PhOT0001 AI-FSM Procedure

Version 2.0

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Author	Javier Fernández
Modified by	Lorea Belategi
Reviewed by	Irune Agirre
Approved by	Irune Agirre
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1 Review / Modification History

Version	Date	Description Change
V2.0	15/02/2024	Changes Applied as a result of TÜV Review 2024-01-19
V1.0	04/12/2023	First version after complete internal review
V0.2	01/12/2023	Modifications and improvements based on internal review
V0.1	30/08/2023	First draft

*Note: Since Artificial Intelligence - Functional Safety Management (AI-FSM) utilizes templates from both the traditional FSM and its own templates, this annex distinguishes the AI-FSM templates by color-coding them in orange and the traditional Functional Safety Management (FSM) templates in green. Additionally, the folders' names will be enclosed in quotation marks and the files' names created from the templates are written in italics and underlined. These files' names are preceded by "REF_", which should be changed to reflect the specific safety project reference. The paragraphs/name of the project/Rev./Ref./history table in **blue** must be replaced with the information for the specific project. The paragraphs written in **red** are instructions that can be used as a guide, so they must be deleted.*

2 Objective

This document defines the additional steps, actions and considerations that shall be addressed in the FSM when incorporating AI components into a safety-critical system. It is complementary to the traditional FSM procedure, so any information related to the overall project that is missing here should be collected in the traditional FSM procedure.

3 Scope

This document is for all projects that are related to AI-based safety development systems.

4 AI-FSM

As AI-FSM is an annex to the traditional FSM of Ikerlan, this document refers to the document generated from the *Ph0T0003_FSM_CSM_Template.docx* template to guide the following steps of the FSM:

1. Safety and security policy.
2. Configuration management, which includes the project development – configuration management. Highlight in this step that the list of documents to be realized according to the AI lifecycle is defined in the *Ph0T0002_AI_Document_list_template.docx* template instead of the traditional *Ph0T0002_Document_List_template.docx*, and each document will be in the repository according to the AI Life Cycle phase.
3. File Storage.
4. People/Organizations involved in the project. The information relative to the AI life cycle is defined in the *Ph0T0004_AI_Organizational_Chart_template.docx* template, which complements the traditional *Ph0T0012_Organizational_Chart_template*.docx template.
5. Modification process.
6. Test procedures.
7. Traceability. The traditional FSM collects in *REF_Ph0D0011_Traceability_matrix.docx* the relationship of the requirements at the different phases of the life cycle. However, the use of DL involves the apparition of the following interdependencies (as well as the testing mechanisms associated) that will be stored in the *REF_Ph0D0013_AI_Traceability_Matrix.docx*:
    a. Software requirements specifications and DL requirement specifications.
    b. DL requirement specifications and data requirement specifications.
    c. DL requirement specifications and learning requirements specifications.
    d. DL requirement specifications and inference requirements specifications.
8. V&V Plan.
9. Safety and Security Audits.
10. Safety Assessment.
11. Security Assessment.
12. Interaction with external participants.

This template focuses on the procedure to be followed in the AI safety lifecycle phases.

4.1 Description of the Safety Lifecycle Phases

In every phase of the life cycle a set of activities, techniques/measures and files to be followed, identified or generated have been defined.

The phases are structured in the following way:

- Phase definition. The activities that must be carried out in every phase. At the end of each phase a Techniques and measures table summarizes the necessary techniques and measures that must be used.
- Verification and Validation activities. The Verification and Validation activities are those that must be carried out in every phase. At the end of each phase, a Techniques and measures table summarizes the necessary verification and validation techniques and measures that must be used.
- Document table. A summary of the files involved in every phase.

The phases of the life cycle will be described with the following information:

- Phase name. Name of the life cycle phase.
- File input. Name of the files with the information necessary to start the phase.
- File output. Name of the files generated at the end of the phase.
- Responsible. The name of the team responsible for the activity.
- Assessment. The name of the entity that is responsible for the assessment (the name only appears if the action has been finished satisfactorily).

