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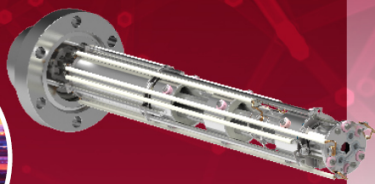
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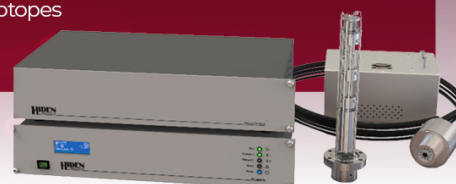
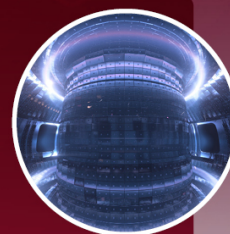
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Safety engineering approach and licensing strategy of IFMIF-DONES

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Abstract

Safety is a fundamental and transversal discipline throughout the design, construction, operation, and eventual decommissioning of the IFMIF-DONES facility, which will be classified as a Category 1 Radioactive Installation according to the Spanish law. The singularity and one-of-a-kind characteristics of IFMIF-DONES (both in Spain and worldwide) requires the development of an ad-hoc Safety Approach and Licensing Strategy that guarantees Safety to Personnel, Public and the Environment with very low acceptable risks, following the uppermost standards while keeping an optimized balance with the associated technological complexity and feasibility. This work provides a comprehensive overview of this Approach and Strategy that is being developed, involving: (i) Top-level Safety regulations and the adapted methodology to apply them to the singularities of IFMIF-DONES, including dose and risk limits to public and workers. (ii) Engineering inputs necessary to implement the radiological safety engineering approach, such as material-at-risk, Hazard Categorization and Seismic aspects. (iii) Methodology for the hazard analysis through the identification and study of Reference Accident Scenarios, definition of lines-of-defense, Safety Important Class Systems, Structures and Components (SIC-SSCs) and their requirements. (iv) Description of the SIC-SSCs that are being implemented from an engineering perspective, such as confinement barriers, safety interlocks, area classifications, access controls and radiation monitoring. (v) Implementation of ALARA principles from the design phase to reduce the occupational radiation exposure of workers to fulfill the targets of maximum individual and collective dose during operation. (vi) Experimental programs ongoing to support Safety aspects. This work paves the way for the next stages in the development of the IFMIF-DONES facility and program.

Keywords: safety engineering, licensing radioactive facilities, IFMIF-DONES

(Some figures may appear in colour only in the online journal)

^a See the Appendix in Ibarra *et al* (<https://doi.org/10.1088/1741-4326/adb864>) for the EUROfusion WPENS Team.

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1. Introduction

The IFMIF-DONES Facility will be a first-class scientific infrastructure consisting of an accelerator-driven neutron source that delivers around 10^{17} n s^{-1} with a spectrum tailing above 40 MeV. This intense neutron flux will be generated through nuclear stripping reactions, produced by directing a continuous wave (CW) deuteron beam of 125 mA at 40 MeV (with an output power of 5 MW) onto a liquid lithium jet target, circulating at a velocity of 15 m s^{-1} [1].

Safety is a fundamental and transversal discipline throughout the design, construction, operation, and eventual decommissioning of the IFMIF-DONES facility. In this context, Safety Engineering is dedicated to the design, analysis, and implementation of measures and procedures that ensure the protection of workers, the public, and the environment from potential hazards associated to its inherent activities over the facility's life-cycle. This paper is a follow-up of previous works [2, 3].

This paper aims to outline a tailored safety approach that addresses the unique challenges of IFMIF-DONES by providing a comprehensive overview of the Safety Engineering Approach and Licensing Strategy for this one-of-a-kind facility. Such uniqueness involves aspects such as safe management of an extremely high-power particle accelerator (5 MW beam), safe management of a 15 m^3 liquid lithium loop housing activation products (APs), and safe management of material irradiation campaigns and their post-irradiation paths, among others radiological and industrial hazards. Such safety challenges must be addressed without losing the perspective of following a graded approach, establishing safety requirements that are commensurate with the risks and avoiding a blind application of principles which were conceived for nuclear facilities or nuclear power plants.

The overview is organized into ten sections. In section 2, we provide a brief description of the facility. Sections 3 and 4 present the top-level safety regulations, licensing strategy, and radiological safety approach. Sections 5 and 6 focus on the basic engineering inputs necessary to implement the radiological safety engineering approach, specifically material-at-risk (MAR) and Hazard Categorization (including the Seismic Strategy). These inputs form the foundation for the hazard analysis, which is conducted through the risk methodology and identification and study of Reference Accident Scenarios (RASs) in sections 7 and 8. Section 9 outlines the main Safety Systems that are being implemented from an engineering perspective, such as confinement barriers, safety interlocks, and radiation monitoring, among others. Section 10 introduces the application of ALARA (As Low As Reasonably Achievable) principles to minimize occupational radiation exposure (ORE) by ad-hoc design methodologies. Finally, section 11 summarizes several key experimental programs related to safety that are ongoing.

2. Background description of the facility

Figure 1 shows a descriptive lay-out of the IFMIF-DONES facility with the distribution of its components. From an engineering perspective, the facility is organized into five primary Groups of Systems:

- (i) Deuteron Accelerator (Accelerator Systems): A 100 m length LINAC capable of accelerating a CW deuteron beam with a nominal intensity of 125 mA up to 40 MeV, leading to an output power of 5 MW [4, 5].
- (ii) Liquid lithium Target and loops (Lithium Systems): The Target will consist of a 25 mm thick 260 mm wide liquid lithium curtain or jet, circulating at 15 m s^{-1} and at 300°C – 330°C inside the Target Vacuum Chamber (TVC), which is directly connected to the accelerator vacuum chamber [6, 7]. For providing such jet, a closed loop of liquid Li with a flow of $0.1 \text{ m}^3 \text{ s}^{-1}$ is required. The Target accomplishes a double function; (i) it produces the required neutron field for samples irradiation and (ii) evacuates the 5 MW power deposited by the incident beam via heat exchangers and secondary cooling oil loops. In the current design, the rooms housing the Li loop will be in Ar atmosphere to provide inertization and minimize the risk of fires due to air–lithium reaction. The lithium loop is equipped with a parallel purification loop (Impurity Control Subsystem ICS) which continuously extracts both corrosion products and traces of radionuclides that are generated in the lithium as a consequence of the beam-target nuclear interactions. This is done by circulating the lithium through the so-called Traps, which are vessels in which these impurities and radionuclides (such as tritium, Be7 and Activated Corrosion Products (ACPs)) are collected, either by precipitation or chemical bounding. There are three types of traps:
 - (a) Cold Traps to extract impurity compounds by precipitation thanks to their low solubility in lithium at lower temperatures. ACPs will be extracted by these traps as well as the traces of Be7 produced in the target as a consequence of deuteron–lithium reactions. These Be7 traces will be present in the form of nitride compounds. The Cold Trap does not need to be replaced over the life-time of the Facility.
 - (b) Hot Traps (also called tritium traps) to extract the traces of tritium present in the Li loop, also generated as a consequence of deuteron–lithium reactions. This is done by means of yttrium pellets which chemically trap the hydrogen dissolved in the liquid lithium. The tritium Traps will be exchanged in a monthly basis, when an inventory of 0.3 g of H3 is reached in the trap.
 - (c) Nitrogen Traps to extract nitrogen also by chemical reactions. Differently from the two other traps, these traps are placed inside the Dump Tank and nitrogen extraction is not done in a continuous process.

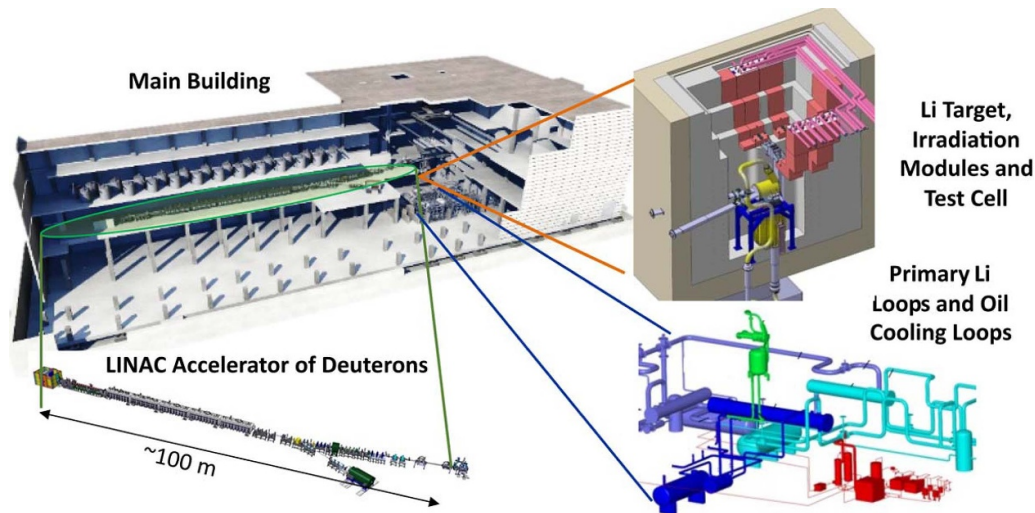


Figure 1. Descriptive lay-out of the facility with the distribution of its main Group of Systems: (i) Accelerator, (ii) Lithium Target and Systems, (iii) Test Cell and Irradiation Modules.

- (iii) Irradiation Modules (Test Systems): Downstream the TVC, separated by a few millimeters, the so-called High Flux Test Module (HFTM) will house the material samples and specimens for irradiation. The specimens shall be kept in a controlled temperature range within 250 °C and 550 °C while continuously monitoring the neutron flux received [8]. Both the TVC and HFTM are placed inside a leak-tight bunker, called Test Cell (TC), filled by He at an absolute pressure of about 90 mbar to provide inertization as well as radiological shielding and confinement [9]. Leak-tightness is provided by a metallic enclosure called TC Liner.
- (iv) Plant, Main Building and Services (Plant and Building Systems) [10]: This Group of Systems houses all the Systems, Structures and Components (SSCs) of the facility that provide services such as Electric Power, industrial water, HVAC, gas supplies, Radioactive Waste Treatments (RWTS), handling and remote handling (RH) systems, etc.
- (v) Central Instrumentation and Control Systems (CICS) [11]: It is in charge of managing, monitoring and controlling all the plant processes, parameters and variables, as well as the data storage and visualization. It is composed by three independent and segregated systems:
 - (a) The Control, Data Access and Communication System (CODAC) coordinates the IFMIF-DONES local control systems, orchestrating their operation and gathering and archiving all the data the plant will produce.
 - (b) The Machine Protection System (MPS) is devoted to the implementation of all the identified functions of investment protection.
 - (c) The Safety Control System (SCS) is devoted to the implementation of all the identified protection functions regarding the personnel, public and environment. More details of the SCS are provided in section 9.

3. Top safety regulations and licensing process

The Safety Approach in IFMIF-DONES is determined by the Top-level Regulation Framework to which is subjected, which is the Spanish law. At this point it is necessary to clearly differentiate between Radiological Safety and Industrial Safety.

3.1. Radiological safety

From a radiological safety perspective, Spain's top-level nuclear and radioactive regulation is governed by the Royal Decree 1217/2024 [12], which establishes specific definitions and categorizations for nuclear and radioactive installations. In short, the term 'Nuclear Facility' is reserved for Nuclear Power Plants, Reactors, and so on, while on the other hand, there are definitions for 'Radioactive Facilities', which are further classified into three categories based on their characteristics and inventory.

