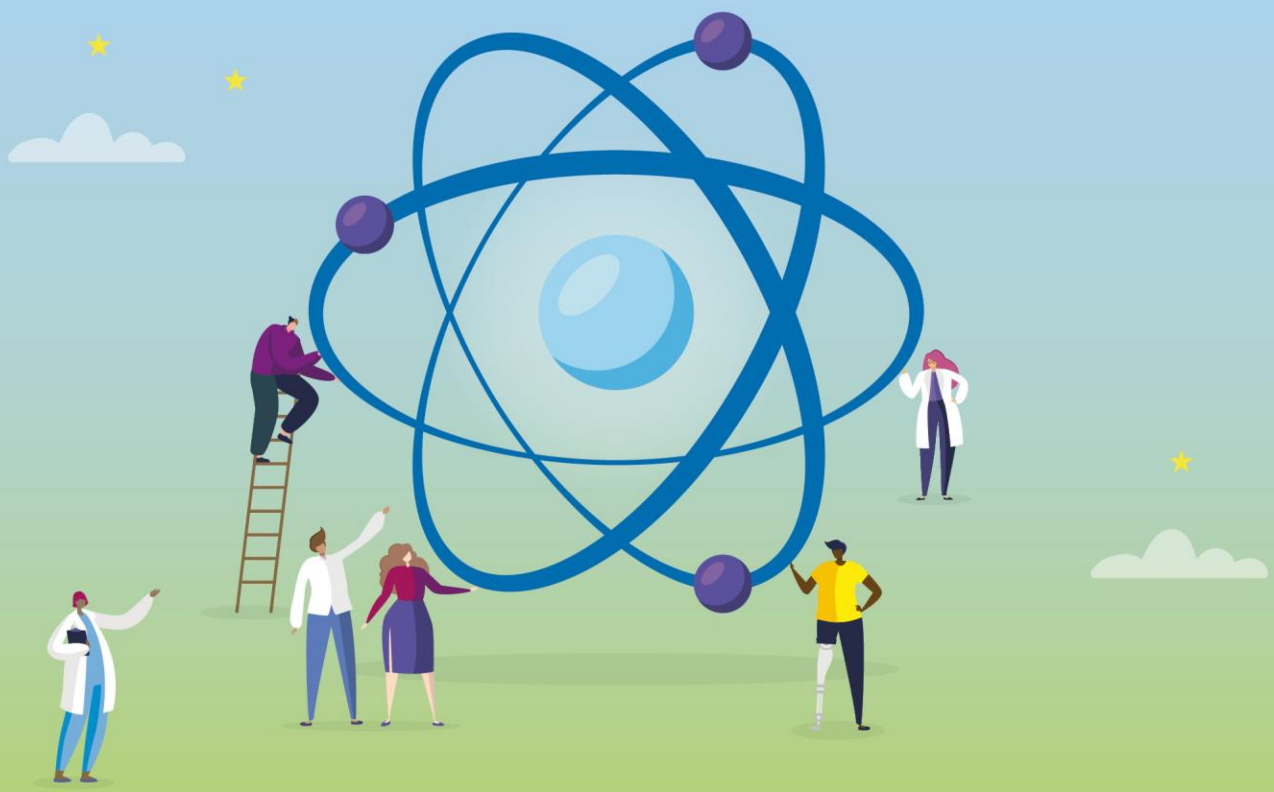
European Commission

Exploring Regulatory Options for Fusion Power Plants



Research and Innovation

Exploring Regulatory Options for Fusion Power Plants

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Manuscript completed in June 2021
1st edition.

PDF	ISBN 978-92-76-40673-0	doi: 10.2777/980320	KI-09-21-324-EN-N

Luxembourg: Publications Office of the European Union, 2021

EUROPEAN COMMISSION

Exploring Regulatory Options for Fusion Power Plants

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edited by Roberto Passalacqua, Lars-Goran Eriksson, Christopher Ibbott

2021

Directorate-General for Research and Innovation
Euratom Research and Training Programme

TABLE OF CONTENTS

SUMMARY 3

1. INTRODUCTION 4

2. COMPARISON BETWEEN FUSION AND FISSION FACILITIES 5

2.1 SPECIFIC SAFETY CONCERNS OF FUSION FACILITIES 5

2.1.1 Accidents 5
2.1.2 Radioactive Material Release, Toxicity and Occupational Radiation Exposure 6
2.1.3 Radioactive waste 7

2.2 MAIN SAFETY CONCERNS TO BE CONSIDERED FOR DEMO: LESSONS LEARNT FROM ITER 7

2.2.1 Accidents 7
2.2.2 Radioactive Material Release, Toxicity and Occupational Radiation Exposure 8
2.2.3 Radioactive Material Release, Toxicity and Occupational Radiation Exposure 9

2.3 AREAS WHERE A FUSION REGULATION COULD DIFFERENTIATE TO FISSION 10

3. REGULATORY OPTIONS FOR FUSION POWER PLANTS 13

3.1 APPROACHES TO REGULATION 13

3.2 SAFETY ASSESSMENT 16

3.1.2 Radioactive Material Release, Toxicity and Occupational Radiation Exposure 17

3.3 THE 3 S'S: SAFETY, SECURITY AND SAFEGUARDS 22

4. IMPLICATIONS AND RECOMMENDATIONS 24

4.1 IMPLICATIONS 24

4.2 RECOMMENDATIONS 25

5. CONCLUSIONS 27

6. ACKNOWLEDGEMENTS 30

7. BIBLIOGRAPHY 31

8. TERMS AND ACRONYMS 34

9. APPENDICES 35

APPENDIX A: SAFETY FUNDAMENTALS 35

Appendix A.1: EU Legislation 35
Appendix A.2: Safety Concerns 37
Appendix A.3: Safety Objective, Goals and Functions 40

APPENDIX B: IAEA SAFETY STANDARDS 42

APPENDIX C: DEFENCE IN DEPTH 43

SUMMARY

The European research roadmap to fusion energy paves the way for commercial electricity generation from fusion as a potential long-term solution for clean energy. Future fusion power plants that will generate electricity for commercial use will require national regulators to establish and maintain a suitable framework for safety. Such a legal framework would allow assessing licensing applications to construct and operate fusion power plants. Yet, unlike fission power plants, there is to date no specific approach for regulating fusion energy. As a result, this has created a regulatory vacuum, which has led to a tendency to apply the fission regulatory regime to fusion reactors. That was the case for both ITER and the recent regulatory developments in the US and Canada.

This report first reviews the differences between fusion and fission facilities, focusing on the safety concerns of fusion. It then examines the main regulatory options for future fusion power plants. The conclusion is that while there are some common safety aspects between fission and fusion, there are also some fundamental differences. For example in a fission plant there is the need to prevent criticality as well as the need to limit the release of long-lived radioactivity. Any fission-based regulatory framework is going to be driven by the safety issues unique to fission, which are sometimes inapplicable to fusion. Therefore, adopting a fission-based regulatory approach could be overly conservative in addressing certain fission-specific safety aspects and disproportionate to the safety risk to people and the environment. This approach could, in turn, negatively affect the regulatory burden and investments. On the other hand, the potential for offsite radioactive release from fusion power stations (mainly due to tritium) could require different regulations from current fusion experimental facilities, which are classified as irradiation installations.

It is thus necessary to adopt a thoughtful regulatory approach tailored to the safety concerns of future fusion power plants by being consistent and proportionate to their hazard potential. Among the attributes recommended for a fusion regulatory framework are flexibility and adaptability, to accommodate the high uncertainty associated with the current and future technology development. The framework must also be transparent regarding regulatory control and licensing to facilitate political and public acceptance. Further work could focus on ways to promote cross-border regulatory cooperation, explore the differences between asset protection and public and environmental safety, and clarify the concepts of risk tolerance and risk acceptance.