4.1.1 Overall Lifecycle – Phase 0 (Ph0)

In this phase, documents related to the overall lifecycle must be specified. These documents guide through the whole lifecycle complemented with the traditional FSM documentation.

Table 1: Overall lifecycle - Phase 0 summary

Phase	File input name	File output name	Responsible	Assessment
Ph0 AI Overall Lifecycle	• REF_FSM_Procedure • REF_Document_List • REF_Version_Tracking • REF_Organizational_Chart • REF_Traceability_Matrix	REF_Ph0D0001_AI-FSM_Procedure		
		REF_Ph0D0002_AI-FSM_Procedure_IR		
		REF_Ph0D0003_AI_Document_List		
		REF Ph0D0004_AI_Document_List_IR		
		REF_Ph0D0005_AI_Version_Tracking		
		REF Ph0D0006_AI_Version_Tracking_IR		
		REF_Ph0D0007_AI_Organizational_Chart		
		REF_Ph0D0008_AI_Organizational_Chart_IR		
		REF_Ph0D0009_AI_Log_of_Tests		
		REF_Ph0D0010_AI Log_of_Tests_IR		
		REF_Ph0D0011_AI_Tools_Selection		
		REF_Ph0D0012_AI_Tools_Selection_IR		
		REF_Ph0D0013_AI_Traceability_Matrix		
		REF_Ph0D0014_AI_Traceability_Matrix_IR		

Phase Definition activities:

- Update the document list in *REF_Ph0D0003_AI_Document_List.docx.* This document has been generated from *Ph0T0002_AI_Document_List_template.docx* and must be updated in order to collect all documents related to AI life cycle. It can be merged with the *Document List.docx* generated from the *Ph0T0002_Document_List_template.docx* in the traditional FSM or it can be explicitly explained in the *Document_List.docx* that those documents related to AI are gathered in the *REF_Ph0D0003_AI Document_List.docx*.
- Complete the traceability between the versions of the elements and structures of the project in the *REF_Ph0D0005_AI_Version_Tracking.docx* document. This file has been generated from the *Ph0T0003_AI_Version_Tracking_template.docx* template and must collect the traceability between the articles/elements/structures and project versions relative to the AI lifecycle. *REF_Ph0D0005_AI_Version_Tracking.docx* document should either be merged within the *Version_Tracking.docx* from the traditional FSM or explicitly explained in the *Version_Tracking.docx* that those relationship between the different elements of the AI project are gathered in the *REF_Ph0D0005_AI_Version_Tracking.docx* document.
- Fulfill the *REF_Ph0D0007_AI_Organizational_Chart.docx* document. This file has been generated from the *Ph0T0004_AI_Organizational_Chart_template.docx* template and must outline the relationship between the company organisation and the methodology, identify the main roles involved in a safety or cybersecurity project, and the relationships between these roles. *REF_Ph0D0007_AI_Organizational_Chart.docx* document should either be merged within the *Organizational_Chart.docx* from the traditional FSM or explicitly explained in the *Organizational_Chart.docx* that those relationships between the different participants of the AI project are gathered in the *REF_AI_Organizational_Chart.docx* document.

- Collect the tool selection in the *REF_Ph0D0011_AI_Tools_Selection.docx*. To prevent inconsistencies or omission of information, create a *REF_Ph0D0011_AI_Tools_Selection.docx* file from *Ph0T0010_Tools_selection_template* to include AI tools and frameworks. Again, this file should either be merged within the *Tools_Selection.docx* file from the traditional FSM or explicitly explained in the traditional *Tools_Selection.docx* that those related to the AI lifecycle are gathered in the *REF_Ph0D0011_AI_Tools_Selection.docx*.
- Collect in the *REF_Ph0D0013_AI_Traceability_Matrix.docx* generated from the *Ph0T0011_Traceability_Matrix* the interdependences of the requirements at different levels of the development process as well as the relationship between requirements and V&V mechanisms in the traceability matrix. The use of Deep Learning (DL) involves the apparition of the following interdependencies (as well as the testing mechanisms associated):
  - Software requirements specifications and DL requirements specifications.
  - DL requirements specifications and data requirements specifications.
  - DL requirements specifications and learning requirements specifications.
  - DL requirements specifications and inference requirements specifications.