In this context, IFMIF-DONES is classified as a Category 1 Radioactive Facility, since it perfectly fits within the definition provided in the law by *Complex installations in which very high inventories of radioactive substances are handled or very high energy flux radiation beams are produced, such that it have a significant potential radiological impact.*

The law establishes that for Category 1 radioactive facilities, such as IFMIF-DONES, the Ministry of Industry is responsible for granting the operating permits, authorizations of changes of ownership, and declarations of decommissioning. This is different from Nuclear Facilities, in which Construction Permits are also required before starting building. This Operation Permit is granted after a positive report and approval from the Spanish Nuclear Regulatory Body, Consejo de Seguridad Nuclear (CSN), which is an independent institution with technical and inspection competences. The documentation required by the

Royal Decree 217/2024 for the operation licensing is the following [12]:

- (i) Descriptive Report of the facility (including site and surrounding land).
- (ii) Safety Analysis Report (including hazard analysis, postulation of accidents and protective measures).
- (iii) Verification of the facility (compliance tests and documentation including maintenance and periodic inspection plans).
- (iv) Operating Rules: Including (i) Quality Assurance Manual, (ii) Radiation Protection Manual and (iii) Technical Specifications of Plant operation.
- (v) Internal Emergency Plan.
- (vi) Provisions for closure and financial coverage.
- (vii) Economic budget of the investment to be made.
- (viii) Physical Protection Plan (Security).

Another key Spanish regulation directly applicable to IFMIF-DONES is the Royal Decree 1029/2022 [13], which addresses health protection against risks associated with exposure to ionizing radiation. This law sets the dose limits for both workers and the public, applicable during planned exposures (normal operation) as well as in emergency situations. These limits are in line with the ICRP recommendations and are consistent with international guidelines: 20 mSv yr⁻¹ for workers, 6 mSv yr⁻¹ for students and trainees, and 1 mSv yr⁻¹ for the public. Additionally, the law defines the responsibilities of the facility's Radiation Protection Unit, outlines the application of the ALARA principle to minimize exposure for both workers and the public (i.e. below the legal limits), and establishes the required classification of areas with exposure risks, such as Controlled Zones and Supervised Zones (more details are provided in sections 9.4 and 10).

With respect to the specific safety design criteria that must be met by IFMIF-DONES, there is a notable distinction from nuclear facilities or nuclear power plants, where design criteria and requirements are governed by the *Instrucciones de Seguridad* (Safety Instructions), which carry the force of law. Category 1 Radioactive Facilities, by definition, are unique and singular installations, and as such, no predefined Safety Instructions exist for them. Instead, the licensing process and design requirements are guided by a specific *Guía de Evaluación* (Evaluation Guide) issued by the CSN on an ad-hoc basis for each Category 1 Radioactive Facility. Currently, there are two Category 1 Radioactive Facilities in Spain [14], one of which is the ALBA Synchrotron [15].

The Evaluation Guide will be developed in collaboration with the CSN during the licensing request process, which is required for operation but not for construction. However, this situation poses a challenge: Specific safety design criteria must be established internally within the project well in advance of this license process request in order to lay the groundwork for the facility's engineering designs. To overcome this situation and provide a safety design framework that is resilient to the uncertainties of the future licensing process, the safety design criteria have been done following the methodologies outlined in the so-called *IS-26, about Basic*

Nuclear Safety Requirements applicable to Nuclear Facilities. This Instruction (which strictly speaking is not mandatory for Radioactive facilities such as IFMIF-DONES), establishes safety design principles such as:

- Defense-in-depth concept based on confinement barriers and prevention, detection and mitigation measures.
- Safety analysis involving identification and evaluation of RASs (Design Basis Accidents (DBAs)), unmitigated vs mitigated analysis, and evaluation of Design Extended Conditions.
- Identification of Safety Functions, and Safety Important Class SSCs.
- General requirements of Safety Functions and components such as Inherent Safety, Passive Safety, Fail-Safe systems, Single failure, Double contingency, Independence, Redundancy and Diversity.

IS-26 concepts are very useful and applicable to IFMIF-DONES as they provide a solid umbrella of guidelines for its design and safety analysis. However, these concepts are applied in *qualitative terms*, focusing on its methodologies and ensuring that the derived safety requirements are always properly balanced with the potential consequences of accidents. Therefore, this approach is being applied taking into account the unique characteristics of IFMIF-DONES, which differ considerably from those of nuclear facilities and reactors (for which the IS-26 is defined). Therefore, referencing aspects and methodologies of the IS-26 in IFMIF-DONES does not necessarily mean imposing the same standards and reliability requirements as those applied to nuclear facilities (commonly referred to as nuclear standards). A Working Group with CSN has already been established to progress in this subject.

3.2. Industrial safety

In addition to Radiological Safety, other aspects that one should not disregard are the ones related to Industrial Safety, i.e. the protection of workers and population from the any other (non-radiological) harmful effects inherent to the IFMIF-DONES activities. This involves, among others, the following fields:

- Construction Safety.
- Electrical Safety.
- Fire Protection Safety (with non-radiological implications).
- Pressurized Components Safety.
- Mechanical Components and Machinery Safety.
- Cranes and handling Safety.
- Cryogenic Safety and Oxygen Deficiency Hazards (ODHs).
- Chemical Process Safety.
- Workplace habitability Safety.

The regulation of these non-radiological safety aspects are not within the competences of the Spanish Nuclear Regulatory body but to the national and regional authorities. The top level regulation is the *Ley 31/1995* [16] about prevention of occupational hazards and the Industry Law *Ley 21/1992* [17],

while there is list of identified standards (royal decrees, guides) which develop a second level of the specific risks.

The design requirements associated to these hazards are then defined within national laws and directives that are in line with the European Harmonized Standards as well as the procedures associated to the CE marking, which apply to products which are intended to be put into service on the European market. The respective *Construction* and *Use Permits* shall be requested to the corresponding authorities to start activities that involve occupational hazards.

3.3. Other international and national guidelines and regulations

All the regulatory principles and guidelines regarding the Radiological Safety outlined in subsection 3.1 are in line with international principles. In particular, the fundamental safety objectives and principles of protection and safety, which provide the basis for the safety requirements, are derived from the IAEA Safety Fundamentals No. SF-1 [18]. Such principles are present in the Spanish RD 1217/2024 [12] and RD 1029/2022 [13]. Similarly applies to aspects of the IAEA General Safety Requirements (GSRs), from Part 1 to 7 (except the ones strictly defined for nuclear facilities, not applicable to IFMIF-DONES).

Regarding comparison to other national regulations, it is particularly interesting to compare the regulatory frameworks of accelerator facilities in USA. In USA, all the large accelerator facilities as well as non-commercial reactors belong to the Department of Energy (DOE) and are regulated through the Code of Federal Regulation, Title 10-Energy, (CFR-10) [19]. There, as in Spain, the norm defines ‘Nuclear Facility’ (Reactor and Non-Reactor) and specifically excludes ‘the accelerators and their operations’ inside the classification of ‘Nuclear Facility’. This is done in the definitions of the CFR 10-830 [19]. In addition, the CFR 10-830 establishes an ‘Hazard Categorization’ for their nuclear facilities through the standard DOE-STD 1027 [20]. This standard again emphasizes that accelerators and their operations are outside the scope of 10 CFR Part 830 because they are excluded from the regulation’s definition of nuclear facility and that this exclusion is irrespective of the radioactive material quantities. Due to this exclusion, the Accelerators in the USA are then specifically regulated by the DOE Order DOE O 420.20 D [21], which is the Order through which facilities such as SNS-ORNL, NSLS-2 BNL, or accelerators in Fermilab are licensed. Complementary to the 420.2 D, another very relevant document taken as reference is the DOE Guideline G420.2-1A [22].

Finally, in addition to the US Regulatory Framework for accelerators, it is interesting to compare with France. In France the Nuclear Facilities are classified by the ‘Nucleaire de Base’ identification. The IFMIF-DONES facility would not be a ‘Nucleaire de Base’ neither in France since it does not fulfill the two conditions of Article R593-3 [23] (ions energy above 300 MeV).

3.4. Licensing and permitting strategy

The strategy to obtain the radiological Operational License of IFMIF-DONES (granted by the CSN) follows a phased approach that aligns with the various installation and commissioning stages of the IFMIF-DONES Accelerator. The approach foresees that the operational licenses will be sought initially for the injector and the low-energy sectors of the accelerator in CW, and 40 MeV operation in a low-duty-cycle pulsed mode (without the target). This results in a radioactive inventory, residual doses, and radiation hazards that are several orders of magnitude lower than those expected during full 40 MeV continuous-wave operation with the beam on target. Consequently, the initial operational licenses will categorize the first commissioning phases of IFMIF-DONES as a Category 2 Radioactive Facility. A facility license modification request to upgrade to Category 1 Radioactive Facility will be submitted later on to the regulatory body, in order to start commissioning with beam into the liquid lithium target.

The requests of *Use Permits* will be carried out as well following a progressive approach, as the respective buildings of the facility are constructed and equipment not involving radiological hazards are installed and put into operation.

4. Radiological safety approach in IFMIF-DONES

As introduced in section 3, the radiological safety approach for IFMIF-DONES incorporates several key principles. Firstly, it adheres to the ALARA (As Low As Reasonably Achievable) principle, which focuses on minimizing radiation doses by optimizing materials to use, exposure times, distances, and shielding, as well as limiting the release of radioactive materials into the environment during both normal operations and abnormal conditions. Additionally, the approach references methodological aspects from IS-26, employing the Defense-in-Depth concept. This concept involves implementing multiple, successive, and independent levels of protection to ensure that several safety layers and barriers must fail before any harmful effects could impact people or the environment. This approach is integrated from the early design phases, incorporating principles of prevention, detection, and mitigation. In particular:

- Minimise the possibility of deviations from normal operation, system failures and human errors (Prevention).
- Detect, control and interrupt deviations from normal operating conditions (Detection).
- Implement the necessary safety systems and procedures to bring the installation to a safe condition following a design-basis accident situation (Mitigation). This safe condition is defined as Plant-Safe-State as described in section 9. In addition, reduce the probability of the occurrence of serious conditions, the uncontrolled release of radioactive materials and the doses received by the workers (Mitigation).

The procedure to apply these principles is the following:

- (i) Definition of Safety Functions.
- (ii) Performing Hazards and Accident Analysis to identify sequence of events that could lead to harmful effects to the personnel, public or environment to capture the so-called 'Reference Accident Scenarios' (RASs). The Hazards and Accident Analysis are based on systematic failure modes and effect analysis (FMEA), and comparison with analysis of other facilities, and they are supported with simulations tools such as MELCOR, ANSYS, or MCNP. Dedicated experimental setups are also being built to provide key information.
- (iii) Identification Safety SSCs to guarantee the success of the Safety Functions, both in normal operation and in accident conditions. These are labeled as Safety Important Class (SIC) SSCs.
- (iv) To establish Requirements to ensure that the Safety Functions of the identified SIC SSCs are fulfilled.
- (v) To establish a Safety Organization, Quality and Management system applied to SIC SSCs, processes and procedures important to Safety in order to ensure that they perform their Safety Functions during the full life-cycle of the Facility.

4.1. IFMIF-DONES safety functions

The main radiological safety functions required for IFMIF-DONES are:

- I. Confinement of radioactive material: ensuring that workers, public and environment are protected against radioactive material releases.
- II. Limitation of exposure to ionizing radiation.

