Integrating the Healthcare Enterprise

IHE IT Infrastructure Technical Framework Supplement

Non-patient File Sharing (NPFS)

HL7® FHIR® R4

Using Resources at FMM Level 3 and Normative

Rev. 2.1 – Trial Implementation

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Please verify you have the most recent version of this document. See here for Trial Implementation and Final Text versions and here for Public Comment versions.

Foreword

This is a supplement to the IHE IT Infrastructure Technical Framework V16.0. 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 December 5, 2019 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 may 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.

CONTENTS

Introduction to this Supplement

Whenever possible, IHE profiles are based on established and stable underlying standards. However, if an IHE domain determines that an emerging standard has high likelihood of industry adoption, and the standard offers significant benefits for the use cases it is attempting to address, the domain may develop IHE profiles based on such a standard. During Trial Implementation, the IHE domain will update and republish the IHE profile as the underlying standard evolves.

Product implementations and site deployments may need to be updated in order for them to remain interoperable and conformant with an updated IHE profile.

This NPFS Profile is based on Release 4 of the emerging HL7®[1] FHIR®[2] standard. HL7 describes FHIR Change Management and Versioning at https://www.hl7.org/fhir/versions.html.

HL7 provides a rating of the maturity of FHIR content based on the FHIR Maturity Model (FMM): level 0 (draft) through N (Normative). See http://hl7.org/fhir/versions.html#maturity.

The FMM levels for FHIR content used in this profile are:

FHIR Resource Name	FMM Level
DocumentReference	3
Bundle	N
Binary	N
OperationOutcome	N

This profile 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 profile identifies three actors: File Manager, File Consumer, and File Source. To fulfill use-case requirements, this profile defines three new transactions (Submit File [ITI-87], Search File [ITI-88], and Update DocumentReference [ITI-89]) and re-uses an MHD transaction: Retrieve Document [ITI-68].

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

There are IHE profiles that define the content of files 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.

The NPFS 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).
- 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.

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

Open Issues and Questions

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

NPFS_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.

Closed Issues

NPFS_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 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*

NPFS_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.*

NPFS_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 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?*

The Update DocumentReference transaction has been added to fulfill this issue

NPFS_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.*

NPFS_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.*

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. and transaction names needs to be changed?

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

NPFS_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.*

NPFS_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.

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.*

NPFS_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.*

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:

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-87]	This transaction allows a File Source to publish a file and related metadata, or to update or replace an existing file.
Search File [ITI-88]	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.

Glossary

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

No new glossary terms.

Volume 1 – Profiles

Copyright Licenses

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

NA

Domain-specific additions

NA

Add Section 47

47 Non-Patient File Sharing (NPFS) Profile

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 NPFS 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.

The NPFS 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")
- 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 NPFS and that can be classified using the metadata model described in this profile.

47.1 NPFS 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 https://www.ihe.net/resources/technical_frameworks/#GenIntro.

Figure 47.1-1 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 participation in other related profiles are shown in dotted lines. Actors which have a mandatory grouping are shown in conjoined boxes.

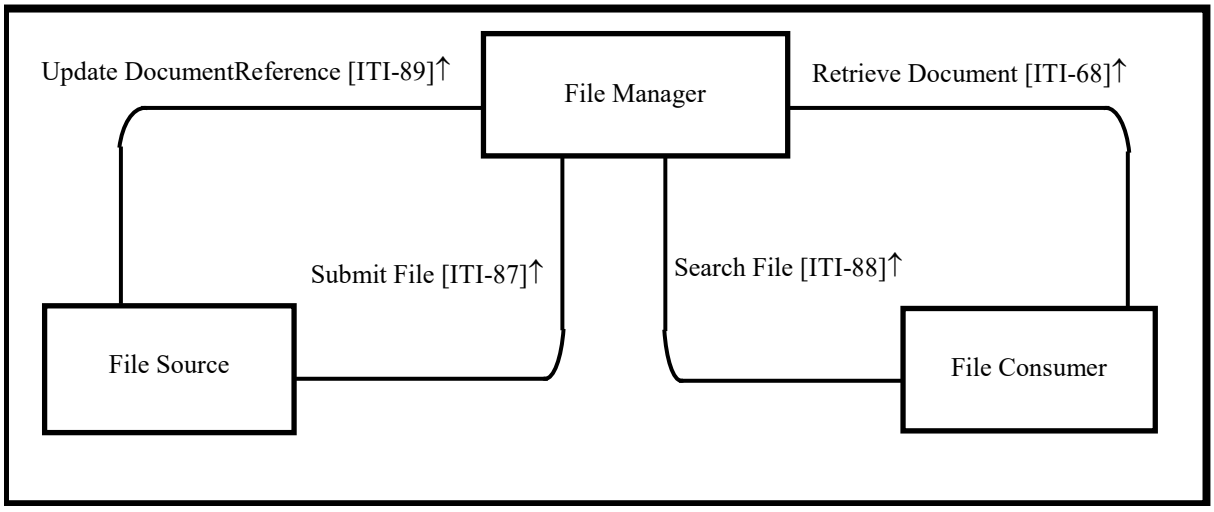


Figure 47.1-1: NPFS Actor Diagram

Table 47.1-1 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 47.1-1: NPFS 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

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 NPFS 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	Section 47.2.1
File Source	Update File Metadata	Section 47.2.2

47.2.1 File Retrieve Option

The File Retrieve Option enables a File Consumer to retrieve a 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 the metadata of a file 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 NPFS Required Actor Groupings

This profile does not mandate the grouping with other actors.