Verification and Validation activities

- Internal review of *REF_Ph0D0001_AI-FSM_Procedure.docx*, *REF_Ph0D0003_AI_Document_List.docx*, *REF_Ph0D0005_AI_Version_Tracking.docx*, *REF_Ph0D0007_AI_Organizational_Chart.docx*, *REF_Ph0D009_AI_Log_of_Tests.docx*, *REF_Ph0D0011_AI_Tools_Selection.docx* and *REF_Ph0D0013_AI_Traceability_Matrix.docx,* fulfilling the following internal review reports:
  - *REF_Ph0D0002_AI_FSM_Procedure_IR.xlsx.*
  - *REF_Ph0D0004_AI_Document_List_IR.xlsx.*
  - *REF_Ph0D0006_AI_Version_Tracking_IR.xlsx.*
  - *REF_Ph0D0008_AI_Organizational_Chart_IR.xlsx.*
  - *REF_Ph0D0010_AI_Log_of_Tests_IR.xlsx.*
  - *REF_Ph0D0012_AI_Tools_Selection_IR.xlsx.*
  - *REF_Ph0D0014_AI_Traceability_Matrix_IR.xlsx.*

4.1.2 DL-Related Concept Specification – Phase 1

In this phase, the ODD and the operational scenarios must be defined in order to specify the operational conditions, environmental conditions, etc., that limit the system's defined safety functionality.

Table 2: DL-Related Concept Specification - Phase 1 summary

Phase	File input name	File output name	Responsible	Assessment
Ph1: DL-Related Concept Specification	• *REF_System_Requirements_Specifications*	*REF Ph1D0001_DL_Operational_Design_Domain*		
		REF_Ph1D0002_DL_Operational_Design_Domain_IR		
		REF Ph1D0003_DL_Operational_Scenarios		
		REF Ph1D0004_DL_Operational_Scenarios_IR		

Phase Definition

Activities to be done:

- Define the ODD in the *REF Ph1D0001_DL Operational Design Domain.docx* document generated from *Ph01T0001_DL_Operational_Design_Domain_template.docx*. This document has been generated in order to collect the information related to Operational Design Domain (ODD), where the systems must assure functional safety. The template has an internal guide that eases the generation and

organization of the required information. However, it is important to note that templates should be used as baselines, providing a framework for the information to be collected, but they should not limit the scope of information nor guarantee that fulfilling them is sufficient. In the case of the ODD, the required information is specific to the application and domain.

- Define the operational scenarios fulfilling *REF_Ph1D0003_DL_Operational_Scenarios.docx.* This document has been generated from *Ph01T0002_DL_Operational_Scenarios_template.docx* in order to collect different operational scenario specifications for the system. The template has an internal guide that eases the generation and organization of the required information.

Reminder: Update the state of *REF_Ph0D0003_AI_Document_List.docx*

Verification and Validation activities

- Internal review of *REF_Ph1D0001_DL_Operational_Design_Domain.docx* and *REF_Ph1D0003_DL_Operational_Scenario.docx* fulfilling the associated internal review documents:
  - *REF_Ph1D0002_DL_Operational_Design_Domain_IR.xlsx.*
  - *REF_Ph1D0004_DL_Operational_Scenarios_IR.xlsx*.

Reminder: Update the state of *REF_Ph0D0003_AI_Document_List.docx*.

4.1.3 DL Requirements Specification – Phase 2 (Ph2)

In this phase, based on the software requirements specification, DL requirements specification is elaborated.