In addition to these, there are two derived functions to support their fulfilment:

- III. Provide Protection of SSCs for safe confinement and limiting exposure: This includes management of processes which can lead to a damage of confinements and/or the implemented measures to limit exposure.
- IV. Provide the supply needed for implementing the Radiological Safety functions: This includes providing all the required means to ensure that the two main Radiological Safety Functions can be provided when necessary, such as highly reliability electric power, compressed air, or any other supplies that are necessary so the active SIC SSCs can perform its Safety Function.

In addition, one has to add the non-radiological (Industrial) Safety Functions which is the following:

- V. Provide protection of workers, population, and the environment from the any other (non-radiological) harmful effects.

The above safety functions are further broken down in some 30 subfunctions to help to capture requirements and components for design.

4.2. Categories and types safety important class SSCs

Based on the Safety functions provided, we define three categories of Safety Important Class (SIC) Systems, Structures and Components:

4.2.1. SIC-1 SSCs. This category applies to SSCs that are required during Anticipated Operational Occurrences (AOOs) or Design Basis Accidents (DBAs) with radiological implications to ensure compliance with the established dose limits to workers and public (see figure 2) and to bring the facility to a Plant-Safe-State.

4.2.2. SIC-2 SSCs. This category applies to:

- (i) SSCs that are required to do not to exceed the dose limits established for workers or the public during Normal plant Operation (such as shielding, radiation area monitoring, individual dosimeters).
- (ii) SSCs whose failure could impede the achievement of a SIC-1 or SIC-2 SSC Safety Function when it may be required.

4.2.3. Non-radiological SIC (I-SIC). This category applies to SSCs that required during normal operation and accidental situations for the protection of workers, population, and the environment from any possible non-radiological harmful effects (Industrial and non-radiological occupational hazards).

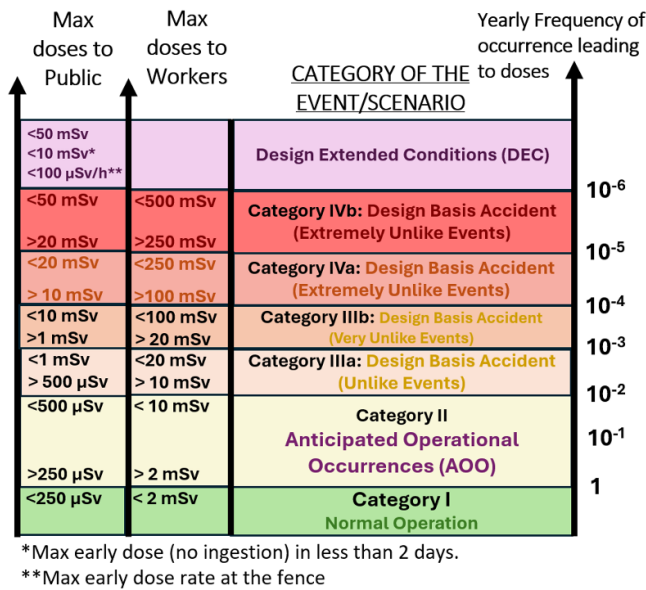
Based on the Safety functions and SIC categories above, we can identify six main types of safety important class SSCs to implement these Radiological and Industrial Safety functions:

- (i) Safety Containments and Enclosures that perform as Confinement Barriers (SIC-1).
- (ii) Safety Instrumentation and Actuators to prevent, detect and mitigate accidental scenarios and to bring the facility to Plant-Safe-State (SIC-1).
- (iii) Required SSCs that are necessary for the operation of the Safety Instrumentation and Actuators (SIC-1).
- (iv) Radiological Area Classification, Shielding, Access Control to radiological Areas and Radiation Monitoring (SIC-2).
- (v) SSCs whose failure could impede the achievement of a SIC-1 or SIC-2 SSC Safety Function when it may be required (SIC-2).
- (vi) Required SSCs that are necessary for the implementation of protection of workers, population, and the environment from any possible non-radiological harmful effects (I-SIC).

During the hazard and accident analysis processes (section 8), these SIC SSCs are identified together with their specific Safety Function. Requirements of these SSCs are also defined based on an assessment of the consequences in case they fail achieving their Safety Function.

Table 1. Occupational radiation exposure (ORE) objectives in normal operation.

Type	Dose Objective
Max worker individual yearly dose	$<2 \text{ mSv yr}^{-1}$ In addition to ALARA application from the design phase based on the procedure of section 10.
Max worker dose in a shift	$<0.5 \text{ mSv/shift}$
Collective Dose to workers	$<250 \text{ person.mSv yr}^{-1}$
Max yearly dose to most exposed individual of the public	$<250 \mu\text{Sv yr}^{-1}$ (counting for gaseous and liquid effluents and skyshine)

**Figure 2.** Chart showing yearly dose limits to public and workers established in the project considering the estimated frequency of occurrence (i.e. Risk limitation).

4.3. Dose objectives and limits in normal operation and accidental conditions

Table 1 and figure 2 show respectively the Radiological dose objectives during normal operation and project limits established for accidental conditions.

For the dose objectives during normal operation in table 1, we distinguish between workers individual yearly dose, maximum workers individual dose in a shift, collective dose and maximum dose to most exposed individual (MEI) in the public. It is worth noting to mention that these are internal objective limits to the project since the legally binding limit is 20 mSv yr^{-1} of individual dose for workers and 1 mSv yr^{-1} to the public as established by the RD 1029/2022 [13]. Nevertheless, internal limits of 2 mSv yr^{-1} and $250 \mu\text{Sv yr}^{-1}$ have been respectively established in line with the limits existing in many other accelerator and scientific facilities to enhance ALARA. Furthermore, additional methodologies are also being established (described section 10) to reduce the ORE from the design phase. In terms of collective dose, an internal limit of $250 \text{ person.mSv yr}^{-1}$ is established, based on the current preliminary ORE estimations that are ongoing.

Regarding dose limits under abnormal and accidental conditions, the approach involves defining these limits based on plant conditions and the frequency of accidents or occurrences. This approach considers some aspects of the methodology outlined in the IS-37 [24], which entitles the design-basis accident analysis of Spanish Nuclear Power Plants (though it is not strictly applicable to IFMIF-DONES). The IS-37 provides a categorization based on the frequency of initial events, distinguishing between normal operation, AOOs, and DBAs. The adaptation to a very low-level risk facility such as IFMIF-DONES involves much lower values of consequences than stated in IS-37. In that sense, it is worth noting that no external emergency plans are deemed necessary for IFMIF-DONES and therefore the dose objective limits are defined taking this requirement into account.

Following the IS-37 conceptual methodology, four main categories of events (or accident scenarios) that lead to consequences to the workers and/or the public have been defined for IFMIF-DONES. Each of them with different dose limits as shown in figure 2. The established limits are following ALARA principle and are much more restrictive than the law for NPP. In addition, they are in line to the ones applied to other similar facilities such as the European Spallation Source in Sweden [25]. Detailed accident analysis are still ongoing but it is worth to mention that current results suggest that even in the worst possible scenarios with no credit to any Safety System the early doses to the public seem to be always well below 10 mSv . This is in line with the Hazard Categorization of the Facility presented in section 6.1.

The categorization, frequency of occurrence and dose limits of figure 2 represent a sort of Risk chart that guides the establishment of Safety Systems and their reliability and robustness requirements during the accident analysis presented in section 8. Safety measures following the defense-in-depth principle to prevent/detect/mitigate accidents are established up to achieving the confidence that these limits are not exceeded within the associated frequency of occurrence. Nevertheless, it is also important to remark that, while efforts to obtain illustrative values are being done, no formal Probabilistic Safety Assessments is expected to be requested during the licensing process. The required success frequency of each defined line-of-defense is set by a top-down approach to fulfill the established risk limits, based on conservative engineering judgment and simplified event trees to provide additional margins. The accomplishment of these success

frequencies by the implemented lines-of-defense will be justified by engineering judgments without performing bottom-up probabilistic analyses.

5. Mobilizable radioactive MAR of the facility

From the point of view of Radiological Safety, one of the main specific Safety aspects of IFMIF-DONES is the generation of radionuclides as a consequence of the interaction of the intense accelerated deuteron beam and the produced neutrons with accelerator components, the lithium Target, and all the surrounding SSCs. This inventory can be of two types: (i) potentially mobilizable and (ii) non-mobilizable. It is considered non-mobilizable all the radionuclides embedded inside the structures when no energy source has been identified capable to release them (implying for instance melting or vaporization). Such immobilization is guaranteed by the high stability of the radionuclides within the matrix of the atoms. On the other hand, we consider the potentially mobilizable inventory the following one:

- Inventory present either in the surrounding gaseous atmospheres of the accelerator, Target or Tests Systems, as well as the one which could migrate to gaseous cooling systems.
- Inventory dissolved in liquids or that could migrate to liquids such as the liquid lithium or water-cooling circuits of the Lithium, Test or Accelerator Systems.
- Inventory that, even if it is in solid state in normal operation, could be subjected to melting or vaporization in AOOs or accident conditions.

Based on these considerations, we present in table 2 the list with estimated activities of the potentially mobilizable radioisotopes currently identified in different areas of the facility. We can refer to this inventory also to as MAR. Activities of the inventory have been estimated in steady state conditions after long term operation of the facility by means of MCNP Monte Carlo Simulations [26]. It shall be noted that activity values of this table could change as the designs progress and more detailed analysis are available. In addition, the following assumptions have been made in the data presented in the table:

- 100% of the H3 produced in the HFTM capsules and structures could end-up in the He cooling circuit due to diffusion, therefore considered mobilizable. This is a very conservative assumption awaiting for more detailed tritium diffusion analysis.
- Only 50% of the ACPs present in the liquid lithium loop are conservatively assumed to be extracted by Cold Traps, the remaining 50% are assumed to be dissolved in the circulating lithium or deposited along the loop.
- 100% of the Back Plate material (placed just downstream the lithium curtain in the Target, with a cross-section area of the beam footprint) are assumed to be potentially volatilized in case of accident with non-detected loss of lithium flow and deposition of the 5 MW of beam power in the Back Plate. Main metallic APs identified in this material are

Mn54, Mn56, Fe55, V52, W185, W187, Co57, Co58 and Co60.

- It is assumed that 5% of the Be7 produced in the Li loop cannot be extracted by the Cold Traps by means of Be_3N_2 precipitation. The solubility of pure Be in the liquid lithium at 300 °C and/or its eventual precipitation/deposition along the Li loop pipes and Heat Exchanger is one of the main uncertainties in the inventory distribution. This uncertainty arises from the lack of reliable data in the literature on beryllium solubility in liquid lithium, primarily due to the extreme difficulty in measuring due to the very low solubility.
- There are currently different proposals of performing tritium breeding experiments inside the TC by placing specific modules behind the HFMT and profiting from the available high neutron flux. From the Safety point of view, a maximum threshold of 0.1 g of tritium production per year is being assumed as an upper bound for these experiments.

The potentially mobilizable inventory leads to a total MAR activity of $2.38 \cdot 10^{15}$ Bq, from which it is worth noting the very large contribution of the Be7 produced in the lithium target, involving a mass of 150 mg in steady state conditions. The design foresees to capture this Be7 in the Cold Traps by Be_3N_2 precipitation. Close to 85% of the total activity of the whole facility is present in these Cold Traps. The second largest contribution is from tritium, also produced in the lithium target, and distributed within the lithium systems: 0.3 g dissolved in the liquid lithium and 0.3 g in the Hot Traps. Actually, a total amount of 3.9 g of tritium is produced in the lithium target per year but the Hot Traps will be monthly replaced when loaded to 0.3 g, so only 0.6 g counts as total tritium inventory in the Lithium Systems during operation.