47.4 NPFS Overview

47.4.1 Concepts – distinguishing files from documents

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

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**."

47.4.2 Use Cases

47.4.2.1 Use Case #1: Manage Stylesheets

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 LISs involved in the HIE so that they can search for the stylesheet and reference it as an XSL transformation of the Laboratory Report.

47.4.2.1.1 Manage Stylesheets - Use Case Description

A Healthcare Organization desires to use a stylesheet for uniform rendering of XML Laboratory Reports produced within the organization. Mr. Black, a technician of the Healthcare 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 LISs involved in the organization.

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 patient's CDA R2 Lab Report document from the HIE. The LIS also issues a query using the Search File [ITI-88] transaction, to search for a stylesheet file 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 Laboratory Report.

[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, that will be retrieved using a Retrieve Document [ITI-68] transaction.

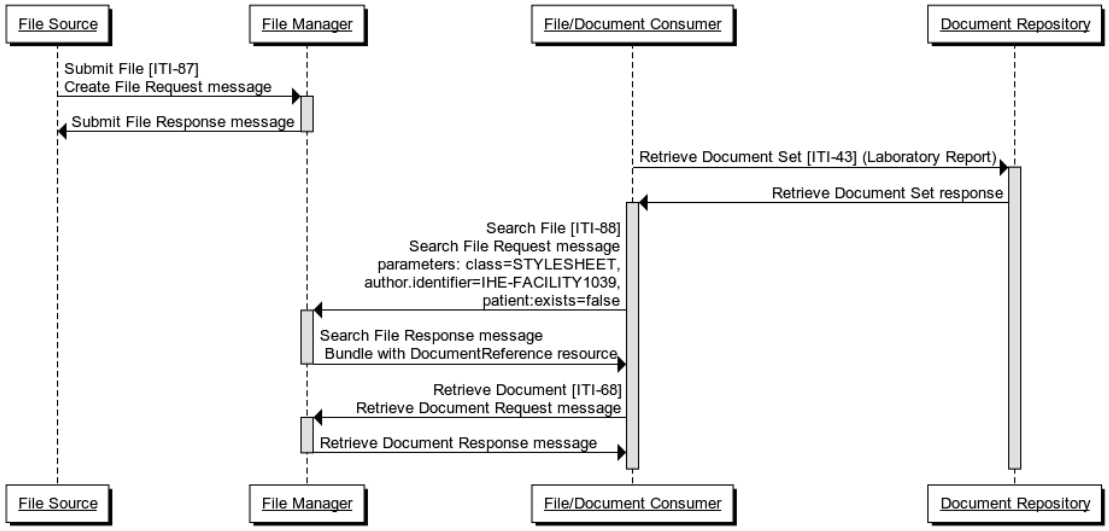


Figure 47.4.2.1.2-1: Basic Process Flow in NPFS Profile for Stylesheets management

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/Document Consumer->+Document Repository: Retrieve Document Set [ITI-43] (Laboratory Report)

Document Repository->+File/Document Consumer: Retrieve Document Set response

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

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

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

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

Figure 47.4.2.1.2-2: Pseudocode for Process Flow Diagram

47.4.2.2 Use Case #2: Replace Privacy Policies

In this use case, the hospital's privacy office creates files that describe the Privacy Policies that the patient can agree to. When a patient is admitted, the admitting nurse uses a NPFS File Consumer to search the File Manager for the current Privacy Policy files available.

Then, when the patient selects a Privacy Policy, the nurse uses a Basic Patient Privacy Consent (BPPC) Content Creator Actor (see ITI TF-1: 19) to create the patient's Privacy Policy Consent document for the patient.

47.4.2.2.1 Replace 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 a Privacy Policy file using the HIS. Using a Submit File [ITI-87] transaction, the application makes the file available to all the systems involved in his organization.

Mrs. Black, a nurse of the Goodcare Hospital, wants to search for the current valid Privacy Policy files that the admitting patient can agree to. She uses a combined BPPC Content Creator and NPFS File Consumer to issue a query, a Search File [ITI-88] transaction, to search for the current valid Privacy Policy files and retrieve them. One of the retrieved Privacy Policy files is used, by the BPPC Content Creator, to create the Privacy Policy Consent document that the patient can read and agree to.

Later, a legal health officer informs the Goodcare Hospital that one of the Privacy Policies has changed. Mr. Blue searches to discover the Privacy Policy file and its related metadata (including FHIR resource ids). He thus needs to replace the Privacy Policy file and uses an HIS to perform the Submit File [ITI-87] to replace the Privacy Policy by submitting a new one (linked to the original file via a replacement association, using the `relatesTo` parameter) and updating metadata for the previous Privacy Policy, changing its status to "superseded".

This use case is different than Use Case #3 because here the original Privacy Policy file needs to be preserved (i.e., it is not overwritten).

47.4.2.2.2 Privacy Domain Policies Process Flow

- The Health Information System, acting as a File Source, issues a Submit File [ITI-87] (create) transaction to the File Manager to submit the original Privacy Policy file and metadata.
- The HIS, acting as a File Consumer, issues a Search File [ITI-88] transaction to the File Manager. The File Consumer uses the `class` parameter and the `status` parameter to search for the metadata (i.e., DocumentReference Resources) for current Privacy Policy files. Once the DocumentReference Resource is found, the File Consumer issues a Retrieve Document [ITI-68] transaction to the File Manager to retrieve the file.
- The HIS, acting as a File Source, issues a Submit File [ITI-87] (replace) transaction to the File Manager to submit the new Privacy Policy file and metadata, and update the metadata of the replaced file to "superseded" (deprecated). (The new DocumentReference Resource is linked to the previous one via a replacement relationship, using the `relatesTo` parameter; see ITI TF-2c: 3.87.4.3.2.)