Table 3: DL Requirements Specification - Phase 2 summary

Phase	File input name	File output name	Responsible	Assessment
Ph2: DL Requirements Specification	• *REF_Software_Requirements_Specifications*	*REF_Ph2D0001_DL_Requirements_Specifications*		
		REF_Ph2D0003_DL_Requirements_Verification_Tests		
		REF_Ph2D0004_DL_Requirements_Verification_Tests_IR		
		REF_Ph2D0006_DL_component_description_IR		

Phase Definition

Activities to be done:

- Define the DL Requirements in the *REF_Ph2D0001_DL_Requirements_Specifications.docx* created from *Ph02T0001_AI_Requirement_Specifications.docx*. This template has been generated in order to collect the DL requirements of the project, including an internal guide that eases the generation and organization of the required information.
- Define the DL Verification tests in the *REF_Ph2D0003_DL_Requirements_Verification_Tests.docx* file generated from *Ph0T0009_Test_definition_and_results_template.docx*. It has been generated in order to collect the needed tests to verify every DL requirement defined in this phase. In this file, it is necessary to define the tests required to prove the right functionality of the DL subsystem. This template includes an internal guide that eases the generation and organization of the required information.

Reminder: - Update the state of REF_Ph0D0003_AI_Document_List.docx.
- Update the REF_Ph0D0013_AI_Traceability_Matrix.docx.

Verification and Validation activities

- Conduct the internal review of *REF_Ph2D0001_DL_Requirements_Specifications.docx* and *REF_Ph2D0003_DL_Requirements_Verification_Tests.docx* fulfilling the associated internal review documents:
  - *REF_Ph2D0002_DL_Requirements_Specification_IR.xlsx.*
  - *REF_Ph2D0004_DL_Requirements_Verification_Tests_IR.xlsx*.
- Collect the tests performed in this phase in the *REF_Ph0D0009_AI Log_of_Tests.docx*.

Reminder: -Update the state of REF_Ph0D0003_AI Document_List.docx.

4.1.4 Data Management – Phases DM (PhDM)

In this phase, data requirements are defined based on the DL requirement specifications, the ODD and the operational scenarios. The data is collected in datasets and subsequently prepared. Verification activities are also specified.

Table 4: Data Management - PhDM summary (related to Ph3, Ph4 and Ph5 of the traditional lifecycle)

Phase	File input name	File output name	Responsible	Assessment
PhDM: Data Management	• *REF_Ph2D0001_DL_Requirements_Specifications* • *REF Ph1D0001_DL Operational Design Domain* • *REF Ph1D0003_DL_Operational Scenarios*	*REF_PhDMD0001_Data_Requirements_Specifications* *REF_PhDMD0007_Data_Requirements_Verification tests*		
		REF_PhDMD0002_Data_Requirements_Specifications_IR *REF_PhDMD0008_Data_Requirements_Verification Tests_IR*		
		REF_PhDMD0003_Data_Collection_Log Raw data files structured in datasets(1)		
		REF PhDMD0004_Data_Collection_Log_IR		
		REF PhDMD0005_Data_Preparation_Llog Prepared data structured in datasets(1)		
		REF_PhDMD0006_Data_Preparation_Log_IR		
		Verified datasets(1)		

Phase Definition

- Define and collect the data requirements specifications in the *REF_PhDMD0001_Data_Requirements_Specifications.docx* file.
- Define the data requirement verification tests in the *REF_PhDMD0007_Data_Requirements_Verification_Tests.docx* document.
- Collect the data according to the specifications outlined in the *REF_PhDMD0001_Data_Requirements_Specifications.docx* file and store it in the "Collected Data" folder within the corresponding dataset folder.
- Collect all the information related to the data collection in the *REF_PhDMD0003_Data_Collection_Log.docx* document.

[1] Datasets include: i) development (training and validation) dataset and ii) verification datasets.

- Prepare the data according to the specifications outlined in the *REF_PhDMD0001_Data_Requirements_Specifications.docx* file and store it in the "Prepared Data" folder within the corresponding dataset folder.
- Collect all the information related to the data preparation in the *REF_PhDMD0005_Data_Preparation_Log.docx* document.
- Complete the *REF_PhDMD0009_Data_Requirements_Verification_Tests.docx* file with the tests and measures to be implemented in this phase.