1. INTRODUCTION

Fusion has the potential to provide a safe, cost-efficient and sustainable solution to European and global energy needs. European fusion laboratories collaborate through the European Consortium for Development of Fusion Energy (EUROfusion) in line with the long-term strategy set out in the European research roadmap to the realisation of fusion energy[1]. ITER is of key importance in the roadmap, as it aims to prove the scientific and technological feasibility of fusion as a future energy source. Although ITER itself will not produce electricity, DEMO – the device that will follow – will likely model a real future fusion power plant and produce electricity, with the goal of fusion electricity in the grid by 2050. The exploitation of fusion energy for commercial power generation will require national regulators to establish and maintain an appropriate legally-binding framework for safety. This framework would allow assessing licensing applications to construct and operate fusion power plants.[2] However, even though the concept of fusion power plants has been developed since the 1950s, to date there has been no national or international regulatory framework for fusion. As a result, this has created a 'regulatory vacuum', which could lead to the application of the fission power-plant approach to fusion power plants. This has been the case for ITER. The ITER reactor was classified as a nuclear reactor facility (Installation Nucléaire de Base, INB) by ASN (Autorité de Sûreté Nucléaire), therefore a fission-based regulatory framework was applied. A similar tendency has been also observed in the recent regulatory developments in the US and Canada.[3] There are however reasons why a fission regulatory approach would not be appropriate for fusion. These reasons mainly concern the distinctions between the fusion and fission process, as well as the technologies, fuel and materials used that can change the hazard potential and the key safety issues.

National and international nuclear regulatory landscapes have been shaped by the special characteristics associated with nuclear fission. However, regulatory regimes need to follow an approach proportionate to the risk to people and the environment. The development of a regulatory framework should also consider the impacts on the size, structure and resources of the organisations involved in licensing, as well as on the core competencies necessary. Moreover, the type of regulatory regime adopted can influence investments and the promotion of technology deployment. Furthermore, it can affect the public and the decision-makers confidence, ultimately impact knowledge creation and the development of science and innovation for the benefit of society.

Therefore, the three main questions that this report attempts to answer are:

- What are the specific safety concerns of fusion facilities that should be regulated?
- What lessons could be learnt from existing fusion facilities that could help shape a regulatory framework?
- Which attributes or qualities would enable a regulatory framework to effectively address the safety concerns of fusion power plants?

Work is structured with the aim to first provide a review of the main safety-related differences among fusion and fission facilities (chapter **Error! Reference source not found.**). The goal is to identify areas where a f usion regulation could differentiate to fission. It aims to lay the groundwork towards a regulatory framework tailored to fusion power plants. The emphasis is on the safety-related concerns of fusion technology and

[1] EUROfusion website: https://www.euro-fusion.org/ and on the European Research Roadmap for Fusion Energy: https://www.euro-fusion.org/eurofusion/roadmap/

[2] The current relevant EU Directives (Council Directive 2009/71/Euratom, 2009; Council Directive 2011/70/Euratom, 2011) impose obligations on the Member States to establish and maintain a national framework for nuclear safety for all nuclear installations. This also concerns enrichment plants, nuclear fuel fabrication plants, nuclear power plants, reprocessing plants, research reactor facilities, spent fuel storage facilities, as well as for their radioactive waste storage facilities.

[3] In Canada, with the annexed Class I Nuclear Facilities Regulations made by the Canadian Nuclear Safety Commission, classifying fusion reactors as 'Class IA nuclear facilities', the same as nuclear fission reactors: https://laws.justice.gc.ca/eng/regulations/SOR-2000-204/page-1.html#h-656998. In the U.S. 'S.512 - Nuclear Energy Innovation and Modernization Act', classifying fusion reactors in the same category as advanced nuclear fission reactors: https://www.congress.gov/115/plaws/publ439/PLAW-115publ439.pdf.

therefore a detailed analysis of fission technology is beyond the scope of this work. Chapter **Error! Reference source not found.** reviews the regulatory approaches that are likely to be part of a future regulatory framework for fusion power plants. A brief outline of the relevant concerns with respect to security and safeguards is also included in this chapter, although safety-related aspects remain the focus of this report. Chapter **Error! Reference source not found.** gives an overview of the potential implications and the relevant recommendations for the safety regulation of fusion. The final chapter (chapter **Error! Reference source not found.**) summarises the main policy-related conclusions for developing a regulatory framework for future fusion power plants.

2. COMPARISON BETWEEN FUSION AND FISSION FACILITIES

This chapter provides a comparison between the main safety concerns of fusion and fission facilities (section 2.1). Given the significant differences expected between ITER and DEMO, the chapter also highlights potential lessons learnt from the licensing experience of ITER that could be of value for DEMO (section 2.2). Finally, areas are identified where a fusion regulation could differentiate from the existing fission regulation (section 2.3). The main safety concerns are organised similarly to fission nuclear installations. They are organised according to accidents, potential radioactive material release, occupational radiation exposure and radioactive waste (more details in Appendix A.2). Since this report aims to support the development of a regulatory framework for fusion power plants, it focuses on the safety concerns of fusion technology. Detailed analysis on the safety aspects specific to fission technologies is beyond the scope of this work.

2.1 SPECIFIC SAFETY CONCERNS OF FUSION FACILITIES

Fusion installations display specific physical and technological characteristics that differ from fission installations. These are outlined in the following subsections and are organised according to the safety concerns with respect to accidents (subsection 2.1.1), potential radioactive material release, toxicity and occupational radiation exposure (subsection 2.1.2) and radioactive waste (subsection 2.1.3). As elaborated below, differences are also expected between the current ITER facility and future fusion demonstration reactors, like DEMO. This is mainly because ITER is an experimental facility, whereas DEMO is intended to be much closer to a commercial power plant, which influences the management of safety and the development of a safety approach.

2.1.1 Accidents

Fission and fusion facilities share similar types of concerns in terms of Design Basis Accidents (DBAs, see definition in Appendix A.3). These involve changes in the reactor coolant inventory and heat removal, changes in the flow rate from the reactor coolant system and anomalies in the power supply. The fundamental difference is that, in the event of an accident, a fusion reaction would intrinsically terminate and, unlike fission, there is no need to consider in the design the potential risk of a supercritical chain reaction (i.e. power rising exponentially). From this point of view, fusion is inherently safer than fission. There are yet DBAs considered at ITER linked to potential abnormalities of fusion-specific components. These include in-vessel, tritium, magnet, cryostat and hot-cell events (Taylor et al., 2009).

For Design Extension Conditions (DECs, see definition in Appendix A.3), there are two main considerations in fusion facilities compared to fission facilities. These are explosions due to hydrogen or dust[4], which could

[4] In addition, beryllium, used as a liner for the first wall, has a high risk of explosion and is highly reactive with air, water and carbon dioxide, releasing high amounts of energy. Graphite, used as a neutron reflector at the outside periphery of the blanket, can release large amounts of energy by combustion if exposed to air at high temperatures (Petrangeli, 2006b, p. 24).

compromise the integrity of the vacuum vessel (VV), or fire at an auxiliary tritium plant. Both could result in a potential release of radioactive materials. However, analysis for ITER showed that radiological consequences of such events would not require the evacuation of surrounding populations. For extreme external hazards, such as earthquakes, flooding and aircraft crashes, safety standards and categorisation could be similar to fission reactors (Taylor et al., 2009). Specifically, in the case of ITER, the French regulators required that buildings that contain radioactive inventories have earthquake protection (ITER, 2011; Taylor et al., 2009).

2.1.2 Radioactive Material Release, Toxicity and Occupational Radiation Exposure

Fusion and fission facilities have significant differences in their potential for radioactive material release and occupational radiation exposure.