The potentially mobilizable inventory, or MAR, serves as the foundation for calculating dose consequences to the public and workers in the RASs discussed in section 8. However, MAR represents only the maximum available quantity of radionuclides to be acted on by a given physical stress during the accident scenario. The actual doses resulting from both mitigated and non-mitigated accidents are determined using the Respirable Source Term and Cloud-Exposure Source Terms (ST). These terms quantify the amount of radioactive material that becomes airborne during an accident, could be released, and has the potential to affect the MEI among personnel or the public. Ground deposition and ingestion exposures may also be considered if relevant to the accident scenario. These Source Terms are estimated using the following formula, which is based on a methodology similar to that outlined in a DOE handbook for non-reactor nuclear facilities [27], albeit with some simplifications:

$$\text{ST} = \text{MAR} \cdot \text{DR} \cdot \text{ARRF} \cdot \text{LPF} \cdot \text{DF}$$

where:

- MAR is the material-at-risk for the accident.
- DR is the damage ratio for the accident, which represents the fraction of the MAR actually impacted by the accident-generated conditions.

Table 2. List of the currently identified potentially mobilizable radioisotopes (or material-at-risk) present in the facility.

Area/Sector	Radionuclide	Activity (Bq)
Atmosphere in Accelerator Rooms	H3	$3.8 \cdot 10^4$
	Ar41	$2.4 \cdot 10^{10}$
	Ar37	$6.1 \cdot 10^8$
	N13	$1.0 \cdot 10^6$
	N16	$1.3 \cdot 10^6$
	O15	$7.7 \cdot 10^5$
	C14	$6.0 \cdot 10^1$
TC Atmosphere	H3	$3.3 \cdot 10^7$
Lithium Loop Cell Atmosphere	H3	$4.9 \cdot 10^4$
Test Systems He Cooling Loops	H3	$2.8 \cdot 10^{12}$
TC Water Cooling Loops	H3	$1.3 \cdot 10^{12}$
	Be7	$2.6 \cdot 10^{10}$
	N16	$4.0 \cdot 10^{13}$
	O15	$8.0 \cdot 10^{13}$
	N13	$1.8 \cdot 10^{12}$
	C11	$1.3 \cdot 10^{12}$
	O14	$1.4 \cdot 10^{11}$
Liquid Lithium Loop	H3	$1.1 \cdot 10^{14}$
	Be7	$9.7 \cdot 10^{13}$
	ACPs	$2.3 \cdot 10^{11}$
Primary Oil Loop	H3	$2.0 \cdot 10^8$
Target Back Plate at Risk of Vaporization	H3	$2.9 \cdot 10^8$
	Other APs	$7.0 \cdot 10^{11}$
Liquid Lithium Traps	H3	$1.1 \cdot 10^{14}$
	Be7	$1.9 \cdot 10^{15}$
	ACPs	$2.3 \cdot 10^{11}$
Acc. Equipment Water Systems	H3	
	N16/N13	$1.0 \cdot 10^8$
	O15/O14	
Max Design inventory Tritium Breeders Experiments	H3	$3.6 \cdot 10^{13}$
Total Mobilizable Inventory		$2.38 \cdot 10^{15}$

- ARRF is the airborne release and respirable fraction, which represents the amount of radioactive material suspended in air as an aerosol (thus available for transport), multiplied by the fraction of particles that can be transported through air and inhaled into the human respiratory system. This commonly assumes particles with a 50% cut-size $10 \mu\text{m}$ Aerodynamic Equivalent Diameter. An equivalent parameter could be used as well when cloud, ground or ingestion exposure are also relevant in addition to inhalation.
- LPF is the leak-path-factor, which represents the fraction of airborne particles effectively transported outside a confinement, taking into account passive mechanisms as internal dispersion, re-deposition in surfaces, and/or filtration.
- DF is the dispersion factor of radioactive material outside the Main Building, which is relevant for the estimations of eventual doses to the public (the public fence is situated at 100 m), or the workers situated in office buildings or the Control Room. As a first approach, conservative DFs of the NRC Regulatory Guide 1.145 for accident conditions are being used. Nevertheless, more detailed dispersion estimations are ongoing by means of CFD simulations considering real meteorological data currently recorded on the site. Dispersion Factors are known also as χ/Q parameter.

Most of these factors are assigned based on reasonable yet conservative engineering judgments during the consequence analysis of each RAS. Data from experimental values or deterministic analysis are used when available.

The establishment of Confinement Barriers and their requirements (introduced in section 9.1) are carried out accordingly with this inventory, so the Safety Function *Confinement of radioactive material* is accomplished.

6. Hazard categorization of the facility and seismic strategy

Even though IFMIF-DONES is not a Nuclear Facility, another aspect from the applied IS-26 methodology consists in the design of Safety SSCs resistant to external hazards anticipated during the lifetime of the Facility. Particular attention is given to the potential impact of strong earthquakes that could compromise the safety functions of these SSCs. For this reason, the facility is being designed to withstand the effects of such earthquakes and other extreme natural phenomena that might occur at the site, ensuring that the relevant SIC SSCs continue performing their functions. The strategy to accomplish this is developed in detail in [28], with key points summarized in the following subsections.

6.1. Hazard categorization

In this context, we adopt the methodology outlined in the IAEA SSG-67 *Seismic Design for Nuclear Installations* [29], even though IFMIF-DONES is not classified as a nuclear facility. The SSG-67 is particularly suitable because it incorporates the Graded Approach principle, which aligns the requirements with the potential radiological consequences of a facility's failure under seismic loads. This flexibility allows us to effectively apply the IAEA guidelines to IFMIF-DONES.

The Graded Approach is implemented through the Hazard Categorization of the facility, which is defined by assigning Seismic Design Categories (SDCs). These categories distinguish five different levels of hazards based on the potential on-site and off-site consequences of seismic-driven accidents. Once a category is assigned, the SSG-67 guide provides specific methodologies to determine the reference earthquake, seismic performance goals, and whether to apply nuclear or conventional construction standards. However, the SSG-67, as an international guide, does not provide explicit quantitative criteria for classifying a facility within these categories.

To address this and establish a hazard categorization to IFMIF-DONES, we have taken as reference the standard ANSI/ANS-2.26-2004 *Categorization of Nuclear Facility Structures, Systems, and Components for Seismic Design* [30]. The ANSI/ANS-2.26 establishes a quantitative threshold in unmitigated accidents for considering that no permanent health effects to workers take place and, regarding the public, that they are small enough to require any public warnings. These thresholds are set in doses of 250 mSv and 50 mSv for workers and public respectively in case in which the SSC under analysis fails due to an earthquake. We then establish

an equivalence between this Category in the ANSI/ANS-2.26-2004 and the *Low Hazard Nuclear Installation* provided in the SSG-67, considering the entire IFMIF-DONES installation as it was a single SSC that could fail.

Following this approach, we postulate the worst accident and radiological release that could happen in the IFMIF-DONES facility (the facility 'fails') and therefore categorize its *intrinsic* hazard by comparing with the thresholds of the ANSI/ANS-2.26-2004. We consider this worst-case scenario to be a massive lithium fire involving the entire 15 m³ of lithium inventory. This accident would be triggered by an earthquake that somehow could lead to lithium ignition and the release of the tritium and Be7 dissolved in the loop as well as in the Cold and Hot traps. This scenario is highly conservative, as the unmitigated consequence analysis in ANSI/ANS-2.26-2004 allows for crediting robust safety features and the use of mean values for parameters related to material release, environmental dispersal, and health impacts. Nevertheless, we do not credit any Safety SSC or function, such as the inertization of the lithium rooms. In addition, our current unmitigated analysis of this massive lithium fire and release (which would certainly be a Design Extended Conditions Accident) is done under very conservative assumptions such as:

- (i) A very strong earthquake breaks the lithium primary loop and components, leading to a large spill of 15 m³ at 300 °C of lithium over a surface of 20 m². The earthquake also affects the Cold and Hot Traps, leading to their rupture and spill of their lithium and radionuclides content.
- (ii) The earthquake breaks the metallic liners present in the Lithium loop and Trap Cells, leading to an instant atmosphere replacement and complete loss of inertization of the rooms housing lithium, without time for the spilled Li to cool down.
- (iii) Ignition of the liquid lithium at 300 °C takes place (even if lithium self-ignition below 400 °C in air with normal humidity conditions has never been clearly reported in the literature [31–35]).
- (iv) After ignition, an extensive lithium fire takes place with air continuously entering in the rooms to feed a sustained fire ('unlimited-air' reaction). A constant reaction rate of 11 g m⁻² s⁻¹ is assumed, which corresponds to maximum peak rates measured in experiments burning 43 kg with unlimited supply of normal humidity air [35].

The unmitigated analysis considers as well reasonable yet conservative airborne release fractions and leak-path factors from the rooms of the fire to the exterior of the building, based on engineering judgments and experimental data when available. Dispersion calculations outside the building are being refined by CFD simulations with meteorological data measured on-site. Despite these assumptions and not giving credit to any Safety SSC or function (Design Extended Conditions), the current results suggest that the doses in case of such beyond design accident are at least within 1 and 2 orders of magnitude below the thresholds criteria outlined in the ANSI/ANS 2.26. This implies that material releases that cause health or

environment concerns are not expected to occur in IFMIF-DONES. This result supports classifying IFMIF-DONES as a Low Hazard Installation according to the SSG-67 [29], paving the way for the establishment of a well-justified and solid Seismic and Normative Strategy.

6.2. Seismic strategy

As mentioned in the previous section, the seismic strategy for IFMIF-DONES follows a similar approach to the one used in nuclear facilities, particularly in terms of methodology and nomenclature, while being adapted to our particularities. In that sense, two main levels of seismic vibratory ground motion hazard are defined as the design basis earthquakes for the Facility, the so-called SL-1 and SL-2 earthquakes. The SL-2 earthquake is defined as the vibratory ground motion for which the SIC SSCs of the facility must be designed to perform their safety function during and/or after the occurrence of a seismic event of such severity [29]. The SL-1, on the other hand, is defined to ensure the possibility of continued operation in the event of a less severe, but more probable, earthquake. They could also be seen as the ‘Safety Important’ and ‘Operational’ earthquakes respectively. A third type of earthquake, known as SL-3 or Beyond Design Basis earthquake, is also defined and derived from the SL-2. Safety Important SSCs do not need to withstand this SL-3 earthquake to the same extent as a SL-2, but it is used in the verification that seismic design margins are adequate.

From Safety point of view, the most important aspect of the Seismic Strategy is to define the SL-2 earthquake. This is being carried out following these procedures:

- (i) Performing a site-specific probabilistic seismic hazard analysis (PSHA), which considers the collective contribution from all potential sources of earthquake shaking at the site, while treating explicitly the uncertainties. This is done following the general guidance given in IAEA Safety Guide SSG-9 [36] as well as the ANSI/ANS 2.29 [37]. In addition, these seismic hazard curves have been modified to include site effects (i.e. specific ground conditions at the IFMIF-DONES site) by applying a probabilistic methodology, to be coherent with the probabilistic nature of the PSHA. This has been done by performing local Geotechnical and geophysical characterizations of the soil profile using the methodologies of appendix B of [38].
- (ii) Establishing the SL-2 earthquake following a ‘Performance-based’ approach. The Seismic Target Performance Goal (STPG) is defined in terms of a maximum acceptable annual frequency of losing the fundamental safety functions of the installation as a result of earthquakes. This STPG goal is set in 10^{-4} per year consistent with the Low Hazard Categorization achieved by the SSG-67 application presented in section 6.1.
- (iii) Defining the SL-2 earthquake and obtaining the Design Response Spectra (free field) for the selected STPG following the procedures of the standard ASCE 43-19 [39].