Reminder: -Update the state of REF_Ph0D0003_AI_Document_List.docx.
- Update the REF_Ph0D0013_AI_Traceability_Matrix.docx.

Verification and Validation activities

- Implement the tests previously defined in the *REF_PhDMD0007_Data_Requirements_Verification_Tests.docx* and record the results in the same *REF_PhDMD0007_Data_Requirements_Verification_Tests.docx* file.
- Conduct the internal review of *REF_PhDMD0001_DL_Requirement_Specifications.docx*, *REF_PhDMD0007_Data_Requirement_Verification_Tests.docx*, *REF_PhDMD0003_Data_Collection_Log.docx* and *REF_PhDMD0005_Data_Preparation_Log.docx* fulfilling the associated internal review documents:
  - *REF PhDMD0002_Data_Requirements_Specifications_IR.xlsx*.
  - *REF_PhDMD0008_Data_Requirements_Verifications_Tests IR.xlsx.*
  - *REF_PhDMD0004_Data_Collection log IR.xlsx.*
  - *REF_PhDMD0006_Data_Preparation_Log_IR.xlsx*.
- Collect the tests performed in this phase in the *REF_Ph0D0009_AI_Log_of_Test.docx*.

Reminder: -Update the state of REF_Ph0D0003_AI_Document_List.docx.

4.1.5 Learning Management – Phase LM (PhLM)

In this phase, learning requirements are specified based on DL requirements. A model is designed, trained, evaluated and verified.

Table 5: Learning Management - PhLM summary (related to Ph3, Ph4 and Ph5 of the traditional lifecycle)

Phase	File input name	File output name	Responsible	Assessment
PhLM: Learning Management	*REF_Ph2D0001_DL_Requirements Specifications*	*REF_PhLMD0001_Learning_Requirements_Specifications* *REF_PhLMD0005_Learning_Requirements_Evaluation_Tests* *REF_PhLMD0007_Learning_Requirements_Verification_Tests*		
		REF_PhLMD0002_Learning_Requirements_Specifications_IR *REF_PhLMD0006_Learning_Requirements_Evaluation_Tests_IR* *REF_PhLMD0008_Learning_Requirements_Verification_Tests_IR*		
		REF_PhLMD0003_Model_Election_Log		
		REF_PhLMD0004_Model_Election_Log_IR		
		Trained Model(s)		
		Evaluated Model(s)		
		Verified Learning Model(s)		

Activities to be done:

- Complete the *REF_PhLMD0001_Learning_Requirements_Specifications.docx* file with the learning requirements specifications of the project.
- Complete the *REF_PhLMD0005_Learning_Requirements_Evaluation_Tests.docx* file and *REF_PhLMD0007_Learning_Requirements_Verification_Tests.docx* with the tests and measures to be implemented in this phase.
- Perform the training of the model to obtain the trained model.

Reminder: -Update the state of REF_Ph0D0003_AI_Document_List.docx.
- Update the REF_Ph0D0013_AI_Traceability_Matrix.docx.

Verification and Validation activities

- Implement the tests previously defined in the *REF_PhLMD0005_Learning_Requirements_Evaluation_Tests.docx* and, in case of meeting the learning requirements specifications, implement the *REF_PhLMD0007_Learning_Requirements_Verification_Tests.docx.* Record the results in the same *REF_PhLMD0005_Learning_Requirements_Evaluation_Tests.docx* and *REF_PhLMD0007_Learning_Requirements_Verification Tests.docx* files, respectively.
- Internal review of *REF_PhLMD0001_Learning_Requirements_Specifications.docx*, *REF_PhLMD0005_Learning_Requirements_Evaluation_Tests.docx*, *REF_PhLMD0007_Learning_Requirements_Verification_Tests.docx* and *REF_PhLMD0003_Model_Election_Log.docx,* fulfilling the associated internal review documents:
  - *REF_PhLMD0002_Learning_Requirements_Specifications_IR.xlsx*.
  - *REF_PhLMD0006_Learning_Requirements_Evaluation_Tests_IR.xlsx.*
  - *REF_PhLMD0008_Learning_Requirements_Verification_Tests_IR.xlsx.*
  - *REF_PhLMD0004_Model_Election_Log_IR.xlsx*.
- Update the *REF_Ph0D0009_AI_Log_of_Tests.docx.*

Reminder: -Update the state of REF_Ph0D0003_AI_Document_List.docx.