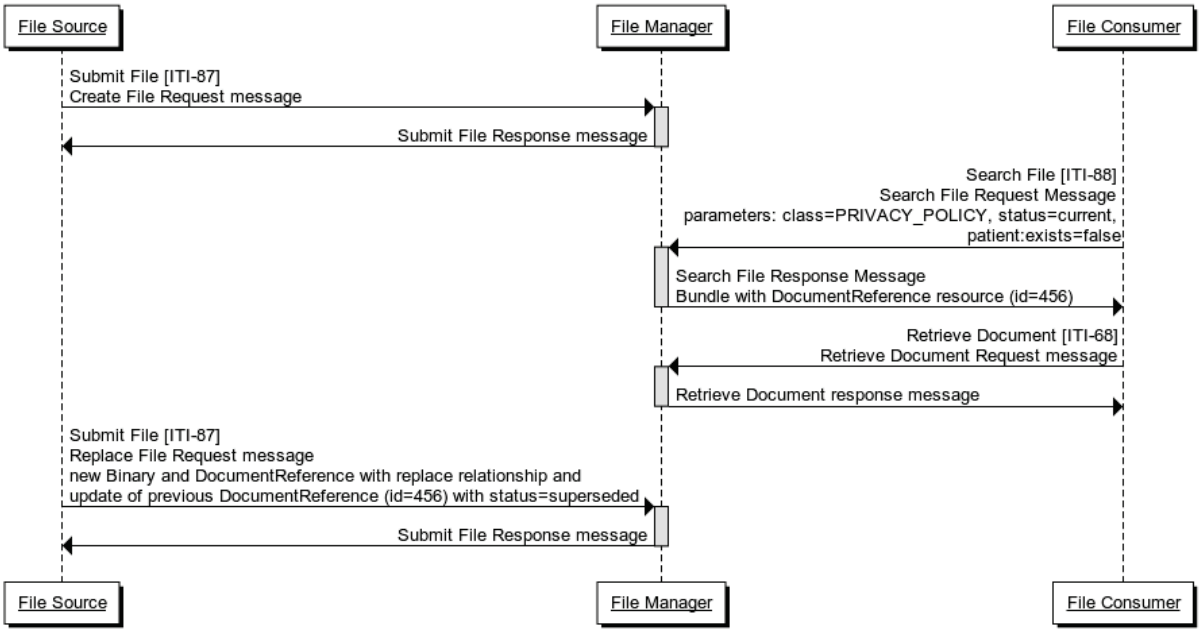


Figure 47.4.2.2.2-1: Basic Process Flow in NPFS Profile for Privacy Policies management