- (iv) Obtaining the In-Structure Response Spectra of the SL-2 (i.e. accelerations in the different floors of the Main Building) by means of structural calculations and following the procedures of the ASCE 4-16 standard [40]. Safety Important SSCs should be designed and qualified to withstand these accelerations without losing their capability to perform their Safety Functions.

Finally, and once all the SIC SSCs are designed, an additional evaluation will be done to ensure that the design is adequately conservative and that margins are available to withstand external events more severe than those selected for the design. Part of this assessment is done to confirm that those margins are enough to avoid cliff-edge effects. This evaluation is carried out by following the international procedures of [41] and the definition of the Beyond Design Basis earthquake (SL-3), which has been set to be 1.25 times the SL-2 design basis earthquake.

7. Risk assessment methods

As introduced in section 4, the corner stone of the implementation of the Radiological Safety approach is done through the hazard analysis and risk assessment consisting in the identification and evaluation of RASs. This is consistent with the requested documentation during the licensing process for Category I radioactive Facilities [12] as well as with the Defense-in-depth methodology that is being applied to IFMIF-DONES taking as reference the IS-26 [42] (for nuclear facilities).

The starting point of the hazards and risk assessment are extensive FMEA [43] carried out across the facility, following a top-down approach [2, 3, 44, 45]. From these analyses, different Postulated Initiating Events (PIEs) that could derive in harm to the workers or public are identified, together with an initially assigned frequency of occurrence (based on engineering judgments guided by failure rates data or operational experience when is available, keeping some conservative margins).

Then, the possible development of the sequence of events triggered by each PIE are thoughtfully studied leading, when applicable, to the identification a RAS. The current set of RAS under study for the facility is enlisted in section 8.

During each RAS analysis, the so called ‘un-mitigated consequences’ of the accident are estimated (i.e. as if there was not any specific prevention/detection/mitigation measure in place). These unmitigated consequences (in terms of doses to public and workers) are studied by means of deterministic analyses and event trees methodology. These deterministic analyses involve the use of simulations tools such as MELCOR [46, 47], finite elements simulations (ANSYS®) or Monte Carlo simulations (MCNP) [26]. In addition, experimental programs are launched when necessary to reduce uncertainties, as described in section 11.

Conservative assumptions are systematically applied to compensate uncertainties, while efforts are made to use parameters that fall within the range of possible values considering the physical and chemical conditions of the accidents. With these analyses, the parameters of the Source Term formula introduced in section 5 are assigned. The Dispersion Factors (χ/Q parameters) of releases outside the building that are currently being applied have been obtained following the methodology of the NRC Regulatory Guide 1.145 for accident conditions [48] (class D weather conditions, 1 m s^{-1} wind velocity, and 100 m distance to the fence). Nevertheless, more detailed studies based on CFD simulations are ongoing with the use of real site meteorological data given the limitations of these dispersion models to short distances. Once the Source Terms are assigned, doses to the MEI are estimated by applying the ICRP dose coefficient [49]. Support with alternative methods to estimate dose consequences is also obtained based on GENII and UFOTRI [3].

The obtained unmitigated doses with the associated yearly frequency of occurrence of these accident analyses are then compared with the Risk chart of the established Dose Limits presented in figure 2. If doses in an accident sequence are above the thresholds, Safety Important SSCs are then defined to implement Safety Functions and limit or eliminate the consequences in an iterative process. The reliability requirements of these SIC SSCs are then also assigned to guarantee that these dose limits are not exceeded over the life-cycle of the Facility, taking into account the frequency of occurrence of the PIE and the assigned probability of success/failure of the defined lines-of-defense made of SIC SSCs, as well as other Safety administrative procedures. As introduced in section 4, the assignation and fulfillment of these frequencies are made by engineering judgments considering conservative margins and no formal bottom-up probabilistic analysis are performed.

This methodology allows the management of the potential radiation hazards, by defining the specific Safety Important Class SSCs and safety administrative procedures to minimize the risks and mitigate their consequences.

8. RASs and safety important class SSCs

Table 3 shows the current list of the main RASs that are under study. Since this is an ongoing work, this list does not provide yet a detailed categorization within AOOs, DBAs or Beyond Design Accident (DEC), according to the Dose Limits presented in figure 2. Nevertheless, it can be advanced that the consequences of most of these RAS will be within the reduced doses of the AOO category and the frequency of occurrence of the most critical ones will be within DEC. In addition, current results indicate that doses to the public in the worst-possible scenario (without credit to any SIC SCC) are not exceeding 10 mSv, consistently with the Hazard Categorization of the Facility introduced in section 6.1. The list of accidents in table 3 is also including at this stage some scenarios that are not radiologically relevant (related to non-radiological safety) but are in any case quite specific to the Facility, such as the ones of ODH and cryogenic hazards.

9. Main IFMIF-DONES safety systems

Based on the different types of SIC SSCs introduced in section 4, and the accident analysis present in section 8, we provide in the next subsections a description of the main IFMIF-DONES engineering safety systems, which are transversally distributed across its Groups of Systems.

9.1. Safety confinement barriers

The definition of Confinement Barriers is one of the cornerstones to fulfill the Safety functions of IFMIF-DONES. These confinements barriers are being established following the defense-in-depth principle, in terms of consecutive and independent levels of protection that would need to fail to lead to harmful effects on the personnel, public or environment. A clear definition of the barriers and the inventory and processes which are being confined by them is an essential aspect to establish their manufacturing requirements and their applicable codes and standards (consistently the consequences of their failure).

Figure 3 shows a sketch with the boundaries distribution of the Confinement Barriers that are currently proposed for the Facility. In this context, it is important to highlight the difference that we establish between Confinement Barrier and Safety Confinement Barrier. There are some confinement barriers that are not safety-credited due to the technological complexity to ensure their reliability in all the design base RASs, such as the lithium loop piping. To compensate this, an enclosing safety credited barrier, such as the liner in the LLC is defined. In addition, it is important to remark that each Safety Confinement Barrier has a passive part (the walls of the confinement) and active parts (e.g. safety isolation valves that isolate all the barrier enclosure when triggered by a Safety Interlock). In any case, the design is aiming at having most of these active valves fail-safe.

Taking this into account, the Safety Confinement Barriers are established taking particular attention at the inventory that is enclosed within them (table 2). The main ones are the following:

- The lithium traps containers, in which most of the radioactive inventory of the facility will be present (Be7, H3 and ACPs). These are leak-tight metal vessels with safety isolation valves at the inlet and outlet lithium pipes.
- The Trap Cell liners, which are leak-tight metal liners covering the internal concrete walls of the trap cells (one for each trap). These liners keep an Ar atmosphere at C4 relative pressure to provide inertization and dynamic confinement.
- The enclosure involving the TC Liner, LLC Liner, Target Interface Room (TIR) Liner and RIR-Cabinet Liner. This is the primary confinement of most of the process of the Facility (except the traps, which have independent liners). These are Safety Confinement Barriers composed by multiple independent leak-tight metallic liners adjacent to each others. They are physically separated by metallic boundaries, since the operation conditions of the rooms/cells are

Table 3. List of the main Reference Accident Scenarios that are currently under study, classified according to their relation of Lithium Systems, Accelerator Systems, Test Systems or Building & Plant Systems. For simplicity, the presented list does not discriminate between consequences to the public or worker, or if these postulated accidents are categorized within Anticipated Operational Occurrences, Design Basis Accidents or Beyond Design Accident (DEC), as this is part of the ongoing analyses.

RAS key	Description
LS2-1	Loss of flow in the lithium loop while Beam is ON
LS2-2	Loss of heat sink for removal of heat loads from Li loop due to failure of secondary Loop pump
LS1-1-3	Lithium fire events in LLC, ICS or TC Areas during operation
LS1-4-5	Lithium fire events in LLC, TC or AC Areas during maintenance
LS3-1/4	Loss of lithium in lithium loop cell due to large or small breaks at the electromagnetic pump outlet
LS3-2/5	Loss of lithium in the TC due to large or small break in piping running inside the cell
LS3-6	Li spill in Cold Traps Cell or in Hot Traps Cell
LS3-3	Loss of vacuum in Target Vacuum Chamber due to BP failure
AS3-2	Loss of vacuum in beam duct and air ingress
AS3-1	Cooling water ingress in the accelerator beam duct
AS2-1	Leaks of D2 or H2 into the Accelerator Vault due to rupture of gas supply system
AS3-3	ODH inside Accelerator Vault or CryoPlant due to cryogenic circuit failure
AS2-2	Excessive power on the beam dump
AS4-2	Beam mis-steering event or excessive beam spill with consequences outside the Accelerator Vault
AS4-3	Inadvertent or unauthorized removal of moveable radiation shielding
TS3-1	Loss of helium gas from HFTM cooling circuit inside TC
TS3-2	Loss of flow in the TS-HCS-LP due to spurious valve closure
TS3-3	Loss of helium gas from HFTM cooling circuit inside the cooling room hosting TS-HCS-LP equip.
TS3-4	Loss of cooling water flow in the TC-WCS
TS3-5	Leak of activated cooling water from TC-WCS circuit inside the room hosting the TC-WCS equipment
TS3-7	Loss of TC liner confinement and tritium release to neighbor rooms
TS4-1	Direct exposure to TC-WCS pipes running in occupied area
TS4-2	Direct exposure due to cracks or gaps in TS shielding blocks
TS4-3	Failure of neutron shutter while Complementary Experiments room is occupied
WM3-1	Leaks in Radioactive Waste Treatment Systems
MB1-1	Conventional fire event in Main Building
MB3-1	Loss of negative pressure in activated rooms leading to radiological risk
MB3-2	Leaks of Inert Gasses in inertized rooms leading to ODH
MB7-1	Design basis seismic event
MB6-1	Aircraft impact event

different. e.g. TC operates with He atmosphere at a pressure of 90 mbar absolute (vacuum conditions). Nevertheless, these boundaries between the independent leak-tight metallic liners are not safety credited. The Safety barrier is the enclosure that they form all together.

- Piping of water or gas cooling systems of components of the Test Systems and Accelerator Systems in which there is a significant radioactive inventory flowing and that go outside the primary confinement liners through the ancillary rooms. Non of these loops go outside the Main Building since heat sink is provided by independent loops via heat exchangers. The secondary loops are not Safety credited confinements.
- Main Building HVAC Dynamic Confinement: This is the outer Safety Credited Confinement Barrier that contains all the previous ones. It is based in maintaining under lower pressure those areas with higher contamination potential, thus assuring air ventilation flows from cleaner to more contaminated—or potentially contaminated—areas. There are four levels of potentially contaminated areas (C1–C4),

being C4 the ones at lower pressure. The exhaust of the C4 HVAC is duly filtered.

The application of different design and manufacturing standards to these Safety Confinement Barriers is being studied. In terms of HVAC dynamic confinement, the reference standard that is being followed is the ISO 17873 [50]. In addition, the ISO 10648 [51] is being applied in terms of leak-tightness requirements to inert rooms such as Li Loop Cell liner, Trap Cell liners, TIR liner and RIR-Cabinet. For the TC liner, and Trap Cells vessels, design, manufacturing and quality aspects of the RCC-MRx [52] Levels N2 and N3 are being under study (taking also in mind that the RCC-MRx is conceived for pressurized equipment while the TC liner operates at vacuum conditions). For the cooling systems outside the primary confinement, both RCC-MRx or the conventional pressurized equipment standard Directive 2014/68/EU (EN 13445 [53]) will be applied with some enhancements, depending on the inventory and consequence assessments.