The differences in the radioactive material release are due to the radioactive source term, which concerns the radioactive isotopes (i.e. kind and physical-chemical speciation) and their inventories (i.e. quantity). In fission reactors, the main contributors to the radioactive source term are iodine, caesium, noble gases and fission product aerosols resulting from the fission and activation reactions. In fusion reactors, and specifically in ITER, only a small fraction of tritium injected in the VV is burned and almost all tritium is exhausted and re-used as fuel (Wu et al., 2016). However, a small quantity of tritium is retained and trapped,[5] which can gradually accumulate to a significant inventory. This quantity of tritium could be released following a significant temperature increase, or injection of air or water in the VV during normal operation and accident conditions[6] (ITER, 2011; Taylor et al., 2009). Similarly, radioactive dust, resulting from the erosion of plasma-facing materials (mainly beryllium and tungsten at ITER) could be released during maintenance operations or accident conditions in the event of ingress of water or air. Therefore, the approach followed at ITER is to set safety limits for both the quantity of tritium and the amount of activated dust, at 1 kg and 1 tonne, respectively (ITER, 2011; Taylor et al., 2009).[7] In addition, potential releases of toxic products have to be avoided, especially relating to beryllium (Be), used as a liner for the first wall at ITER. Be if inhaled causes lung illnesses and in contact with the skin, dermatitis and conjunctivitis. Therefore Be zoning has been adopted at ITER based on threshold values for occupational exposure[8] (ITER, 2011; Petrangeli, 2006b). An issue that should not be overlooked and is closely followed at ITER is that Be may contain impurities, such as natural uranium and/or thorium.[9] The irradiation of Be containing uranium with fusion neutrons during plasma operations would generate radioactive fission products, including radioactive volatile products (caesium, antimony, tellurium, cadmium, barium, technetium, strontium, etc.), radioactive noble gases (xenon, krypton etc.) and radioactive forms of iodine. Such volatiles would not remain in the Be material and would be released in the VV, and the higher the Be temperature, or the defects in the Be material, the higher the gas release.

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[5] The tritium inventory in the VV is due to the unburnt tritium, to the outgassing of the tritium retained in the plasma-facing components and to the tritium retained in the dust particles generated by the plasma erosion. The outgassing flow depends on the temperature reached by the VV walls: in case of a significant temperature increase, higher than in normal operation, the tritium release from the material contributes to the tritium source term in the VV.

[6] Tritium, or hydrogen-3, is a rare and radioactive isotope of hydrogen. In fusion facilities, where there is tritium and deuterium, there is the potential for an energetic hydrogen interaction in the event of a significant air ingress (the ignition energy required for a hydrogen explosion in the air is low). In addition, a hydrogen explosion may provide enough energy to initiate a more severe dust explosion.

[7] In a plant, tritium can be located in the VV, the fuelling system and fuel cycle, the heat transfer system, and the hot cell, and, in smaller quantities in the turbine building, or the energy storage system (e.g. molten salt) in case of adoption of the indirect power conversion system. For ITER, the maximum tritium allowed on site is 4 kg (ITER, 2011).

[8] Be zoning in ITER is based on threshold values for atmospheric contamination by beryllium of 0.01 micro-g/m^3 (a threshold for which an increased health risk for staff is possible) and 0.02 micro-g/m^3 (a threshold for which specific dispositions are imposed about the inhalation of material (ITER, 2011)).

[9] For ITER, the maximum acceptable concentration of natural uranium in beryllium was initially established at 30 ppm (in weight), which would amount to a maximum of 360 grams of natural uranium in the vacuum vessel across the 440 blanket modules.

The risk of occupational exposure to ionising radiation in fission facilities is largely associated with neutrons emitted from the fission reactions and γ-radiation generated from the decay of fission and activation products. On the other hand, the risk of occupational exposure to ionising radiation in fusion facilities is mainly linked to neutrons emitted from the plasma and γ-radiation emitted by neutron-activated components,[10] X-rays emitted by some heating and current drive generators, and β-radiation emitted from tritium[11] (ITER, 2011; Taylor et al., 2009).

2.1.3 Radioactive waste

Radioactive waste is an additional area where differences exist between fusion and fission facilities. Indicatively, a fission reactor of 1 GWe produces approximately 30 tonnes of high-level waste in the form of un-used fuel (Petrangeli, 2006a), whereas no long-lived radioactive waste is expected at ITER (Wu et al., 2016) (more details on radioactive waste classification in Appendix A.2). However, a large quantity of low-level and intermediate-level waste is expected to be generated, mainly owed to neutron activation of materials and tritiated waste. Therefore ways to treat those low-level and intermediate-level wastes are investigated at ITER (ITER, 2011).

The ITER fusion device is the first fusion facility for which a complete safety case has been prepared and subjected to the scrutiny of a nuclear regulator. Therefore, lessons learnt during this process could be of particular relevance and use for DEMO and other future fusion facilities. The section below outlines some of the safety concerns and possible differences between ITER and DEMO.

2.2 MAIN SAFETY CONCERNS TO BE CONSIDERED FOR DEMO: LESSONS LEARNT FROM ITER

2.2.1 Accidents

Plasma events have not been considered as DBAs at ITER, as it is designed to achieve plasma-burn durations between 300-500 sec (ITER, 2011). In DEMO, however, the frequency of plasma events (e.g. disruptions, a sudden increase in fuelling rate or auxiliary heating, etc.) could differ that would necessitate their inclusion in the DBAs (Perrault, 2016). The main reason is that for DEMO an essentially steady-state operation or alternative long regular pulses of 4 to 6 hours are expected for the efficient production of energy. In addition, for some DEMO reactors, the magnetic energy stored in a toroidal coil could be considerably greater than ITER which could negatively impact the VV integrity (e.g. the energy stored in a European DEMO reactor toroidal coil will probably be about 10 GJ, instead of the 2.28 GJ foreseen for an ITER coil) (Perrault, 2016).[12] Therefore, it would be necessary to ensure for a DEMO reactor from an early design stage the capability to absorb the energy from a quench from the load of the magnets. **Tritium-breeding-blanket events** should also be investigated in DEMO from an early design stage (Perrault, 2016) for possible tritium releases and the consequences of liquid or gas leakage within and outside the VV (e.g. during the blankets transfer and maintenance in hot cells). In certain DEMO reactors using gaseous helium as the cooling fluid for tritium breeding blankets, there could be a possible increase of a source of helium. Such cases should also consider at an early design stage the risk of a possible **helium leak** into equipment

[10] The intense high-energy γ-radiation from the decay of ^{16}N that is generated in water (has a neutron energy threshold of 10.5 MeV, but a half-life of only 7.1 s) is sufficient to make all parts of a water cooling circuit a prominent source of radiation during operation. For DEMO this problem could be excluded by choosing a coolant other than water, else additional shielding must be incorporated into the design to protect personnel from exposure to the cooling circuit pipes and components (Taylor & Cortes, 2014).

[11] Tritium decays with half-life of 12.33 years, emitting a β-radiation with average energy of 5.7 keV and a maximum energy of 18 keV. The exposure paths are either by inhalation and ingestion or through the skin. The biological half-life of tritium, either ingested or inhaled, is 10 days. Due to the easy absorption of water by the body, it is more dangerous in the form of tritiated water than as elemental tritium (Petrangeli, 2006b).

[12] The magnetic inventory in a fusion power plant is expected to be even greater, with toroidal and poloidal coils having energies up to 180 GJ and 50 GJ, respectively (Lukacs & Williams, 2020).

and rooms (Perrault, 2016).[13] On the other hand, **maintenance-initiated events**, e.g. a stuck divertor cassette and the failure of its transport cask, which were included in the list of ITER DBAs, may not be included in the DEMO DBAs (ITER, 2011; Taylor et al., 2009). DEMO may ultimately follow the practices of commercial PWRs and not consider maintenance-initiated events in the list of DBAs, since successful commercialization of fusion will depend on the development of highly effective remote handling technology for reliable system operations and on the long service life of their components (Wu et al., 2016).