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=PRIVACY_POLICY, status=current,\n patient:exists=false
File Manager->-File Consumer: Search File Response Message\nBundle with DocumentReference resource (id=456)
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]\nReplace File Request message\nnew Binary and DocumentReference with replace association and\nupdate of previous DocumentReference (id=456) with status=superseded
File Manager->-File Source: Submit File Response message
```

Figure 47.4.2.2.2-1: Pseudocode for Process Flow Diagram

47.4.2.3 Use Case #3: Manage change to Workflow Definitions

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/) 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.

47.4.2.3.1 Manage change to Workflow Definitions - 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 the next steps in the eReferral process.

Later the HIE decides that the Workflow Definition file submitted is no longer valid and wants to use a new Workflow Definition file, so it updates the previous file using the Submit File [ITI-87] transaction.

This use case is different than Use Case #2 because here the original Workflow Definition file does not need to be preserved so it is, in effect, overwritten.

47.4.2.3.2 Workflow Definitions Process Flow

- The Health Information System acting as a File Source issues a Submit File [ITI-87] (create) transaction to the File Manager to submit the original Workflow Definition file.
- Later, to find the Workflow Definition in order to update it, the HIS acting as a File Consumer issues a Search File [ITI-88] transaction to the File Manage. The File

Consumer uses the `class` parameter and the `type` parameter to search for Workflow Definitions related to eReferral workflow. Once the Document Reference 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] (update) to the File Manager to make available the newer Workflow Definition file and metadata (updating the previous resources on the File Manager).

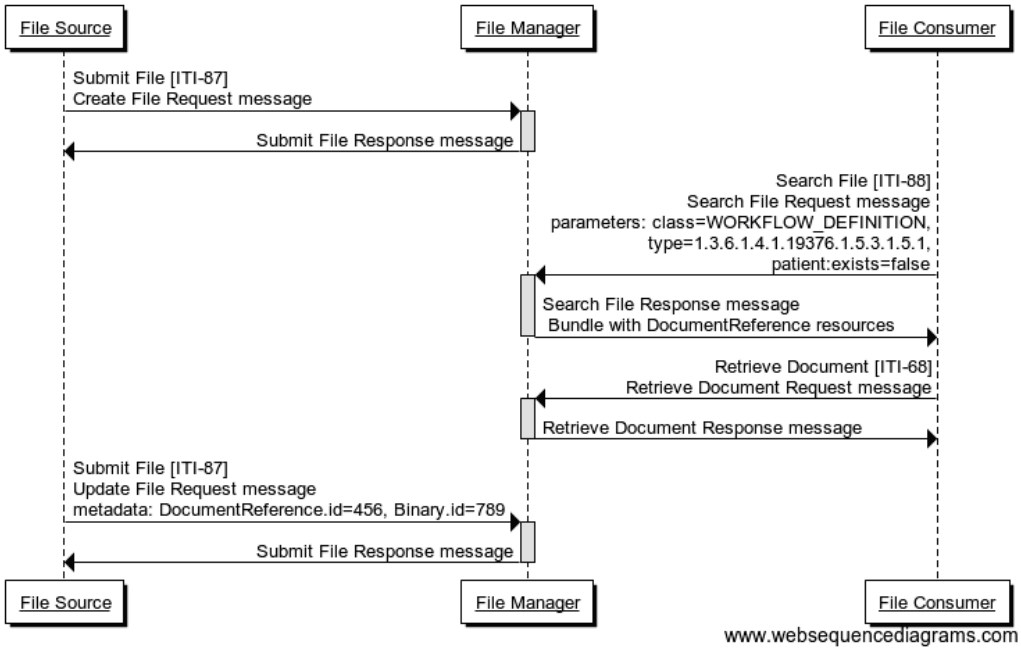


Figure 47.4.2.3.2-1: Basic Process Flow in NPFS Profile for Workflow Definition Documents management

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=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]\nUpdate File Request message\nmetadata: DocumentReference.id=456, Binary.id=789

File Manager->-File Source: Submit File Response messageFile 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=superseded

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

Figure 47.4.2.3.2-2: Pseudocode for Process Flow Diagram

47.4.2.4 Use Case #4: Update of file's ownership

A technician creates a stylesheet to render the XML documents produced by document producers belonging to Hospital Hope. After some time, the same stylesheet also needs to be made accessible to Hospital Peace. In order to accomplish this task, the technician updates metadata that describe the file in order to extend the ownership also to Hospital Peace.

47.4.2.4.1 Update of file's ownership - Use Case Description

Hospital Hope desires uniform rendering of XML documents produced within the organization, so it creates a stylesheet file. Mr. Black, a technician of the Hospital Hope, 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 document producers belonging to Hospital Hope. According to the local policies, the technician needs to extend the ownership of this file also to Hospital Peace. In order to do that, Mr. Black executes an update of the DocumentReference associated with the stylesheet using the Update DocumentReference [ITI-89] transaction. Now the stylesheet's DocumentReference reflects the ownership of Hospital Hope and Hospital Peace.

47.4.2.4.2 Update of file's ownership Process Flow

- The Health Information System acting as a File Source issues a Submit File [ITI-87] (create) transaction to the File Manager to submit the stylesheet
- The Health Information System acting as a File Source issues an Update DocumentReference [ITI-89] transaction to the File Manager to modify the `DocumentReference.author` list.

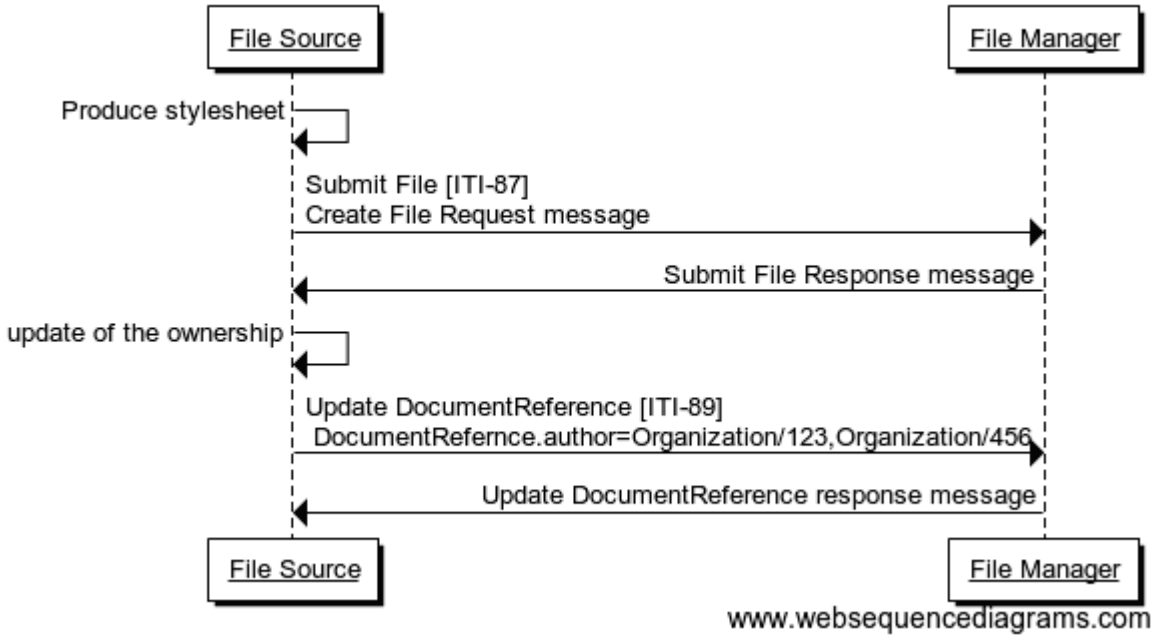


Figure 47.4.2.4.2-1: Basic Process Flow in NPFS Profile for Update of file's ownership

The text in Figure 47.4.2.4.2-2 was used to generate the diagram in Figure 47.4.2.4.2-1. Readers will generally find the diagram more informative. The text is included here to facilitate editing.