4.1.6 Inference Management – Phase IM (PhIM)

In this phase, inference requirements are specified based on DL requirements and learning specifications. The learning model from the previous phase is converted, optimized and verified.

Table 6: Inference Management – PhIM summary (related to Ph3, Ph4 and Ph5 of the traditional lifecycle)

Phase	File input name	File output name	Responsible	Assessment
PhIM: Inference Management	*REF_Ph2D0001_DL_Requirements_Specifications* *REF_PhLMD0001_Learning_Requirements_Specifications* Verified Learning Model	*REF_PhIMD0001_Inference_Requirements_Specifications* *REF_PhIMD0007_Inference_Requirements_Verification_Tests*		
		REF_PhIMD0002_Inference_Requirements_Specifications_IR *REF_PhIMD0008_Inference_Requirements_Verification_Tests_IR*		
		REF_PhIMD0003_Model_Conversion_Log		
		Converted Model		
		REF_PhIMD0004_Model_Conversion_Log_IR		
		REF_PhIMD0005_Model_Optimization_Log		
		Optimized Model		
		REF_PhIMD0006_Model_Optimization_Log_IR		
		Verified Inference Model		

As it was previously mentioned, we refer the reader to the *PhIMG0003_Inference_Management_guideline.docx* for further guidance on this process. The subsequent documents should be stored in the "Inference Management" subfolder, located in the "AI-FSM" folder.

Phase Definition

- Complete the *REF_PhIMD0001_Inference_Requirements_Specifications.docx* file with the inference requirements specifications of the project.
- Complete the *REF_PhIMD003_Model_Conversion_Log.docx* document and perform the model conversion of the verified model to obtain the converted model.
- Complete the *REF_PhIMD005_Model_Optimization_Log.docx* document and perform the model optimization of the converted model to obtain the optimized model.
- Complete the *REF_PhIMD0007_Inference_Requirements_Verification_Tests.docx files* with the tests and measures to be implemented in this phase.

Reminder: -Update the state of REF_Ph0D0003_AI_Document_List.docx.
- Update the REF_Ph0D0013_AI_Traceability_Matrix.docx.

Verification and Validation activities:

- Implement the tests previously defined in the *REF_PhIMD0007_Inference_Requirements_Verification_Tests.docx* and record the results in the same *REF_PhIMD0007_Inference_Requirements_Verification_Tests.docx* file.
- Conduct the internal review of *REF_PhIMD0001_Inference_Requirements_Specifications.docx*, *REF_PhIMD0003_Model_Conversion_Log.docx,* *REF_PhIMD0005_Model_Optimization_Log.docx* and *REF_PhIMD0007_Inference_Requirements_Verification_Tests.docx,* fulfilling the associated internal review documents:
  - *REF_PhIMD0002_Inference_Requirements_Specifications_IR.xlsx*.
  - *REF_PhIMD0004_Model_Conversion_Log_IR*.xlsx.
  - *REF_PhIMD0006_Model_Optimization_Log_IR*.xlsx.
  - *REF_PhIMD0008_Inference_Requirements_Verification_Tests_IR.xlsx*.
- Update the *REF_Ph0D0009_AI_Log_of_Tests.docx.*

Reminder: -Update the state of REF_Ph0D0003_AI_Document_List.docx

5 Acronyms and Abbreviations

Below is a list of acronyms and abbreviations employed in this document:

- AI – Artificial Intelligence
- AI-FSM – Artificial Intelligence - Functional Safety Management
- DL – Deep Learning
- FSM – Functional Safety Management
- ODD - Operational Design Domain

6 Bibliography

Add here the reference to used bibliography/references (if any).