Finally, due to the potentially larger size and complexity of DEMO, explosion mitigation tactics and a robust substantiation of the fire safety design would require further investigation throughout DEMO's lifecycle, in the vacuum vessel and the tritium handling buildings (Taylor et al., 2009). Moreover, **extreme external hazards such as earthquakes, flooding, and aircraft crashes**, should be further investigated, since some measures planned for ITER could be difficult to implement in DEMO. For instance, in the event of a plane crash, the tokamak protection planned for ITER of a 0.8-m-thick bio-shield lid over the cryostat could prove to be difficult to implement to DEMO reactors with vertical access to the VV (Perrault, 2016).

2.2.2 Radioactive Material Release, Toxicity and Occupational Radiation Exposure

The **potential for radioactive materials release and toxicity** in DEMO facilities may differ from ITER (Wu et al., 2016). The reason is that the materials used and their inventory will not be necessarily the same, due to an effort to minimise the radioactive inventory and toxicity. For example, Beryllium will not be used to the same extent in DEMO. The potential for radioactive material release will eventually depend on:

- the *plasma-facing materials* e.g. lithium could have mitigating effects on the accumulation of dust (Bell et al., 2009; D. Maisonnier et al., 2005; David Maisonnier et al., 2005); however lithium would require additional safety measures to prevent and mitigate fire, since it is highly reactive to water, air and concrete, flammable and toxic following excessive intake;
- *the higher total inventory of tritium* owed to the factors of fusion power and tritium burn fraction, the tritium processing system, as well as the tritium breeding in the blanket (Wu et al., 2016).

Different materials and operating conditions could potentially allow reducing the safety limits for DEMO compared to ITER (e.g. considering the use of different plasma-facing materials, higher operating temperatures, etc.). However, choosing these limits would also depend on ensuring a balance between facility availability and maintenance schedules (i.e. for dust removal and the rate of tritium retention). An approach of shutdowns for radioactive material removal would strongly influence facility availability and maintenance schedules and, as a result, ITER's safety limits on the quantity of tritium and activated dust may not be feasible for DEMO.[14] In addition, DEMO will have a tritium production rate four orders of magnitude greater than ITER, due to the tritium breeding in the blanket, which would pose challenges for effective tritium extraction, permeation and detritiation systems (Wu et al., 2016). Therefore, DEMO could adopt the Gen-IV reactors' approach and concentrate on **strengthening multiple barriers against the releases during routine operation and potential accidents.** Moreover, as previously discussed, **potential releases of toxic products** would have to be mitigated in DEMO too, in particular concerning the use of beryllium (Be) (Petrangeli, 2006a). Be, as mentioned, may contain impurities, such as natural uranium and/or thorium, which would result in radioactive fission products during plasma operations and the higher the Be temperature or the defects in the Be material, the higher the gas release.

[13] The accidental leakage within the ITER vacuum vessel is limited to 50 kg, since the helium is incondensable in the VV pressure suppression system (Perrault, 2016).

[14] The ITER safety limits are carefully chosen to ensure a balance between the frequency within which the machine is shut down for tritium and dust removal and the rate of tritium retention and dust generation. These limits have not been verified yet for DEMO (Wu et al., 2016). The implementation of a tritium accountancy system may be complicated for DEMO due to the increased throughput of tritium via fuelling and pumping systems which could increase uncertainties requiring additional measurements (e.g. of tritium production rates in the blanket module) to provide sufficient information (Taylor & Cortes, 2014).

In DEMO, the occupational radiation risk is expected to be similar to ITER and the main difference would be **the size of the inventories of the typical radioactive products** (Wu et al., 2016). Therefore, it is important for DEMO reactors to consider the effects of the higher fluence of fusion neutrons, minimize the release of tritium and use as much as possible low-activation materials and remote handling maintenance. Several radiation protection provisions should also be put in place to limit individual occupational doses for workers to ALARA (e.g. confinement barriers, radiation shielding, radiation zoning and access control, instrumentation, including portable instrumentation, for hazard monitoring and a sufficient number of escape routes, suitable alarm systems and means of communication) (Wu et al., 2016). Furthermore, as the magnetic inventory is expected to be larger, disruptions that could lead to a **release of magnetic energy** need to be better understood to ensure that potential risks to workers and the public are kept ALARP.[15]

2.2.3 Radioactive Material Release, Toxicity and Occupational Radiation Exposure

Assuming that low or reduced activation materials are used for the DEMO VV structures and first wall, the **radioactive waste activity** of in-vessel components after 100 years could still be around 20-50 times larger than ITER, which is due to the higher neutron fluences and an expected larger tritium inventory (Pamela et al., 2014)[16]. The larger tritium inventory is expected to be also significant for tritiated waste management. It has been estimated that the total inventory of radioactive products (i.e. tritium, material activation and fission products) of a future fusion reactor is comparable with a fission reactor, assuming the same electrical power output (e.g. 1.2 GWe) and the use of stainless steel as a first-wall and structural material. Main reason is the radioactivity due to materials activation, which may be three orders of magnitude higher than a fission reactor (Petrangeli, 2006b).[17] Therefore, it is important to develop low-activation materials (i.e. materials with reduced or short-lived activation and with low tritium retention) to control the build-up of tritium inventories in the materials and activated products. It is further important to consider the construction of special treatment repositories for the conditioning of a large amount of low-level and intermediate-level waste, while ensuring the waste characteristics are compatible with the disposal path (Taylor et al., 2012).[18]

Given the specificities of fusion facilities, especially compared to fission facilities, and in an effort to lay down the groundwork for the eventual commercial deployment of fusion, new regulatory questions are generated:

- How can future fusion power plants be regulated?
- Should future fusion power plants be regulated as fission nuclear plants, or not and why?

Learning from the fission sector and other industry sectors suggests that the regulatory approach that will ultimately apply to fusion power plants will affect their regulatory burden and, as a result, the time-to-market and the cost to the industry. Following the above analysis, the following section examines possible areas that a regulatory framework specific to fusion power plants should address.

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[15] The terms ALARA and ALARP are considered to be equivalent in meaning and purpose. ALARA is the internationally recognized term for radiation protection. ALARP is generally used more broadly in the UK legislation than ALARA since the term is applicable in various fields of the regulation and management of safety-critical and safety-involved systems. In particular, in the Health and Safety at Work etc. Act 1974, when looking at risks to people from the operations of nuclear installations, whether during normal operations or accident conditions.

[16] Owed to higher neutron fluences of 40–150 displacements per atom (dpa). Compared to ITER DEMO reactors are expected to accumulate one to two orders of magnitude more fluence in only a few years before in-vessel components removal (Pamela et al., 2014).

[17] In a fission reactor, a large amount of radioactivity is owed to fission products that are practically absent in fusion reactors, unless Beryllium is used for the first wall, which contains uranium and thorium impurities (Kolbasov, Khripunov, & Biryukov, 2016).

[18] See '**Error! Reference source not found.**' for guidelines on the disposal options according to different classes of radioactive waste.

2.3 AREAS WHERE A FUSION REGULATION COULD DIFFERENTIATE TO FISSION

The three targets of any regulatory framework for safety is the public, the workers and the environment. National nuclear safety frameworks should ensure that nuclear installations achieve at all plant stages the **objective** to control the radiation exposure of people and the release of radioactive material to the environment, prevent accidents and, should an accident occur, mitigate and avoid its consequences (Council Directive 2014/87/Euratom, 2014; *Fundamental Safety Principles*, 2006). Fusion facilities share the **fundamental safety objective** with fission on protecting people and the environment from harmful effects of ionising radiation within the plant and any potential release of radioactive material from the plant (*Fundamental Safety Principles, 2006*). Similarly, fusion power plants should meet **the general safety goal and the more specific radiation protection and technical safety goals** (see more details in Appendix A.3).