```
File Source->File Source: Produce stylesheet
File Source->File Manager: Submit File [ITI-87]\nCreate File Request message
File Manager->File Source: Submit File Response message
File Source->File Source: update of the ownership
File Source->File Manager: Update DocumentReference [ITI-89]\n
DocumentRefernce.author=Organization/123,Organization/456
File Manager->File Source: Update DocumentReference response message
```


47.5 NPFS Security Considerations

Non-patient files do not contain Patient Health Information (PHI), but they may contain other sensitive information such as physician reviews, work schedules, etc. In addition, 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 files may convey private information.

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 NPFS actors with actors in the Internet User Authorization (IUA) Profile enables deployments to mitigate these security issues.

47.6 NPFS 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 a new file and related metadata. It also enables update of an existing file and update its metadata and replacement of a file.

The files are not associated with a patient.

3.87.2 Actor Roles

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 R4 http://hl7.org/fhir/R4/index.html

3.87.4 Messages

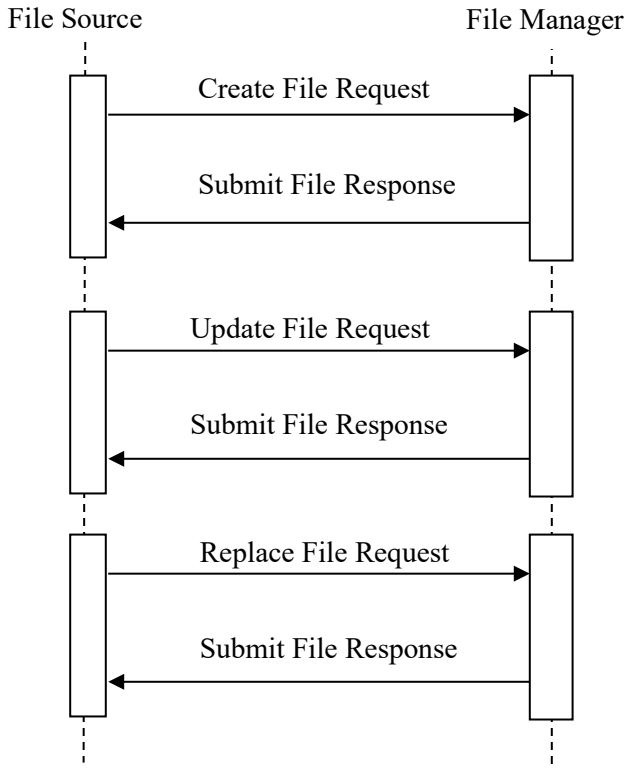


Figure 3.87.4-1: Interaction Diagram

3.87.4.1 Create File Request Message

The File Source uses this message to submit a new file (Binary Resource) and related metadata (DocumentReference Resource) to a target File Manager using a FHIR transaction.

3.87.4.1.1 Trigger Events

The File Source needs to submit a new file to a File Manager. The file may have been created by the File Source itself or by another file creator.

3.87.4.1.2 Message Semantics

The File Source shall issue an HTTP request according to requirements defined in the HL7® FHIR® standard for "create" interaction (http://hl7.org/fhir/R4/http.html#create). The message uses an HTTP POST method to submit a FHIR Bundle Resource.

The Bundle Resource:

- shall contain one Binary Resource (https://www.hl7.org/fhir/R4/binary.html) representing the file. The Binary Resource shall contain the base64-encoded file in the `content` element and the mime-type of the file in the `contentType` element.

- shall contain one FHIR DocumentReference Resource (https://www.hl7.org/fhir/R4/documentreference.html) with the file's metadata. Constraints on the DocumentReference Resource are listed in Table 3.87.4.1.2-1.
- may contain other resources that are referenced by the DocumentReference Resource.

565 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).

Table 3.87.4.1.2-1: DocumentReference Resource Constraints

Element Name	IHE Constraint	Notes
id [0..1]		The id element shall be provided if the File Source is sending a Replace File Message Section 3.87.4.2.2). The value is the id of the DocumentReference Resource to be updated.
masterIdentifier [0..1]		See Section 3.87.4.1.2.4.
status [1..1]		
type [0..1]	[1..1]	See Section 3.87.4.1.2.2.
category [0..1]	[1..1]	File's class (e.g., Workflow Definition, Stylesheet, Privacy Policy). See Section 3.87.4.1.2.1.
subject [0..1]	[0..0]	
date [0..1]	[1..1]	Time when the file was submitted.
author [0..*]	[1..*]	The author element shall be valued with at least a reference to an Organization Resource.
relatesTo [0..*]		See Section 3.87.4.1.2.3.
content.attachment.contentType [0..1]	[1..1]	
content.attachment.language [0..1]	Required if known	
content.attachment.data [0..1]	[0..0]	
content.attachment.url	[1..1]	For new submitted files this element shall be

Element Name	IHE Constraint	Notes
[0..1]		valued with the same opaque identifier of the entry.fullurl related to the Binary Resource. For updates to files this element shall be valued with the URL of the Binary Resource that can be used to retrieve the file using the Retrieve Document [ITI-68] transaction.
content.attachment.size [0..1]	[1..1]	
content.attachment.hash [0..1]	[1..1]	
content.format [0..1]	[1..1]	File's format. The values of this metadata should be defined by local domain policies.
context.sourcePatientInfo [0..1]	[0..0]	
context.encounter [0..*]	[0..0]	
context.related [0..*]	[0..0]	

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

Sections below provide specific guidance about how handle metadata for stylesheets, workflow definitions, and privacy policies. If other files types will be managed, local policy should establish values for `type`, `category`, `format`, `mime-type` and `masterIdentifier` elements.

3.87.4.1.2.1 category element

575 Codes in the `category` element shall be from Table 3.87.4.1.2.1-1, 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: Coded values the `category` element

coding.code	coding.display	coding.system
STYLESHEET	Code for Stylesheets	`urn:ihe:iti:npfs:2017:class-codes`

coding.code	coding.display	coding.system
WORKFLOW_DEFINITION	Code for Workflow Definitions	`urn:ihe:iti:npfs:2017:class-codes`
57017-6	Code for Privacy policy Organization Document	`http://www.loinc.org`

3.87.4.1.2.2 type element

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).
- If the file submitted is a Patient Privacy Policy (see ITI TF-1: 19.2.1 Basic Patient Privacy Consent), the `type` element should be valued with the LOINC code 57017-6 "Privacy policy Organization Document" as shown in Table 3.87.4.1.2.1-1 .
- 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 concept of the `type` element shall be defined by both a `code` and a `system` (e.g., code= "laboratory" system="http://localdomain.org/stylesheetstype").

3.87.4.1.2.3 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 (i.e., replacement, sign, transform, or append).

3.87.4.1.2.4 MasterIdentifier element

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 `workflowDefinitionReference` as defined by the XDW Profile (see ITI TF-3: 5.4.2.2).
- If the file submitted is a Patient Privacy Policy (see ITI TF-1: 19.2.1 Basic Patient Privacy Consent),, the `masterIdentifier` element shall be valued with the associated Patient Privacy Policy Identifier.

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

3.87.4.1.2.5 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": "urn:oid:1.3.6.1.4.1.19376.1.5.3.1.5.1",
                    "display": "eReferral workflow "
                }]},
                "category": {"coding": [{
                    "system": "urn:ihe:iti:npfs:2017:class-codes",
                    "code": "WORKFLOW_DEFINITION"
                }]},
                "date": "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": "urn:oid:1.12.234.56",
                    "value": "IHE FACILITY1039"
                }]
            },
            "request": {
                "method": "POST",
```



```
                "url": "http://ihe-npfs.com/Organization"
            }
        }
    ]
}
```