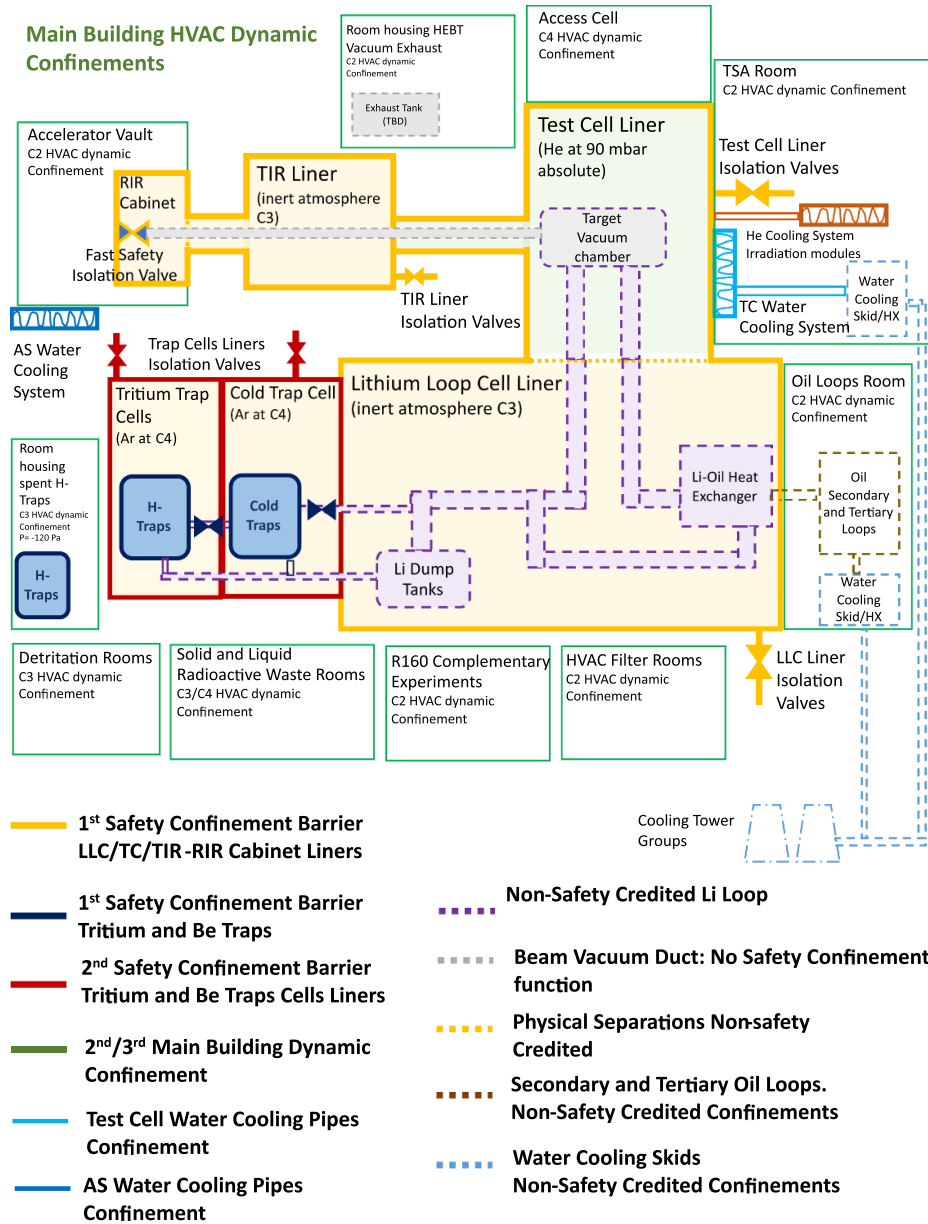


Figure 3. Sketch showing the different Confinement Barriers that are currently foreseen.

9.2. Safety interlocks

Together with the definition of Safety Confinement Barriers, the defense-in-depth principle applied to IFMIF-DONES consists of the definition of a wide set of Instrumentation and Actuators having a role in the achievement of the Safety Functions along the prevention-detection-mitigation criterion.

This is done by the continuous monitoring of the corresponding processes by safety credited instrumentation and automatically triggering Safety Interlocks when defined thresholds are exceeded. These Safety Interlocks are managed by the so-called ‘Plant Safety Subsystem (PSS)’ which belongs to the Central SCS. The PSS centrally orchestrates the respective actuation (Safety Commands) to bring the Facility to the Plant-Safe-State when a Safety Interlock is received from a Safety Local Instrumentation & Control System LICS.

We aim at having a simple and robust fully automatic Interlock system, with no need of manual actions from the Operators.

Figure 4 shows the Safety Interlocks Architecture. This architecture is completely independent, segregated, and blind to other control systems, such as CODAC and the MPSs [54]. Safety credited Transmitters and Actuators are distributed across the facility, together with their local controllers. When Safety transmitter detects that a Safety threshold is exceeded, the Local Safety Controller sends a fail-safe Boolean signal to the SCS.PSS, which works as an ‘OR Logic Gate’, quickly sending another Boolean signal (Safety Command) to the corresponding Safety LICS and actuators to mitigate the potential hazard. Safety Interlocks and Commands are implemented in two independent trains to increase reliability.

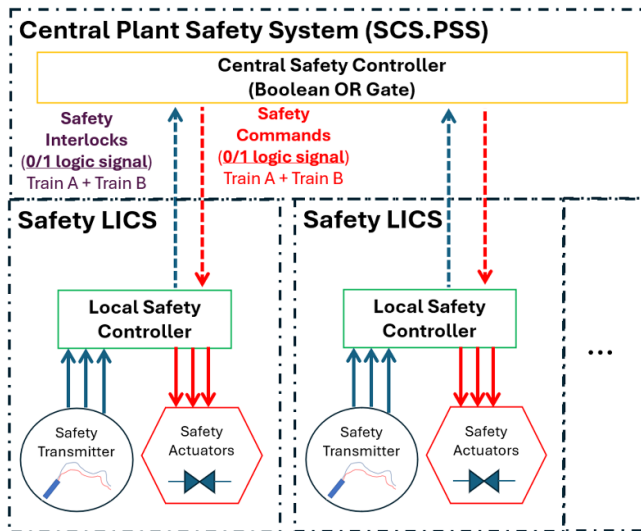


Figure 4. Foreseen Architecture of the Safety Interlocks of the facility. Instruments, actuators and Local Safety controllers are distributed across Safety LICs, while safety command decisions are made centrally by the Plant Safety System.

Currently, around 29 Safety Interlock Signals and 18 Safety Actuation are identified to detect and mitigate potential hazards, according to the RAS analyses. One of the most important one is related to the detection of a potential instability of the Li curtain in the target and performing a fast beam shutdown before damaging the Back Plate. In this sense, we distinguish between to types of Safety Interlocks Architectures:

- (i) Fast Safety Interlocks, which shall actuate in the order of tens of milliseconds from the abnormal physical process. This applies to events that require a Fast Safety Beam Shutdown and Fast Vacuum Isolation of the target chamber [55], such as Li curtain instability, Vacuum loss, or seismic event.
- (ii) Slow Safety Interlock, in which there are not strong time constraints (order of seconds).

The reference design aims at implementing the Safety Interlocks relying only on Safe PLCs for the ‘slow response architecture’ and hardwired, highly reliable, and easy to integrate logic gates architectures for ‘Fast Response’.

The current reference standards for the design of the Safety Interlocks are the IEC 61508 [56] and IEC 61511 [57], which cover the general requirements for the so-called Safety Instrumented Systems (SISs) and Safety Instrumented Functions (SIFs) in all phases of their safety life cycle (SLC). For each SIF, a certain Safety Integrity Level (SIL) is assigned, which indicates the probability of an Instrumented Function for satisfactorily performing the required safety functions under all stated conditions. In addition, the norm is organized in a SLC, which frames all necessary activities in each phase of the life cycle to meet all requirements. In the case of IFMIF-DONES, the SIL requirement for each Safety Interlock will be defined case-by-case, based on the consequence analysis of the

related RAS and consistently with the frequency of occurrence of the dose objectives of figure 2.

9.3. Radiation monitoring

A crucial safety requirement mandated by regulations is the radiation monitoring of people and the environment through continuous measurement of dose rates in areas with potential exposure to ionizing radiation and specific activities where contamination risk exists. This is achieved through the RAMSES (Radiation Monitoring System for the Environment and Safety), which comprises an extensive network of radiation monitors distributed across the facility, the site, and workers. It is composed by:

- (i) Area Radiological Monitoring Subsystem (ARMS)
- (ii) Effluent Releases Monitoring Subsystem (ERMS)
- (iii) Environmental Monitoring Subsystem (EMS)
- (iv) Individual Monitoring Subsystem (IMS)
- (v) Process Monitoring Subsystem (PMS)

In terms of requirements and reliability standards, the current proposal is to use a similar approach as the ones applied in other accelerator facilities (such as CERN or ESS), in which the IEC 61508 is applied with SIL-2 requirements [58]. In this way, IFMIF-DONES could directly profit from the well-proven developed solutions and technologies in the field which are directly applicable.

9.4. Radiological areas classification, shielding and access systems

Shielding and radiological areas classification contribute to the development of the main Safety Function of providing limitation of radioactive exposure. This is achieved by Radiological Areas Classification consistently with the Spanish laws (RD 1029/2022 [13]) and in line with the Council Directive 2013/59/Euratom [59]. Workplaces with potential exposure and/or contamination are divided in the following:

- Supervised areas.
- Controlled areas, which are then divided in the following types:
 - Free Permanence areas.
 - Limited Permanence areas.
 - Specially Regulated Access areas.
 - Forbidden Access areas.

The main forbidden access areas during operation are the accelerator vault and the lithium loop cell. The TC and TIR will be always Forbidden Access areas, both in operation and maintenance, due to the high residual doses present. Hence, all the maintenance operations in the TC and TIR shall be done by RH equipment. The Access Cell (to the TC and TIR) will be a Forbidden Access area in maintenance, while the TC upper shielding is open.

All the rooms adjacent to the AV, TIR, and LLC are shielded by at least 1.5 m thickness concrete walls, so radiation

in these adjacent rooms is low enough and access is possible during operation. The shielding around the TC is within 3.5–5 m (depending on the area), with some zones made of magnetite heavy concrete. The dimensioning of shielding is done based on a systematic application of MCNP analyses, which follows an iterative approach continuously adapted to changes in design, such as more precise geometry of structures, penetrations, feedthroughs, HVAC ducts, etc.

More details of the MCNP modeling tools used in the project, together with the libraries and transport packages, can be found in [26]. Effective doses are systematically calculated both in operation (beam on) as well as in maintenance, by computing residual doses due to activation of components and structures.