However, both Gen-IV and fusion reactors should allow to go beyond those goals and explicitly put forward the following **fourth safety goal** (Maisonnier et al., 2005; Wu et al., 2016):[19]

- **Non-Evacuation, non-sheltering safety goal:** eliminate the need for offsite emergency response in case of an accident and ensure that public doses do not reach levels triggering evacuation.

In addition, fusion power plants specifically could go a step further by adding the following **fifth goal** (Figure 1) (Maisonnier et al., 2005; Wu et al., 2016):

- **Minimise radioactive waste hazards to reasonably achievable levels:** ensure that waste is not a burden on future generations. This goal effectively requires that all active material is cleared or recycled within a period of up to 100 years.

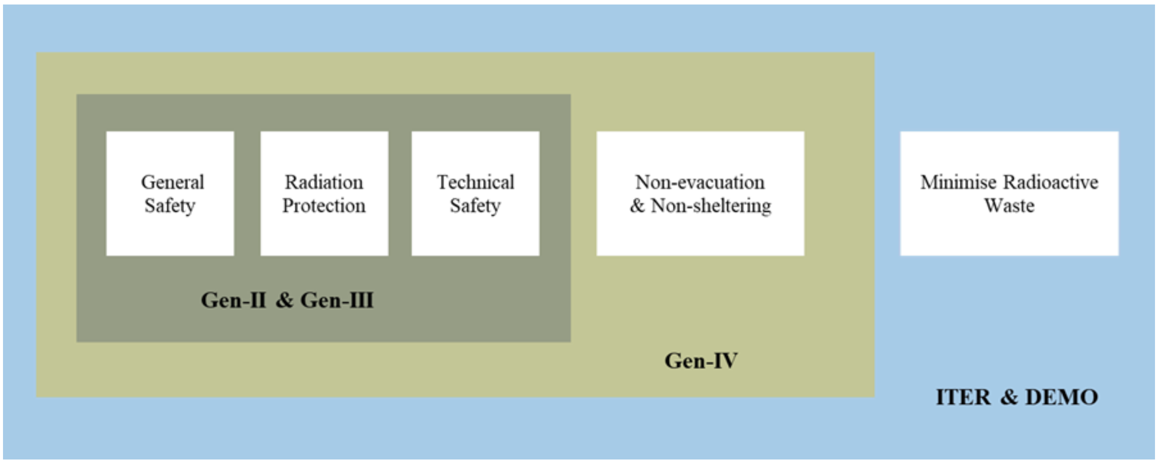

Figure 1. Safety goals for fusion and fission facilities (adapted from (Wu et al., 2016)).

Defence-in-depth (DiD) is a fundamental concept of nuclear safety. It is the primary means of protecting the public and the environment by preventing and mitigating the consequences of accidents (more details on the concept of defence-in-depth in Appendix A.2). In both Gen-IV reactors and ITER, DiD emphasizes eliminating the need for off-site emergency response. Therefore, DEMO designs may have to adopt it as well.

One significant difference between fusion and fission in terms of safety functions is that there is **no safety function for the 'control of reactivity'** in fusion reactors since there is no issue of neutron reactivity.

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[19] Since the Fukushima accident, there has been an international tendency to consider eliminating the need for off-site emergency response including evacuation of affected members of the public for Gen-II and Gen-III reactors. IAEA stresses in the latest safety standard (*Safety of Nuclear Power Plants: Design*, 2016) that in case of a severe accident, only protective actions that are limited in time and area of application would be necessary and that off-site contamination would be avoided or minimised. Event sequences that would lead to an early radioactive release or a large radioactive release are required to be '*practically eliminated'*, meaning physically impossible to arise or considered with a high level of confidence to be extremely unlikely to arise.

Nevertheless, two safety functions have been considered at ITER for radiation protection purposes during its comparatively frequent maintenance activities (ITER, 2011):

1. Confinement of radioactive material;

2. Limitation of exposure to ionizing radiation and hazardous materials.

Two additional *non-safety support functions* exist at ITER to enable the above to be achieved under all conditions (i.e. plant states) (Taylor & Cortes, 2014):

a. **Fire protection and prevention of explosions** (i.e. of hydrogen (tritium, deuterium) and dust) and;
b. **Decay heat removal.**

For DEMO, **decay heat removal** owed to material activation is, however, expected to be a safety function (Figure 2). The reason is that a fusion demonstration reactor is estimated to have an order of magnitude more decay heat power than ITER[20] (Taylor & Cortes, 2014). A passive approach to the removal of decay heat by convection or conduction is to be favoured (i.e. low coolant flow or the introduction of liquid such as air into the cryostat volume).

Similar provisions with ITER could apply to DEMO for the non-safety support functions for fire protection and prevention of explosions (Wu et al., 2016). Passive design measures (e.g. the choice of plasma facing materials and/or coolant) could be employed to reduce the possibility of hydrogen and dust explosions. Otherwise, active design measures may be feasible (e.g. igniters within the vessel or rapid injection of inert gas in-vessel, or even filling volumes surrounding the VV with an inert gas, whose practicality however needs to be further assessed) (Taylor & Cortes, 2014).

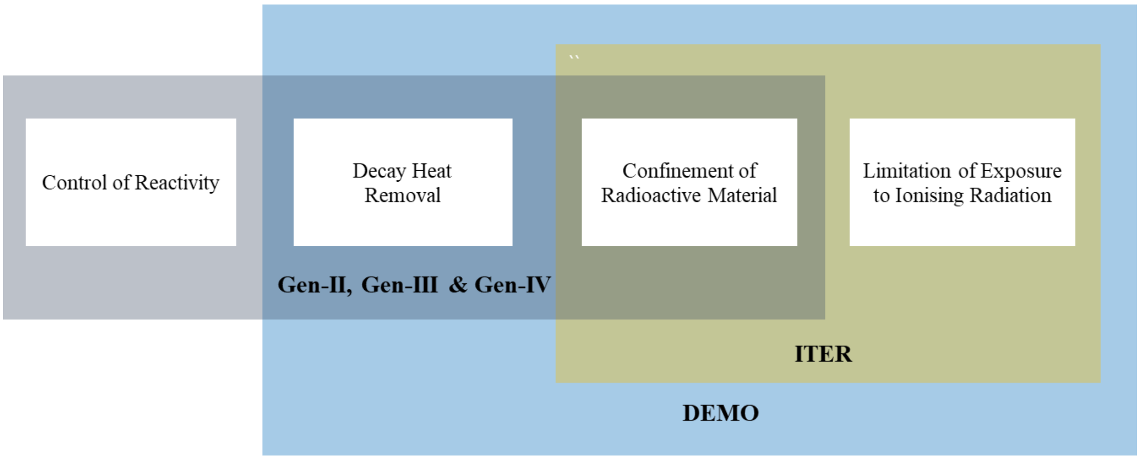

Figure 2: Safety functions for fusion and fission facilities (adapted from (Wu et al., 2016)).

As established below, physical barriers are to provide the above safety functions for future power plants. Their design may vary according to material activity and the likelihood and consequences of barrier failures. At ITER, two confinement barriers are investigated (ITER, 2011; Taylor & Cortes, 2014; Wu et al., 2016):

1. **VV and its extensions:** the VV and its extensions prevent the release of radioactive materials within the facility. In-vessel components are not credited with a safety function, because their experimental nature implies that they are prone to failure. This results in a complex and extensive first confinement

[20] In ITER, temperatures rise only very slowly, not leading to structural degradation. In DEMO, the low activation materials that could be used for the plasma-facing components, could produce lower decay heat (than the 316 stainless steel in ITER), but this could be compensated by the higher plasma power and the much higher duty cycle (Taylor & Cortes, 2014).

barrier with ex-vessel parts (e.g. for cooling systems, heating and current drive systems, diagnostic systems in vessel coil feeders etc.)

