File Manager shall process the query to discover only DocumentReference Resources that
755
are not associated to any patient and that match the search parameters. The File Manager shall send a Search File Response message containing matching results.

The File Manager may return back resources that are not constrained as specified in Table 3.87.4.1.2.1-1.

3.88.4.2 Search File Response Message

760
The File Manager returns a HTTP Status code appropriate to the processing as well as a list of the matching DocumentReference Resources

3.88.4.2.1 Trigger Events

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

3.88.4.2.2 Message Semantics

765   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 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

When the File Manager needs to report an error, it shall use HTTP error response codes and
770   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
775   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 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

3.88.4.2.3 Expected Actions

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

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

3.88.5 Security Considerations

Actors involved in this transaction should be aware that even if the files exchanged do not
785   contain PHI or other private information, action such revision, update and replace of those files could compromise patient care or have other legal ramification. For general security considerations, see ITI TF-2x: Appendix Z.8 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

3.88.5.1 Security Audit Considerations

790   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 files. The audit message for the Search File transaction shall comply with the structure defined in DICOM PS3.15 Annex A.5.1

3.89 Update DocumentReference [ITI-89]

795   ### 3.89.1 Scope

This transaction allows a File Source to update a DocumentReference Resource already submitted. The File Manager is not required to support FHIR resource versioning (see https://www.hl7.org/fhir/STU3/http.html#history).
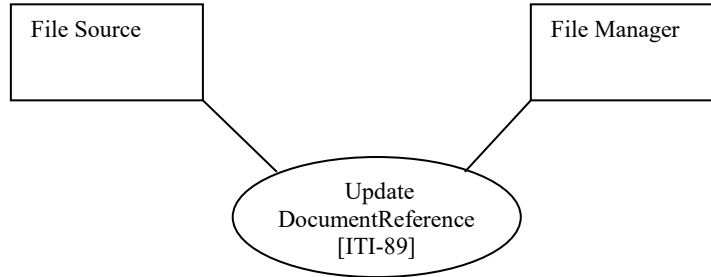
3.89.2 Actor Roles

800

**Figure 3.89.2-1: Use Case Diagram**

Table 3.89.2-1: 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.

805 ## 3.89.3 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

3.89.4 Interaction Diagram
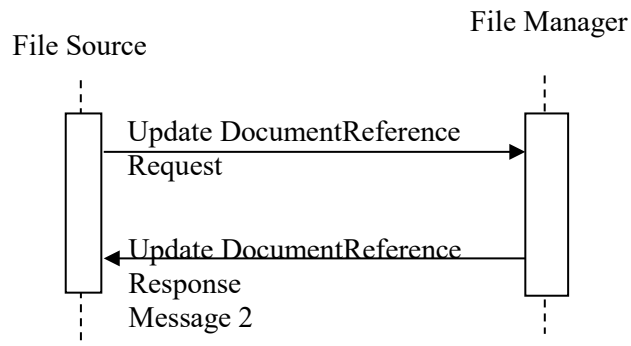
3.89.4.1 Update DocumentReference Request Message

The File Source uses this message to update just a DocumentReference Resource already stored by the File Manager

3.89.4.1.1 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 id related to the DocumentReference Resource already submitted.

3.89.4.1.2 Message Semantics

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

The File Source shall use an HTTP PUT method to submit to the File Manager a FHIR 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; see Section 3.87.4.1.2 for other constraints upon the DocumentReference Resource.

The FHIR DocumentReference Resource can be submitted to the File Manager in XML format or JSON format. Values accepted for media-type of the request message are defined in the ITI TF-2x: Appendix Z.6 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

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

```
{
            "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"}]
            }]
        }
```

3.89.4.1.3 Expected Actions

The File Manager shall support all the media-type listed in ITI TF-2x: Appendix Z.6 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

835   On receipt of the DocumentReference Update Request, the File Manager shall validate and update the resource and respond with one of the HTTP codes defined in Section 3.89.4.2.2 Message Semantics.

3.89.4.2 Update DocumentReference Response Message

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

3.89.4.2.1 Trigger Events

When the DocumentReference 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

3.89.4.2.2 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.

3.89.4.2.3 Expected Actions

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

3.89.5 Security Considerations

Actors involved in this transaction should be aware that even if the files exchanged do not contain PHI or other private information, action such revision, update and replace of those files could compromise patient care or have other legal ramification. For general security considerations, see ITI TF-2x: Appendix Z.8 (currently in the Appendix Z on HL7 FHIR Trial Implementation Supplement).

3.89.5.1 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 audit message for the Update DocumentReference transaction shall comply with the structure defined in DICOM PS3.15 Annex A.5.1
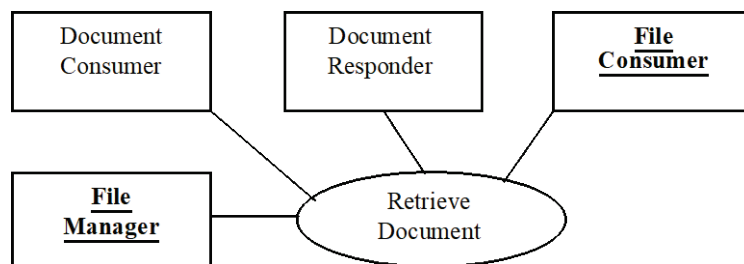
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Editor: Update Volume 2c-Section 3.68.2 Use Case Roles to add File Manager and File Consumer to both text and diagram as shown.

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

3.68.2 Use Case Roles

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Actor: Document Consumer

Role: Requests a document from the Document Responder

Actor: Document Responder

Role: Serves the document to the Document Consumer

880 **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 shall follow all requirements described for the Document Consumer.**

885 **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 Responder and File Manager. The File Manager shall follow all requirements described for the Document Responder.**