Figure 3.87.4.1.2.5-1: Create File Request example

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 3.87.4.4.2 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 processing, e.g., file update or replacement [ITI-87], file metadata update [ITI-89], 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, it may respond to the File Source with a failure (see Section 3.87.4.4.2).

3.87.4.2 Update File Request Message

The File Source uses this message to update a file already existing on 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/R4/versions.html.)

3.87.4.2.1 Trigger Events

The File Source needs to update a file that exists on the File Manager.

Prior to sending the update, the File Source shall discover the resource ids of the existing DocumentReference Resource and the Binary Resource to be updated.

3.87.4.2.2 Message Semantics

The File Source shall issue an HTTP request according to requirements defined in the HL7® FHIR® standard for "update" interaction (http://hl7.org/fhir/R4/http.html#update).

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

The Bundle Resource shall contain:

- one Binary Resource (https://www.hl7.org/fhir/R4/binary.html) representing the file that will update the existing Binary Resource. The `id` of the Binary Resource shall be valued with the `id` of the Binary Resource to be updated on the File Manager.
- one DocumentReference Resource (https://www.hl7.org/fhir/R4/documentreference.html) with updated metadata. The `id` of the DocumentReference Resource shall be valued with the `id` of the DocumentReference Resource to be updated; constraints on the DocumentReference Resource are listed in Table 3.87.4.1.2-1.

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

3.87.4.2.2.1 Update File Request message example

An example of a Replace File Request `Bundle` is presented below.

```
{
    "resourceType": "Bundle",
    "type": "transaction",
    "entry": [
        {
            "fullUrl": "http://ihe-npfs.com/DocumentReference/1234",
            "resource": {
                "resourceType": "DocumentReference",
                "id": "1234",
                "status": "current",
                "type": {"coding": [{
                    "code": "1.3.6.1.4.1.19376.1.5.3.1.5. ",
                    "display": "eReferral workflow "
                }]},
                "category": {"coding": [{
                    "system": "urn:ihe:iti:npfs:2017:class-codes",
                    "code": "WORKFLOW_DEFINITION"
                }]},
                "date": "2017-04-17T11:00:00",
                "author": [{"reference": " http://ihe-npfs.com/Organization/1564"}],
                "content": [{
                    "attachment": {
                        "contentType": "application/pdf",
                        "language": "en-US",
                        "url": "http://ihe-npfs.com/Binary/1236",
                        "size": "3456",
                        "hash":
"07ae8b27c7596b3314601736f32d5f0ed17fc8c0e27a0475e8ea2d8b2c788436"
                    },
                    "format": [{"code": "application/pdf"}]
                }]
            },
            "request": {
                "method": "PUT",
                "url": "http://ihe-npfs.com/DocumentReference/1234"
            }
        },
```



```
        {
            "fullUrl": "http://ihe-npfs.com/Binary/1236",
            "resource": {
                "resourceType": "Binary",
                "id": "1236",
                "contentType": "application/pdf",
                "content":
"PD94bWwgdmVyc2ldHRwOi8vd3d3LncKPC9DbGluaWNhbERvY3VtZW50Pgo="
            },
            "request": {
                "method": "PUT",
                "url": "http://ihe-npfs.com/Binary/1236"
            }
        }
    ]
}
```

Figure 3.87.4.2.2.1-1: Update File Request example

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 3.87.4.4.2 Message Semantics.