2. **Tokamak building:** the containment structure prevents a radioactive release to the environment in case the first barrier has failed.

In DEMO, an electricity-producing fusion power plant of the future, in-vessel components should be highly reliable, and damaging plasma eruptions should be eliminated. That would ultimately make it possible to credit some in-vessel components with a safety function to avoid the extensive ex-vessel parts that complicate the first confinement barrier of ITER (

Figure 3) (ITER, 2011; Taylor & Cortes, 2014). Moreover, considering the large tritium inventory in DEMO, it is possible that the cryostat system or the tokamak building may have to be strengthened to serve as a confinement barrier to prevent, protect against, or mitigate accident sequences (Wu et al., 2016).

Figure 3: Physical barriers providing the safety functions for fission and fusion facilities (adapted from (Wu et al., 2016)).[21]

Having highlighted the main safety concerns of fusion facilities, and identified possible areas where a fusion regulation could differ, the next chapter (chapter 3) will outline and compare regulatory options. The aim is to lay the groundwork towards a regulatory framework for future fusion power plants.

[21] EUROfusion is currently looking at defining the cryostat as a confinement barrier.

3. REGULATORY OPTIONS FOR FUSION POWER PLANTS

3.1 APPROACHES TO REGULATION

Although the prime responsibility for safety rests with the licensee, **governments have an important responsibility in establishing and sustaining an effective legal, regulatory framework for safety, including and independent regulatory body** (more details in Appendix A). The government shall ensure that the body has the legal authority, competence and resources necessary to fulfil its functions and responsibilities. Moreover:

*"The government shall establish a **national policy and strategy for safety**, the implementation of which shall be subject to a graded approach in accordance with national circumstances and with the radiation risks associated with facilities and activities, to achieve the fundamental safety objective and to apply the fundamental safety principles established in the Safety Fundamentals." (Governmental, Legal and Regulatory Framework for Safety, 2016)*

*"The government shall ensure that a graded approach is taken to the **regulatory control of radiation exposure**, so that the application of regulatory requirements is commensurate with the radiation risks associated with the exposure situation." (Update of the Risk Informed Regulation Implementation Plan, 2001)*

A graded approach should apply to the resources devoted by the licensee and the scope, stringency and implementation of the regulations. It means that these have to be commensurate with the magnitude of the radiation risks, their amenability to control and ensure safety and avoid any unnecessary increases in regulatory burden and costs.

The regulatory approach should be one of the first things that the regulatory body should consider in the early stage of planning. It should consider the needs of the state, i.e. its political, legal and industrial practices and culture, as well as the guidance provided by the IAEA safety standards. The regulatory approach[22] influences the size, structure and resources of the regulatory body, and the necessary competencies. Therefore, the government should approve the regulatory approach chosen by the regulatory body. **There are two main regulatory approaches** (**Error! Reference source not found.**) *(Establishing the Safety Infrastructure for a Nuclear Power Programme, 2020):*

a. **a prescriptive approach with a large number of regulations:** it places great importance on the adequacy of safety regulations. It requires thorough development since it involves establishing detailed requirements for the regulatory body and operational organization. These include comprehensive technical requirements or specific issues that the operational organization and its suppliers should address and present for assessment by the regulatory body, derived from relevant international or national industrial standards. The development and updating of detailed regulations place a high demand on the regulatory body's resources.

b. **a goal-setting approach that focuses on performance, functions and outcomes:** it requires establishing specific safety goals and targets yet allows the operational organization more flexibility in determining how to meet these goals, thus necessitating fewer and less detailed regulations. Unless all staff of the regulatory body and operational organization have a high level of professional

[22] Starting with its early organization and preparation of its regulatory framework to the stage where it is able to specify regulations and to make safety assessments as part of the licensing process.

competence and interaction, it may be hard to verify the appropriateness of the safety measures identified.

Table 1: Comparison between prescriptive and goals-setting or performance-based approaches to nuclear safety regulation.

PRESCRIPTIVE APPROACH	GOAL-SETTING APPROACH
Places great importance on the adequacy of safety regulations and requires the development and updating of detailed regulations	Requires the establishment of specific safety goals and targets, necessitating fewer and less detailed regulations
Involves establishing clear requirements and expectations for the regulatory body and the operating organization (i.e. technical requirements or specific issues)	Allows the operating organization more flexibility in determining how to meet the specific safety goals and targets
Places a high demand on the resources of the regulatory body and operating organization	Regulatory body and operating organization need a high level of professional competence and interaction

Each regulatory approach has advantages and disadvantages and some approaches combine features of these two main alternatives.[23] Overall, a prescriptive regulatory regime establishes several detailed legal requirements, regulations and guidance that need addressing to reach the safety goals. On the other hand, a non-prescriptive, goal-setting regulatory regime accepts that there is likely more than one way to achieve the safety goals. It is, therefore, unsurprising that the recent IAEA Safety Guide *(Establishing the Safety Infrastructure for a Nuclear Power Programme, 2020*) recommends developing a regulatory framework that balances prescriptive and goal-setting approaches. As explained, this balance depends on the state's legal system, which influences the necessary resources of the regulatory body and should be considered already in Phase 1 (Figure 4).

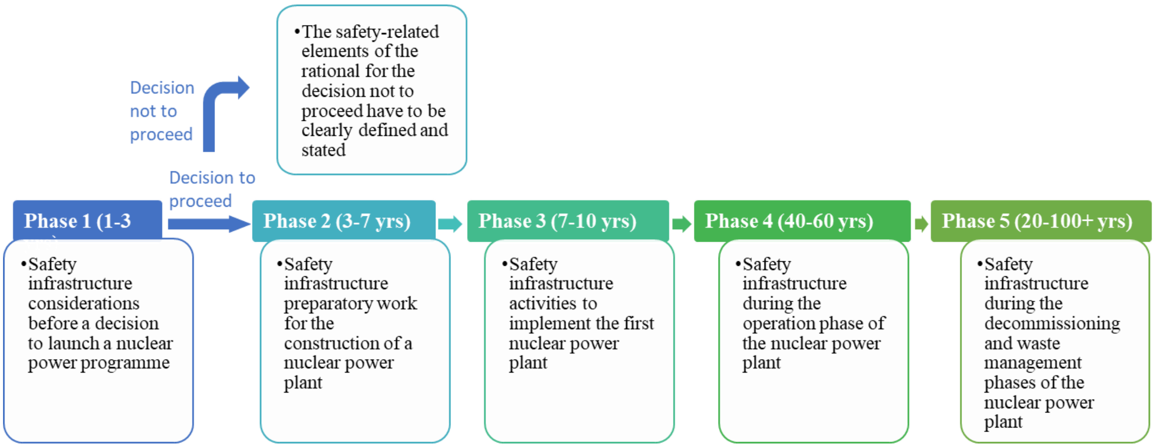

Figure 4: The five main phases over the lifetime of a nuclear power plant from a nuclear safety perspective (adapted from (Establishing the Safety Infrastructure for a Nuclear Power Programme, 2020)).

[23] At ITER, a goal-setting approach was preferred, which included however some of the requirements of the prescriptive approach such as the safety limits for doses to individuals in case of the worst hypothetical accident, for tritium and dust inventory, etc. ITER safety staff answered to questionnaires tackling each safety function sent by ASN and then ASN staff reviewed the answers in periodic meetings.