The Safety System in charge of managing or limiting the access of people to specific areas and enclosures with radiological hazards inside the plant is the Personnel Access Safety Subsystem (PASS), which belongs to the SCS. In addition, this subsystem can trigger Safety Interlocks to the SCS.PSS to shutdown equipment (such as the accelerator) in case non-authorized intrusions take place. The SCS.PASS is composed by four main subsystems:

- (i) The Personnel Access Restriction Subsystem (PARS): It consists of distributed devices across the access points which will ensure a physical barrier and will control access by means of automatic or remotely controlled security gates for personnel and material (Doors Lock, CAMS, Interphone, Alarms, etc). At the access point level, it identifies, authenticates and verifies the user's authorizations by means of identity readers. It communicates and interfaces with the PASS Servers, in which IFMIF-DONES human resource databases and access management are present.
- (ii) The PASS servers in which IFMIF-DONES human resource databases and access management are present and with which the PARS will communicate to allow access.
- (iii) The operator's dedicated desktop and workstations in Main Control Room.
- (iv) The Personnel Access Interlock Subsystem (PAIS): Its purpose is to ensure that at any time each room of the Facility is safe for the worker. The principles of the basic interlocking are:
 - (a) In access mode: no beam or hazard is in the zone;
 - (b) In beam mode: no person is in the zone and the beam shall be shutdown immediately in case of an intrusion.
 In order to implement its safety functions, the PASS-PAIS interfaces with the Plant Safety System PSS (sending Safety Interlocks) as well as with the Global Operation State of the Plant.

This subsystem differentiation is essential for the assignment of applicable normative since not the same reliability requirements apply. The most critical subsystem is the PAIS. The proposal for IFMIF-DONES is to design PAIS subsystem according to the functional safety principles of the IEC 61513 and IEC 61511 standards, as it has been done in other accelerator facilities such as CERN and ESS [60–62].

Access Control due to Security functions is managed independently of the SCS.

10. Application of ALARA principles: criteria for hands-on/hands-off/RH classifications

ORE of IFMIF-DONES workers is being assessed from early design phases pursuing to implement the ALARA optimization principle. In that sense, one of the most relevant aspects for such ORE optimizations is the strategy that is implemented in the design regarding hands-on, hands-off and RH interventions under radiation fields during maintenance. Particularly in 'hot areas' such as the accelerator surroundings, or lithium loop piping, in which a strong trade-off is present between reducing ORE (by means of waiting for longer decay cooling times or/and full RH interventions) and the short maintenance times required to accomplish the strict availability targets of the facility (255 days per year). This is due to the fact that the high availability requirement of the facility pushes for faster hands-on interventions and shorter cooling times. To optimize this balance, we are introducing the following classification based on the maintenance strategy:

- Hands-on (H-on) design maintenance: Applicable to components/sectors in which the worker can be close to the device and perform all the required operations using directly his hands. No additional ad-hoc mechanical-design optimizations are required beyond training and good-engineering practices. Nevertheless, other ALARA optimizations could have been done in a previous design step (for instance, choosing lower activation materials).
- Hands-off (H-off) design maintenance: Applicable to components/sectors in which the main part of the body of the worker is within >1 m from the surface of the device during the maintenance operation, with the help of specially designed tooling. The worker can get closer to the device in particular moments for fast inspections or very quick connections as long as it is below 1–2 min for the specific short intervention. Hands-off classified components require a thorough design, involving aspects such as:
 - Maintenance operation within >1 m with the help of specially designed tooling (although close hands-on operations are possible if they are short enough).
 - Design optimized to speed-up intervention times, taking into account aspects such as accessibility, space, number of operations to be performed, risk analysis during the interventions and 'rescue plans' in case of failure of the intervention strategy.
 - Perform, during the design phase, estimations of the maintenance times for every operation required close to the device. In addition, the design should address a clear definition of the methodology and tooling employed. This includes studies of the eventual use of local shielding to protect the worker body during the intervention.

- All the maintenance operations/interventions of these H-off components shall be carried out under the Radio Protection team supervision.
- RH design maintenance: applicable to components/sections in which the operator shall be at least several meters far from the device for all the required operations so it does not receive relevant doses from its activation. These operations are performed by robots or tele-manipulators specially designed for this purpose.

Together with these definitions, we propose a methodology to define H-on/H-off/RH classification of components in the design phase. The goal with this methodology is to accomplish both the target individual dose limit of 2 mSv yr^{-1} , and the top ORE objectives of collective dose per year ($250 \text{ p-mSv yr}^{-1}$). The methodology is based on criteria that takes into account both the dose rates in the vicinity of the component/sector and the intervention times in such place. In fact, accounting for these intervention times is a crucial aspect of the methodology, as it helps to address the limitations of relying on too simplistic criteria only based on dose rates. A single dose rate criteria overlooks the fact that interventions in areas with relatively high dose rates could often be completed quite quickly, meaning they do not contribute significantly to the overall ORE.

For this reason, we propose a methodology where the criteria for implementing a H-on/H-off/RH design in a specific ‘equipment sector’ are determined based on curves of dose-rate vs total maintenance time in such sector over the course of a year (close to the device). This method considers both the annual individual maintenance time and the collective maintenance time within a given ‘equipment sector’ as illustrated in figure 5. An ‘equipment sector’ could be, for instance, an accelerator cryo-module, a scrapper, a group of magnets in the HEBT, etc). Figure 6 shows an example of sectorization for the IFMIF-DONES Accelerator together with the estimated ambient dose rates after 1 week of decay cooling. For each of these ‘equipment sector’ (red squares) we assign individual and collective ‘yearly dose budgets’ of $800 \mu\text{Sv yr}^{-1}$ and 10 p-mSv yr^{-1} respectively. Furthermore, maximum doses per sector in hands-on interventions are established in $250 \mu\text{Sv yr}^{-1}$ and 3 p-mSv yr^{-1} . These ‘dose budgets’ are consistent with the slope of the curves in figure 5. In addition, cut-offs of the curves are established for very short maintenance times (below 6 min yr^{-1} per worker) and very long ones (above 200 h).

Once the sectorization and ‘yearly dose budgets’ curves are defined, we apply the iterative methodology summarized in figure 7 to decide if the designs of equipment in a specific sector should be done compatible with hands-on, hand-off or RH maintenance (or a combination of them, as long as the ‘yearly dose budgets’ are not exceeded). The input parameters are (i) the Dose Rates around the devices obtained by MCNP simulations such as the ones shown in figure 6, (ii) Rough estimated maintenance times per year close to device and (iii) the curves with individual and collective budgets shown in figure 5. Based on these inputs, the curves indicate in which H-on/H-off/RH Zone this sector is falling. Then, depending of the characteristics and particularities of the devices in such

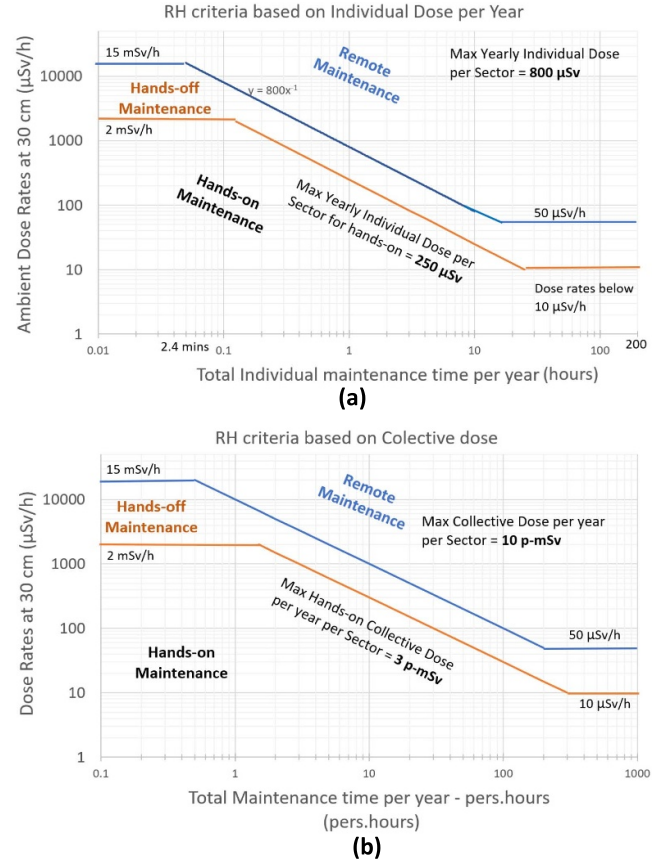


Figure 5. Dose curves vs maintenance time per year close to a device in an ‘Equipment Sector’ for individual exposure (a) and collective exposure (b). These curves are used to define the maintenance mode (H-on, H-off or RH) according to the methodology drafted in figure 7.

sector, it is possible to implement changes in the design (such as optimize maintenance times) to shift from RH to H-off or from H-off to H-on as long as the ‘yearly dose budgets’ are not exceeded.

11. Experimental programs related to safety

As introduced in section 8 and given the innovative combination of equipment and phenomenology, one of the key aspects of the risk assessments and accident analysis is the reduction of uncertainties and the demonstration of taken assumptions. The demonstrations can be done in most of the cases by calculations/analysis as well as by previous experimental works available in the literature. However, due to the singularity of the facility, there are some aspects in which no experimental data is available and direct extrapolations are not straight forward. For these cases, several experimental programs are being carried out to support the safety design and the licensing process. Some of these are the following:

11.1. EMP prototyping and testing

Prototyping and testing of the permanent magnet electromagnetic pump (EMP) is being conducted at the Institute of

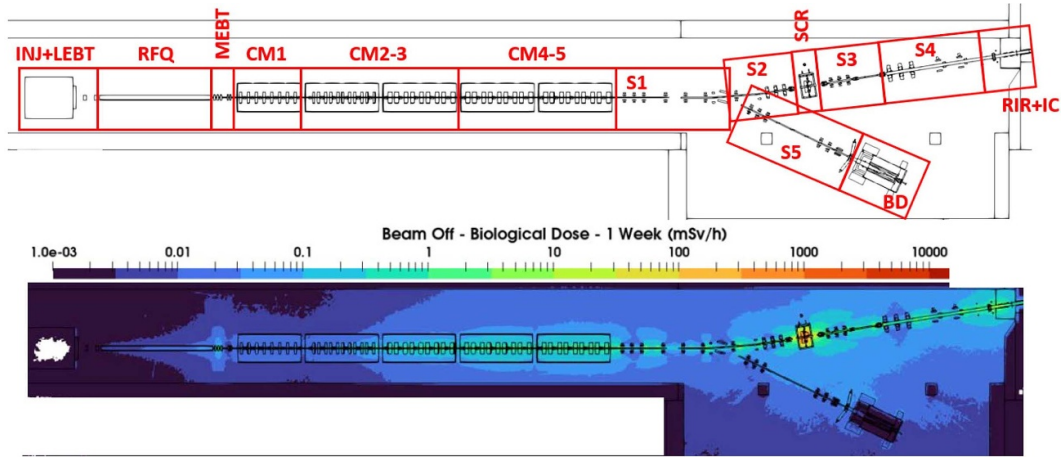


Figure 6. Sketch showing the ‘Equipment Sectorization’ applied to the accelerator (top) and dose rates maps around the accelerator after one week of cooling.

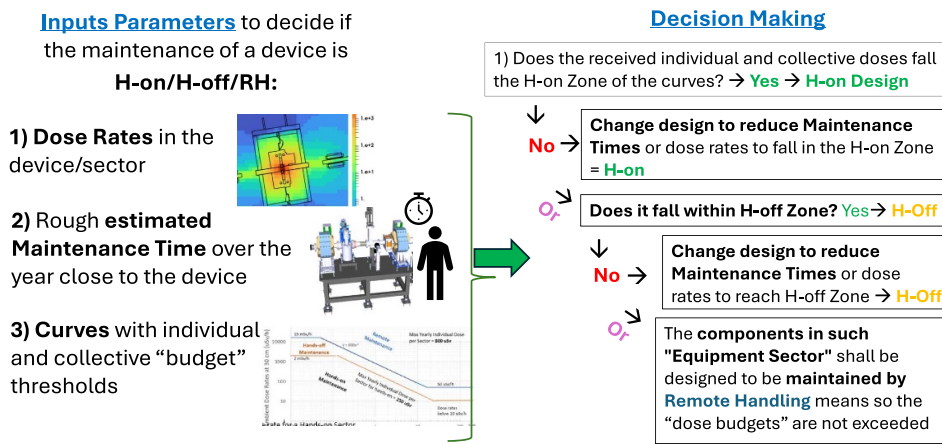


Figure 7. Methodology for the design criteria regarding H-on/H-off/RH maintenance strategy in an ‘Equipment Sector’.