The File Manager shall process the Bundle atomically.

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 processing, e.g., file update or replacement [ITI-87], file metadata update [ITI-89], search [ITI-88], and retrieve [ITI-68]

The previous content in the updated Binary and DocumentReference Resources will be no longer accessible, and the new file will be retrievable using the same `bundle.entry.fullUrl` as the previous one.

If the File Manager receives an Update File Request message that contains resources other than the required ones, it may respond to the File Source with a failure (see Section 3.87.4.4.2).

3.87.4.3 Replace File Request Message

The File Source uses this message to replace a file already existing on the File Manager.

This message is used when there is a prior file that needs to be preserved, so the existing Binary and Document Reference Resources will be superseded (i.e., deprecated).

The File Manager is not required to support FHIR resource versioning (https://www.hl7.org/fhir/R4/versions.html.)

3.87.4.3.1 Trigger Events

The File Source needs to replace a file that exists on the File Manager.

The replace mechanism will be handled by creating a new file and updating the previous DocumentReference Resource in one message.

3.87.4.3.2 Message Semantics

This message uses an HTTP POST to submit a FHIR Bundle that contains the new Binary and DocumentReference Resources and also the prior DocumentReference Resource that needs to be replaced.

The Bundle Resource shall contain:

- one Binary Resource representing the new file, valued according to Section 3.87.4.1.2, with the `bundle.entry.request.method` element set to POST
- one DocumentReference Resource with metadata for the new file, where the `DocumentReference.status` shall be set to "current", the `relatesTo.code` shall be set to "replaces", and the `relatesTo.target` to the URL of the previous DocumentReference Resource, and the `bundle.entry.request.method` element set to POST
- one DocumentReference Resource with metadata of the previous file, valued as specified in Section 3.89.4.1.1 with the `bundle.entry.request.method` element set to PUT and the `DocumentReference.status` to "superseded".

3.87.4.3.3 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 Replace File Request, the File Manager shall validate the Resources and respond with one of the HTTP codes defined in Section 3.87.4.4.2 Message Semantics.

The File Manager shall process the Bundle atomically.

The File Manager shall store these resources and make the new file available for further processing, e.g., file update or replacement [ITI-87], file metadata update [ITI-89], search [ITI-88], and retrieve [ITI-68].

If the File Manager receives a Replace File Request message that contains resources other than the required ones, it may respond to the File Source with a failure (see Section 3.87.4.4.2).

3.87.4.4 Submit File Response Message

The File Manager sends a Submit File Response message in response to a Create File Request, an Update File Request, or a Replace File Request Message.

3.87.4.4.1 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, update or replace request.

3.87.4.4.2 Message Semantics

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

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/R4/http.html#transaction-response.

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 operation is a success, the HTTP status code of the response shall be a 2xx code.

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

- 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 DocumentReference Resource.

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.

3.87.4.4.2.1 Submit File Response message example

```
{
  "resourceType":"Bundle",
  "type":"transaction-response",
  "entry":[
    {
      "response":
        {
          "status":"201"
          "location":"http://www.ihe.org/DocumentReference/453"
        }
    },
    {
      "response":
        {
          "status":"201"
          "location":"http://www.ihe.org/Binary/123"
        }
    },
```



```
    {
      "response":
        {
          "status":"201"
          "location":"http://www.ihe.org/Organization/789"
        }
    }
  ]
}
```

3.87.4.4.3 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 Resources exchanged do not contain PHI or other private information, actions such creating, updating, or replacing those Resources could compromise patient care or have other legal ramifications. 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

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 recommended in order to avoid malicious creation/updating of files associated with 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.

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. The DocumentReference Resources represent files that are not associated with patient.

3.88.2 Actor Roles

Table 3.88.2-1: Actor Roles

Actor:	File Consumer

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

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

3.88.3 Referenced Standards

HL7 FHIR	HL7 FHIR R4 http://hl7.org/fhir/R4/index.html

3.88.4 Messages

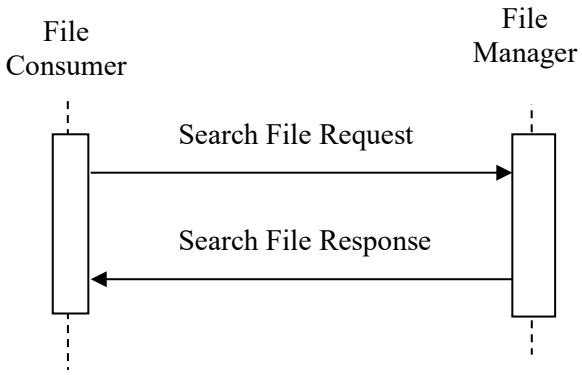


Figure 3.88.4-1: Interaction Diagram

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 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

The File Consumer executes an HTTP GET against the File Manager. This request shall comply with requirements specified in the HL7® FHIR® standard http://hl7.org/fhir/R4/http.html#search.

The search target URL follows the FHIR HTTP specification, addressing the DocumentReference Resource http://hl7.org/fhir/R4/http.html:

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


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 File Manager such as response format, or pagination.