One of the principal functions of a regulatory body is authorizing nuclear installations and their activities through the **'process of licensing'** *(Licensing Process for Nuclear Installations, 2010)*.[24] The licensing process covers all plant stages in their lifetime. Moreover, in a given stage, there may be one or more **'hold points'** (also known as 'regulatory hold points') (Figure 5), set by national legislation and regulatory requirements. These hold points give the regulatory body the power to ensure that the responsible persons or organizations control any safety risks that may arise from nuclear installations. At each hold point, a licence, or authorization, from the regulatory body may be required and conditions may be attached to it. The regulatory body should include provisions in the regulations that the applicant or authorized party is required to accomplish when applying for a license.

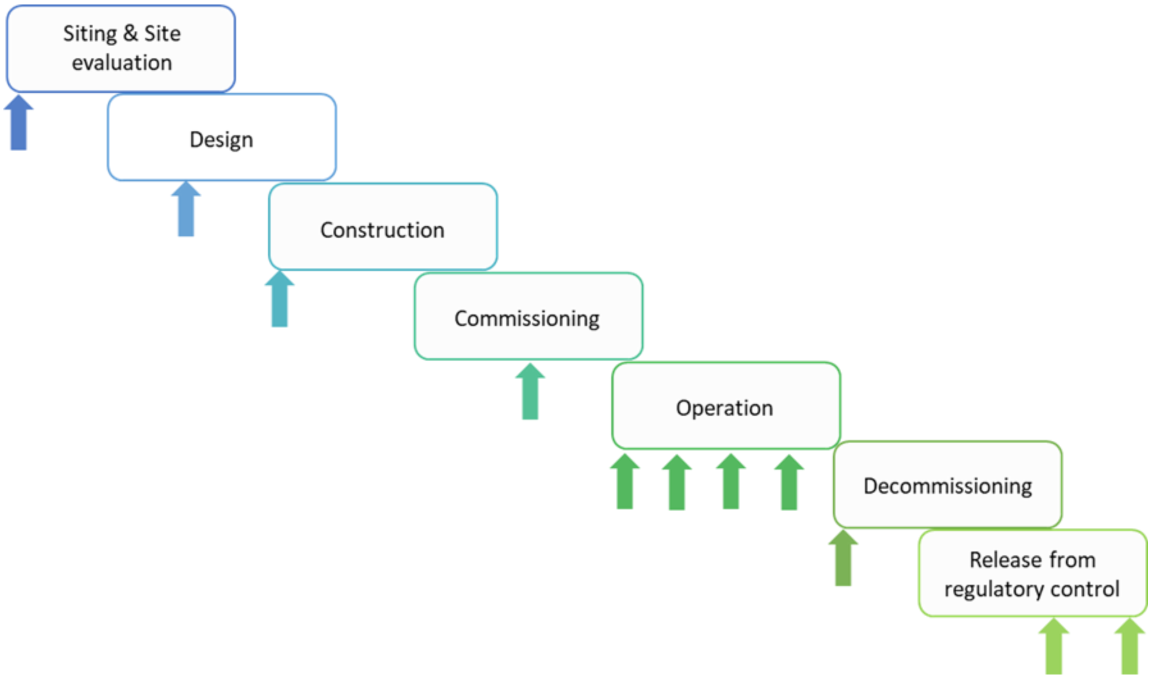

Figure 5: Arrows indicating where hold points may be imposed across all plant stages in the lifetime of a nuclear power plant(adapted from (Licensing Process for Nuclear Installations, 2010)).

Among these provisions is developing a **safety assessment** and submitting it to the regulatory body as part of a comprehensive application. The safety assessment should demonstrate that the highest priority is given to safety[25] (*Fundamental Safety Principles, 2006*). The graded approach shall be used in all aspects of the safety assessment, including in determining its scope and level of detail at a particular stage *(Safety Assessment for Facilities and Activities, 2016*). The following section provides an overview of the two main safety assessment approaches employed today. It also discusses the applicability of the modern integrated safety assessment approach to fusion facilities.

[24] The terms 'licence', 'authorization' and 'permit' are considered to be synonymous. The authorization shall take the form of either licensing or registration. Registration is suitable to those practices for which (a) safety can largely be ensured by the design of the facilities and equipment; (b) the operating procedures are simple to follow; (c) the training requirements for safety are minimal; and (d) there is a history of few problems relating to safety in operations (*Update of the Risk Informed Regulation Implementation Plan*, 2001).

[25] Safety assessment shall be made and submitted to the regulatory body when exposure can be greater than a level as specified by the regulatory body (*Update of the Risk Informed Regulation Implementation Plan*, 2001). The highest priority given to safety means that "*the level of safety is as high as reasonably achievable and that safety will be maintained for the entire lifetime of the facility or duration of the activity, until it is released from regulatory control by the regulatory body*" (*Functions and Processes of the Regulatory Body for Safety*, 2018).

3.2 SAFETY ASSESSMENT

The development and use of the safety assessment provide the framework for acquiring the necessary information to demonstrate compliance with the relevant safety requirements. It also provides the framework for developing and maintaining it over the lifetime of the facility.[26] The safety assessment shall commence at an early point in the design of a nuclear power plant and include iterations. It should identify all possible sources of radiation and evaluate possible doses to workers and the public, including possible effects on the environment, resulting from normal operation, anticipated operational occurrences and accident conditions (*Safety of Nuclear Power Plants: Design, 2016*). The safety analysis aims to identify important safety issues for each plant state and demonstrate that the plant is capable of meeting any authorised limits on the release of radioactive material and on the potential exposure to radiation.

The traditional approach to regulation has been based on **a deterministic analysis.** In this approach, a set of deterministic rules and requirements for the design and operation of facilities are expected to provide a high degree of confidence against radiation risks. The deterministic analysis adopts a conservative approach for providing sufficient safety margins that compensate for the uncertainties in the performance of equipment and personnel. Over the past two to three decades, **probabilistic analyses (PSA)** have been produced for the majority of nuclear facilities in the MS. These were of sufficiently high quality to be incorporated by both plant operators and regulatory bodies in the decision-making process for nuclear safety and regulatory issues (*Risk Informed Regulation of Nuclear Facilities: Overview of the Current Status, 2005)*. The probabilistic approach constitutes a conceptual and mathematical tool for determining all significant contributing factors to the radiation risks of a facility, and deriving numerical estimates of risk using realistic assumptions whenever possible. It uses a comprehensive, structured approach for identifying failure scenarios by addressing many of the uncertainties explicitly and evaluating the extent to which the overall design meets safety criteria.[27] Therefore, a probabilistic analysis may provide insights into system performance, reliability, interactions and weaknesses in the design, the application of Defence-in-Depth (DiD), and risks, which may not be possible with a deterministic analysis.

As regulatory approaches vary among the MS, so do approaches concerning the scope and depth of the safety assessment. Some states have developed a highly prescriptive approach based on deterministic requirements set by the regulatory body. Others have adopted a more goal-setting, performance-based approach, where the plant operator and the regulatory body have much more freedom to determine the method to meet the safety targets (Risk Informed Regulation of Nuclear Facilities: Overview of the Current Status, 2005). In comparison, prescriptive regulations are likely to be more deterministic, whereas goal-setting regulations more risk-informed as performance indicators are often risk-related metrics (see Table 1).[28] Nevertheless, it is important that any changes for 'risk informing' regulations preserve essential factors included in the deterministic formulations to provide reasonable assurance that adequate protection is maintained *(Risk Informed Regulation of Nuclear Facilities: Overview of the Current Status, 2005)*. These factors include the fundamental safety principles of DiD, safety margins, the ALARA/ALARP principles for radiation protection, and adherence to any safety goals that exist in the Member State.

