



GUIDANCE MATERIAL:

FHA REPORT

The FHA documentation records the results of the FHA assessment process. This document will be updated through the complete system life cycle.

In order to make this document readable and conveying efficiently key messages and results of FHA, recommendations are:

- To keep the body of the document short (around 15 pages);
- To make this document conclusive: clearly and concisely list the main findings of the FHA such as main Safety Objectives and assumptions;
- To include an executive summary;

- To contain the results of detailed analyses in annexes.

A possible structure for the FHA report is provided below.

Executive Summary

It should focus on main messages delivered by FHA, such as: what are the main hazards, Safety Objectives and assumptions, recommendations and conclusions.

Introduction

This section describes:

- The objectives of the document.
- The scope of the FHA (What was addressed in the FHA process and what was not addressed).
- The structure of the document.

System Description

This section provides an overview of the system purpose and functions in order to provide an understanding of the safety issues raised.

It will cover, or reference, documentation describing:

- The purpose and boundaries of the system;
- The system operational environment (if appropriate, the assumptions made about this operational environment);
- The operational scenarios;
- System functions and their relationships;
- The external interfaces.

It will also identify whether the system is new, a replacement or a modification of an existing system.

Safety Criteria

This section should identify the specific safety criteria used to define the Safety Objectives. For example,

- Applicable safety regulatory requirement;
- Modifications to the generic Severity Classification Scheme, where appropriate;
- Method used to derive quantitative Safety Objectives, where appropriate.

Hazard Identification - Severity Classification of Hazard effects

This section lists the results of hazard identification and the classification of the severity of the hazard's effects.

The amount of information collected in the FHA process can be very large. Few readers will need to see the entire table of results, so it is often useful to extract key information in more concise and intelligible form, reflecting the needs of the particular audience.

The full results are usually best presented in a tabular format, as described in Chapter 3, Guidance Material H.

Depending on the number of functions, the table presented in the main report could be limited to the description of the hazards having the most severe worst credible effect and referring to more complete and detailed analyses in Annexes.

Safety Objectives

This section lists all the Safety Objectives (always associated to their hazard and their set of assumptions: External Mitigation Means or Operational Conditions which have to be satisfied for such Safety Objective to be valid).

The full results are usually best presented in a tabular format, as described in Chapter 3, Guidance Material H.

Depending on the number of functions, the list of Safety Objectives presented in the main report could be limited to the description of the most stringent safety objectives and referring to more complete and detailed analyses in Annexes.

Summary and Conclusions

This part summarises the results of the FHA process. It should include:

- The list of major hazards and their effects, i.e., those with highest severity classifications;
- The list of quantitative and/or qualitative Safety Objectives;
- The assumptions (External Mitigation Means, Operational Conditions) to be satisfied per Safety Objective;
- The main conclusions of the FHA Verification, FHA Validation and FHA Process Assurance activities;

This part also identifies any hazards requiring additional analysis, and/or other priorities for further attention in the development/ assessment cycle.

Annexes

- Detailed result tables
- Cross references to other documents produced within the FHA process, such as the FHA Plan (as described in Chapter 2) and the results of the FHA Verification, FHA Validation and FHA Process Assurance tasks (as described in SAM-FHA Chapter 4).
- References to external documents – e.g. regulatory requirements, documentation for systems interacting with the proposed system.
- Traceability Matrices:
- Traceability matrices:
 - Hazards <> System Functions
 - Safety Objectives <> Hazards
 - External Mitigation Means <> Safety Objectives
 - Operational Environment <> Safety Objectives