3.88.4.1.2.1 Query Search Parameters

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

- **identifier**

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

- **_id**

This parameter, of type `token`, allows the File Consumer to search on the logical id assigned to the resource.

- **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`).

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

- **date**

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 HL7 FHIR (http://hl7.org/fhir/R4/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 author that has submitted 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.

- **format**

This parameter, of type `token`, specifies the file's format.

- **language**

This parameter, of type `token`, specifies the language of the file.

- **location**

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.

- **relatesto**

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

- **relation**

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/R4/valueset-document-relationship-type.html for the type of relation allowed.

- **relationship**

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

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 DocumentReference Resources that 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 DocumentReference Resources that are not constrained as specified in Table 3.87.4.1.2-1.

3.88.4.2 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.

3.88.4.2.1 Trigger Events

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

3.88.4.2.2 Message Semantics

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 should include a FHIR OperationOutcome with more details on the failure. See FHIR http://hl7.org/fhir/R4/http.html and http://hl7.org/fhir/R4/operationoutcome.html.

If the Search File Request message is processed successfully, whether or not any matching 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 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

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 Resources exchanged do not contain PHI or other private information, exchange of those Resources could compromise patient care or have other legal ramifications. 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

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 recommended 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]

3.89.1 Scope

This transaction allows a File Source to update a DocumentReference Resource previously submitted. The DocumentReference Resource represents metadata for a file that is not associated with a patient.

The File Manager is not required to support FHIR resource versioning (see https://www.hl7.org/fhir/R4/http.html#history).

3.89.2 Actor Roles

Table 3.89.2-1: Actor Roles

Actor:	File Source

Role:	Sends an update to an existing DocumentReference Resource.
Actor:	File Manager
Role:	Updates and maintains DocumentReference Resources.

3.89.3 Referenced Standards

HL7 FHIR	HL7 FHIR R4 http://hl7.org/fhir/R4/index.html

3.89.4 Messages

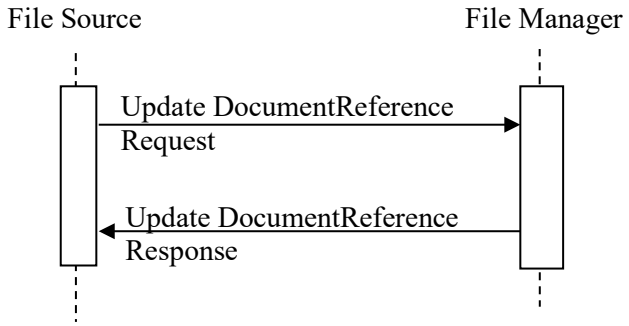


Figure 3.89.4-1: Interaction Diagram

3.89.4.1 Update DocumentReference Request Message

The File Source uses this message to update a FHIR DocumentReference Resource already stored on 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 `id` of the existing DocumentReference Resource.

3.89.4.1.2 Message Semantics

The File Source shall issue an HTTP request according to requirements defined in HL7® FHIR® standard for "update" interaction (http://hl7.org/fhir/R4/http.html#update).

The File Source shall use an HTTP PUT method to submit to the File Manager a DocumentReference Resource. The DocumentReference Resource conveys to the File Manager the update to a 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 Table 3.87.4.1.2-1 for other constraints upon the DocumentReference Resource.

The File Source shall submit the DocumentReference Resource in either 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).

3.89.4.1.2.1 Update DocumentReference Request message example

```
{
            "resourceType": "DocumentReference",
            "id": "112345",
            "contained": [
                {
                    "resourceType": "Organization",
                    "id": "org1",
                    "identifier": [{
                        "system": "urn:oid:1.12.234.56",
                        "value": "IHE Facility"
                    }]
                }
            ],
            "status": "current",
            "type": {"coding": [{
                "system": "urn:oid: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).

905 On receipt of the DocumentReference Update Request, the File Manager shall validate and update the existing 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 File Manager has updated the DocumentReference Resource, the File Manager sends this message to the File Source acknowledging the result of the update request.

3.89.4.2.2 Message Semantics

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

The File Manager returns a HTTP status code appropriate to the processing, conforming to the transaction specification requirements as specified in https://www.hl7.org/fhir/R4/http.html#update.

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 Resources exchanged do not contain PHI or other private information, updating those Resources could compromise patient care or have other legal ramifications. 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

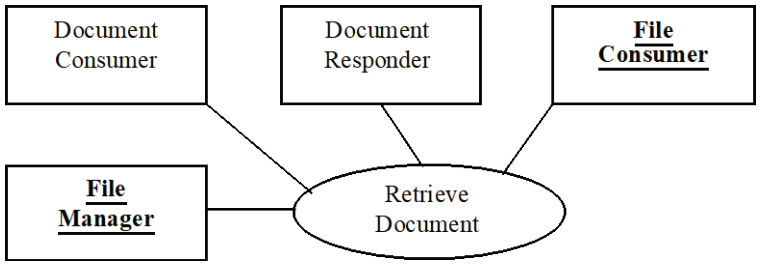
This transaction does not require the actor involved to send audit messages to an Audit Record Repository because does not convey PHI. However, the auditing of the update operation is suggested in order to avoid malicious update of the metadata for files associated with the care of the patient. The audit message for the Update DocumentReference transaction shall comply with the structure defined in DICOM PS3.15 Annex A.5.1

Volume 2c – Transactions (cont.)

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



Actor: Document Consumer

Role: Requests a document from the Document Responder

Actor: Document Responder

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

