

File Reviews – Setup and Configuration

The File Reviews feature must be enabled and several configurations steps performed before File Review-related feature groups, dictionaries, and menu options appear in eTMF.

Enabling the File Reviews Feature

To enable the File Reviews feature, a System Administrator must perform the following steps:

1. From the More Actions Menu on the User Home Page, select “Administration”.
2. Select “System Administration” from the Administration Menu.
3. Select the **File Review**
4. Select the **File Review Enabled** check box.
5. By default, the maximum number of open File Reviews is set to 5. Change this number in the appropriate field if needed.
6. Select “Save” from the Actions Menu in the System Administration header.

Once the File Reviews feature is enabled, a Business Administrator or other user with the appropriate access is responsible for certain configuration steps as explained below.

Controlling Access to File Review Menu Items

First, the Business Administrator must assign users to File Review specific feature groups that control access to File Review list pages and menu items. Feature groups specific to File Reviews include:

- TMF Manage File Review Templates –controls the ability to create and manage File Review Templates

- TMF Create File Reviews –Controls the ability to create and manage File Reviews and close Action Items*
- TMF Delete File Reviews – Controls the ability to delete a File Review*
- TMF View File Reviews–Controls the ability to view File Reviews for a given study*

***Note:** Feature groups are used in conjunction with File Review Template settings to control access to specific File Reviews and menu options. For example, to see the option to delete a File Review, the user needs to have TMF Delete File Reviews permission and must be within a Review Manager group for the template on which the File Review is based.

Maintaining Dictionaries

The Business Administrator is also responsible for maintaining dictionaries that control the File Review values available in operations. These dictionaries contain out of the box values that may be applicable to many organizations, but the Business Administrator can also add values that are specific to your organization***. File Review dictionaries include:

Dictionary	Meaning of Values	Where Used	Examples
File Review Types	Types of File Reviews that can be performed	File Review Template creation	Sponsor, Periodic, Pre-inspection
File Review Non Document Review Items	Review Items that are not document specific	File Review Template creation	Check Correspondence, Confirm All Required ICF Translations Filed

File Review Problem Types***	General types of problems found during review	Action Item creation	Content Issues, Metadata Issues
File Review Issue Category	Specific issues that can cause a Review Item to fail	Action Item creation	Invalid Document, Incorrect Document Date

The File Review Problem Types dictionary is a parent to the Issue Categories dictionary, which means that a single Problem Type can correspond to multiple Issue Categories. This relationship is used by eTMF during Action Item creation to control the Issue Categories available by Problem Type.

File Review Problem Type	Parent	Value	File Review Issue Category
	Metadata Issues	Incorrect Study, Country or Site	
	Metadata Issues	Other Issue (See Comments)	
	Missing Document for Empty Study Item	Document Now Available for Upload	
	Missing Study Item	Missing Document	
	Missing Study Item	Missing Translation(s)	

*****Note:** File Review Problem Types are built into the system and trigger the creation of specific types of workflow tasks. Therefore, you should not modify the values in this dictionary.

Configuring File Review Templates

The Business Administrator must also [configure File Review Templates](#) from which actual File Reviews will be created. File Review Templates define the rules for each type of File Review to be created.