Physics of the University of Latvia (IPUL) [63]. The EMP for the lithium Loop of IFMIF-DONES is particularly challenging, as it must deliver a highly stable flow of $0.1 \text{ m}^3 \text{ s}^{-1}$ in a loop operating under free-surface vacuum conditions, while remaining resilient to potential issues like cavitation at the inlet. The experimental setup at IPUL consists of a sodium circulation loop equipped with a 73 l s^{-1} permanent magnet EMP (a prototype of the one intended for IFMIF-DONES) and a series of valves to adjust the hydraulic resistance of the system. This loop is used to validate both the pump design and the mathematical models, which can later be extrapolated for lithium operation as required in IFMIF-DONES.

From a safety perspective, a key aspect is to characterize the coast-down curves of the EMP in the event of a trip, as this is a potential initiating event in the RAS LS2-1 scenario, shown in table 3 and it is essential to know how much time there is available to shutdown the beam. To address this, the pump design incorporates a flywheel attached to the rotor, which provides additional inertia. Based on current experimental results and lithium extrapolations, this flywheel offers more than 10 s of margin before the lithium flow drops below the critical threshold in which the Back Plate could be damaged by

the beam. The flywheel solution is considered safer and more reliable than using two pumps (whether in series or parallel), as it avoids all the associated complexity.

11.2. Small scale Li ignition experiments

As stated in sections 6.1 and 8, one of the most relevant hazard of the facility is the events of lithium fire. Despite significant literature about lithium fire exists, the results are often scattered and show considerable variability due to the strong dependence on specific conditions, such as initial temperature, gas atmosphere, humidity levels or crucible temperatures among others [32]. For this reason, several small experiments are being carried out in the last years in the context of IFMIF-DONES project regarding the characterization of lithium ignition and reaction kinetics in different atmospheres and conditions. These experiments have been performed mainly in the Karlsruhe Institute of Technology (LiGNIT experiments) by using the VACARC setup [64]. Other small scale experiments are being performed at the Research Institutes of Sweden AB (RISE), studying the reactivity of liquid lithium in different

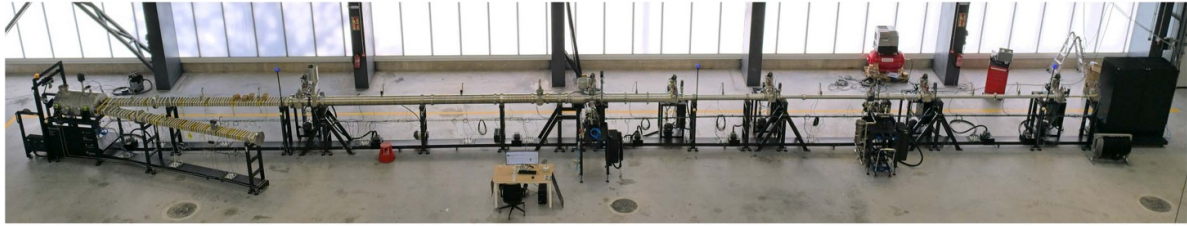


Figure 8. Picture of the MuVacAS experimental setup in the IFMIF-DONES site.

atmospheres, changing moisture, oxygen and nitrogen content as well as the relative latent energy available for the reaction.

11.3. LiFIRE experimental setup

The LiFIRE experimental facility has been recently installed at CIEMAT and represents larger scale experiments with respect to the ones in KIT or RISE [65]. It is equipped with a 2 m³ steel vessel and can handle lithium samples up to 500 g. The objectives of LiFire are: (i) to reduce the uncertainty concerning lithium ignition temperature under selected atmosphere and humidity conditions relevant for DONES applications as well as to demonstrate the effectiveness of gas inertization. (ii) To characterize lithium fire consequences such as reaction rate and generation of aerosols [33].

11.4. LITEC facility

The LITEC (The Lithium TEchnologies CIEMAT loop), which is being installed in premises of the University of Granada at the IFMIF-DONES site, is devoted to the validation of the lithium traps [66]. It consists of a lithium loop conceived at a 1:1 scale of the IFMIF-DONES Impurity Control system, while keeping significant operational flexibility to integrate different traps designs and characterize them under different operation conditions. The LITEC results are very relevant from Safety point of view as the hot a cold traps will house close to 90% of the MAR in the facility.

11.5. Experimental validation of structural and shielding concrete

Experimental optimization and evaluation of structural and shielding concretes to fast neutrons is being carried out using 1 MeV neutrons in the Nuclear Physics Institute of the CAS in the Czech Republic [67]. The shielding properties of samples of ordinary concrete of lime-dolomite aggregate from local Granada sources as well as heavy-weight magnetite aggregate concretes are being studied. The experimental results are very useful from Safety point of view to validate the shielding designs.

11.6. Multipurpose Vacuum Accident Scenarios (MuVacAS) Setup

One distinct feature of the IFMIF-DONES accelerator is the absence of a separation window between the TVC and the rest

of the accelerator's vacuum. This is because the high power and low energy of the beam would result in extreme power deposition on such thin window, with no material capable of withstanding this load and means to effectively cool it. On the other side, the low vapor pressure of lithium during normal operation favors the absence of the window. But this particularity has safety implications in the event of a Loss of Vacuum Accidents (LOVAs) in which incoming air could potentially reach the liquid lithium in the target, or allow activated material to be transported along the accelerator line in case of back plate failure. These potential events are being captured and studied by the Referent Accidents scenarios LS3-3, AS3-2, AS3-1 in table 3. To mitigate these accidents, Fast Safety Isolation Valves (FSIVs) are envisaged, which are capable of isolating the TVC within 100 ms when a LOVA is detected, acting as a safety confinement measure. The MuVacAS experimental setup is designed to study these LOVAs caused by leaks or sudden intrusions, aiming to validate the FSIVs and support their Safety Qualification for the licensing of IFMIF-DONES [55].

The MuVacAS setup is being installed in premises of the University of Granada at the IFMIF-DONES site, as shown in figure 8. To recreate the LOVAs, it reproduces as close as possible the last 30 m of the accelerator vacuum line and the target chamber. It also includes three experimental modules to recreate the identified scenarios as the injection of gas, water, and the recreation of sudden gas intrusion due to Back Plate rupture. It is also equipped with fast acquisition vacuum gauges (1 kHz) to record and characterize these sudden vacuum loss events and the efficacy and reliability of the FSIVs.

12. Conclusion and outlook

Safety is a fundamental and transversal discipline throughout the design, construction, operation, and eventual decommissioning of the IFMIF-DONES facility. Given the facility's unique and unprecedented nature, implementing a robust Safety Engineering Approach and Licensing Strategy is both a complex and critical challenge. Therefore, safety considerations have been prioritized from the earliest phases of the project. In this work, we have provided a comprehensive overview of the current status of safety at IFMIF-DONES, with an emphasis on radiological safety, aiming to present the most complete and up-to-date design available.

From a licensing perspective, the IFMIF-DONES facility is classified as a Category 1 Radioactive Facility under Spanish

law. The Spanish Regulatory Authority, the CSN, is responsible for granting the Operating Permits. The licensing process of Category 1 Radioactive facilities differs from that of nuclear ones, and involves the issue of a specific Evaluation Guide by the CSN that establishes ad-hoc safety design requirements. A Working Group between IFMIF-DONES and the CSN is already established to collaborate in the preparation of such Evaluation Guide.

The current approach to setting top-level safety requirements is to follow concepts and methodologies of the *IS-26, about Basic Nuclear Safety Requirements applicable to Nuclear Facilities*. In particular by the application of the Defense-in-Depth principle, definition of Safety Functions, evaluation of RASs and Identification Safety Important Class SSCs to provide different lines-of-defense. Safety design and qualification requirements are then assigned to these SIC-SSCs to ensure that they fulfill their safety functions throughout the facility's life-cycle. Nevertheless, it is important to note that while IS-26 methodologies and principles are being applied, this does not imply imposing the same standards and reliability requirements typically associated with nuclear facilities (commonly referred to as nuclear standards). Instead, the safety and associated reliability requirements are being carefully calibrated to be commensurate with the consequences of accidents and likelihood, which are very different and much lower than in nuclear facilities. This calibration is done through the establishment of dose limits thresholds in case of accidents, linked with an estimated yearly frequency of occurrence based on conservative yet reasonable engineering judgments. It is worth noting to remark that no formal bottom-up probabilistic assessments are required or performed during this approach. The analyses are still deterministic but the establishments of top-down yearly frequency of occurrence are used to assess up to which extent the lines of defense shall be established and to ensure that enough margins are provided.

We have presented the potentially mobilizable radioactive MAR currently identified, which serves as the foundation for calculating dose consequences to the public and workers in the RASs. These is done through the definition of Source Terms, which are obtained by multiplying the MAR for a series of reducing factors consistent with the accident evolution and the physical process involved. These factors and the accident evolution sequence are estimated by deterministic analysis and supported by experimental data whenever is possible or required. Currently, around 30 RAS have been identified and are being studied to determine their potential consequences, classify them between AOOs, DBAs and Design Extended Conditions, as well as to define the Safety SSCs to prevent-detect-mitigate them.

A Hazard Categorization of the facility has been carried out following the ANSI/ANS-2.26 and SSG-67 to support the Seismic Design Approach. The potentially mobilizable radioactive MAR and the postulated worst accident and

radiological release that could happen in the IFMIF-DONES facility has been used for this purpose, leading to the classification of IFMIF-DONES as a low hazard facility. This classification and the use of several standards and ground characterizations has lead to the definition of the design reference earthquakes SL-1, SL-2 and SL-3 for the facility.

Furthermore, we have presented in this work an overview of the IFMIF-DONES Safety Systems, involving the Safety Confinement Barriers, Safety Interlocks, Radiation Monitoring, as well of Radiation Areas Classification and Access Control. In addition, we have presented the defined strategy to implement the ALARA principles from the design phase to reduce the ORE of workers and fulfill the targets of maximum individual and collective dose during operation. This is done by establishing a methodology to select which components shall be designed following a hands-on/hands-off or RH maintenance approach based on expected dose rates and annual intervention times.

Finally, we provided an overview of different experimental programs that are ongoing or have been carried out to support the risk assessments, accident analysis, reduce uncertainties and demonstrate the assumptions being made. These programs involve aspects such as Li fire experiments, EMP design validations, Li trap technologies validation, shielding materials characterization and loss of vacuum experiments.

The Safety Approach and Strategy presented in this paper paves the way for the further stages in the development of the IFMIF-DONES facility and program. This stages, from safety point of view, involve the progress on the identification of Safety SSCs, definition of their low-level Safety functions and requirements, development of Qualification and Validation plans as well as operation, maintenance and inspections plans to make sure safety functions are fulfilled over the life-cycle of the facility. From licensing point of view, next stages involve the progress of documentation preparation for each of the licensing phases and collaborate with the regulatory body in its assessment.

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