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[26] For many facilities and activities, environmental impact assessments and non-radiological risk assessments will be required before construction or implementation, which, in general, have many commonalities with the safety assessment and may be combined to save resources and to increase the credibility and acceptability of their results (*Safety Assessment for Facilities and Activities*, 2016).

[27] For example, the "frequency of failure" of single equipment/components is used to build complex "fault trees" able to estimate the probability of failure of complex systems. In fact, this methodology is at the basis of the so-called "safety monitors" which are used to train plant operators, by assuming the failure of a component and see how this failure propagates in other equipment/systems.

[28] In a risk-informed approach to regulatory decision-making, insights from probabilistic risk assessment are considered with other engineering insights. Even though a performance-based (i.e. goal-setting) approach can be implemented without the use of risk insights, requiring that the objective performance criteria are based on deterministic safety analysis and performance history, the U.S. Nuclear Regulatory Commission, for example, states that "*To the extent appropriate, staff activities to risk-inform regulations should also incorporate the performance-based approach to regulation. The corollary is also true that performance-based regulations should be risk-informed when possible.*" (*Update of the Risk Informed Regulation Implementation Plan*, 2001)

Table 1: Comparison between prescriptive and goals-setting or performance-based approaches to nuclear safety regulation.

DETERMINISTIC APPROACH	PROBABILISTIC APPROACH
Analysis of a limited subset of initiating events and fault sequences (i.e. DBAs); accident conditions are addressed separately	A comprehensive analysis of initiating events and hazards (incl. DBAs and BDBAs); all initiating events and safety systems are integrated in the same model
Frequencies of initiating events and failure probabilities of systems, structures, and components are approximated	Frequencies of initiating events and failure probabilities of systems, structures, and components are explicitly included
Model and data uncertainties are addressed using conservative assumptions based or best estimate codes and standards, with associated uncertainty evaluated in results	Many uncertainties are explicitly addressed in models (capability to address parameter uncertainties); best estimates are used in all modelling aspects and sometimes conservative assumptions are used to determine success criteria
A rough indication of the relative importance of systems, structures, and components	A wide range of information on ways to measure the importance of systems, structures, and components

Given that both the deterministic and probabilistic analyses present specific advantages and disadvantages, the Gen-IV International Forum's (GIF) Risk and Safety Working Group (RSWG) charter proposed to integrate them in a systematic and balanced way. The aim was to derive insights from both approaches to inform decision making about safety issues at nuclear facilities. This proposal of an integrated approach is particularly relevant to first-of-a-kind facilities, as is the case of fusion power plants where high uncertainties are expected to be present, making it hard to apply a heavily oriented probabilistic approach. The next subsection presents this integrated safety approach, followed by a discussion on its potential applicability to fusion facilities.

3.1.2 Radioactive Material Release, Toxicity and Occupational Radiation Exposure

The modern approach to safety assessment is to apply an **integrated decision-making process**[29]. This integrated process combines the insights from the deterministic and the probabilistic analysis with any other safety requirements (legal, regulatory, cost-benefit, etc.) to better inform decision-makers *(Risk Informed Regulation of Nuclear Facilities: Overview of the Current Status, 2005*). The approach aims to integrate in a systematic manner quantitative and qualitative,[30] deterministic and probabilistic safety considerations, to obtain a balanced decision about safety issues at nuclear facilities. Regulatory bodies are increasingly applying it for decision-making and for organising activities to use resources more efficiently. The result is a reduction in the unnecessary burden on the licensees without compromising safety.

[29] Both deterministic and probabilistic approaches shall be included in the safety analysis, consistent with the graded approach, as they have been shown to complement one another and can be used to provide input into an integrated decision-making process (*Safety Assessment for Facilities and Activities*, 2016). Developing a regulatory framework involves maintaining a balance between prescriptive approaches and more flexible goal setting, risk-informed approaches.

[30] Qualitative considerations refer to checking the system's compatibility with safety principles, requirements and guidelines with those formulated by agencies and organizations responsible for verifying the safety of the installations; quantitative considerations refer to the safety analysis that verifies the conformity with quantitative safety objectives, including uncertainties.

The development and qualification of an **Integrated Safety Assessment Methodology (ISAM)** have been the core objective of the Gen-IV International Forum's (GIF) Risk and Safety Working Group (RSWG) charter (*GIF/RSWG/ISAM report, 2011; GIF/RSWG/2007/002, 2008*). As a result, the group has proposed a *technology-neutral* methodology that can be used to evaluate and document the safety of Gen-IV nuclear facilities. The methodology supports the concept that safety is *"built-in"* rather than *"added on".* This means that PSA and other formal safety assessment methods guide the design from the earliest stages to result in a robust design, free of dominant vulnerabilities and safety-related add-ons. Based on the comments and suggestions by the RSWG in 2011, a guidance document for the ISAM was released to facilitate its use and practical implementation (Ammirabile, 2014).

The ISAM is described in more detail in (GIF/RSW*G/ISAM report,* 2011*)*. It consists of five distinct analytical tools (see Figure 6). Each tool is used to answer specific safety-related questions with different degrees of detail and at different design stages (Ammirabile, 2014). The methodology is integrated, as the results of each analysis tool support or relate to inputs or outputs to the other tools:[31]

1. Qualitative Safety features Review (QSR): a preparatory step to systematically verify and document that the evolving design incorporates the desirable safety principles, requirements and guidelines (IAEA, GIF, INPRO, etc.) so that safety is "built-in, not added-on".

2. Phenomena Identification and Ranking Table (PIRT): a practical and flexible technique used to systematically identify a spectrum of safety-related phenomena or scenarios following a graded approach. These are then ranked based on their importance (often related to their potential consequences) and the state of knowledge i.e. sources and magnitudes of uncertainties.

3. Objective Provision Tree (OPT): a tool used to ensure and document the provision of essential "lines of defence", i.e. DiD, throughout the design phase. As such, while the PIRT tool identifies potentially important safety phenomena, the OPT identifies design provisions intended to prevent, control, or mitigate the consequences of those phenomena.

4. Deterministic and Phenomenological Analyses (DPA): a quantitative analysis, including the consideration of uncertainties. It aims to support the development and sizing of the safety architecture[32] and serves as an essential input to the PSA.

5. Probabilistic Safety Analysis (PSA): a structured means of identifying the answers to three basic questions related to safety: a) what can go wrong? b) what is the likelihood of something going wrong? c) what are the consequences if something goes wrong? While the above ISAM tools have significant value as stand-alone tools, their value is enhanced by serving as inputs for preparing and shaping the PSA to be successfully implemented.

To the best of the authors' knowledge, the systematic approach followed by the Korean DEMO project (Oh, Kang, Heo, & Kim, 2014, 2015) is at present the only study that has investigated the applicability of the ISAM tools to fusion safety.[33] The studies suggest that the ISAM can be applied for addressing regulatory requirements and recognizing technical safety issues for K-DEMO. The authors recommend involving a large and diverse panel of experts on fusion and fission, with working experience in universities, industries, and national institutes.

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[31] Although the analytical tools can be selected for individual use, the full value of the methodology is obtained by using each tool in an iterative manner and in combination with others throughout the different design stages.

[32] Characterises by all the technical provisions (i.e. all systems, structures and components, SSCs) and organizational measures for the design, the construction, the operation, the shutdown and the decommissioning of a facility, taken to prevent abnormal or degraded situations or limit their effects.

[33] A similar method applied to ITER is the Integrated Deterministic and Probabilistic Safety Assessment (IDPSA) framework (Bellaera et al., 2020). In comparison, ISAM also includes QSR, PIRT, and OPT tools, besides DPA and PSA, to influence the direction of the concept and design development from the earliest stage and achieve a 'built-in' safety rather than 'added on'.

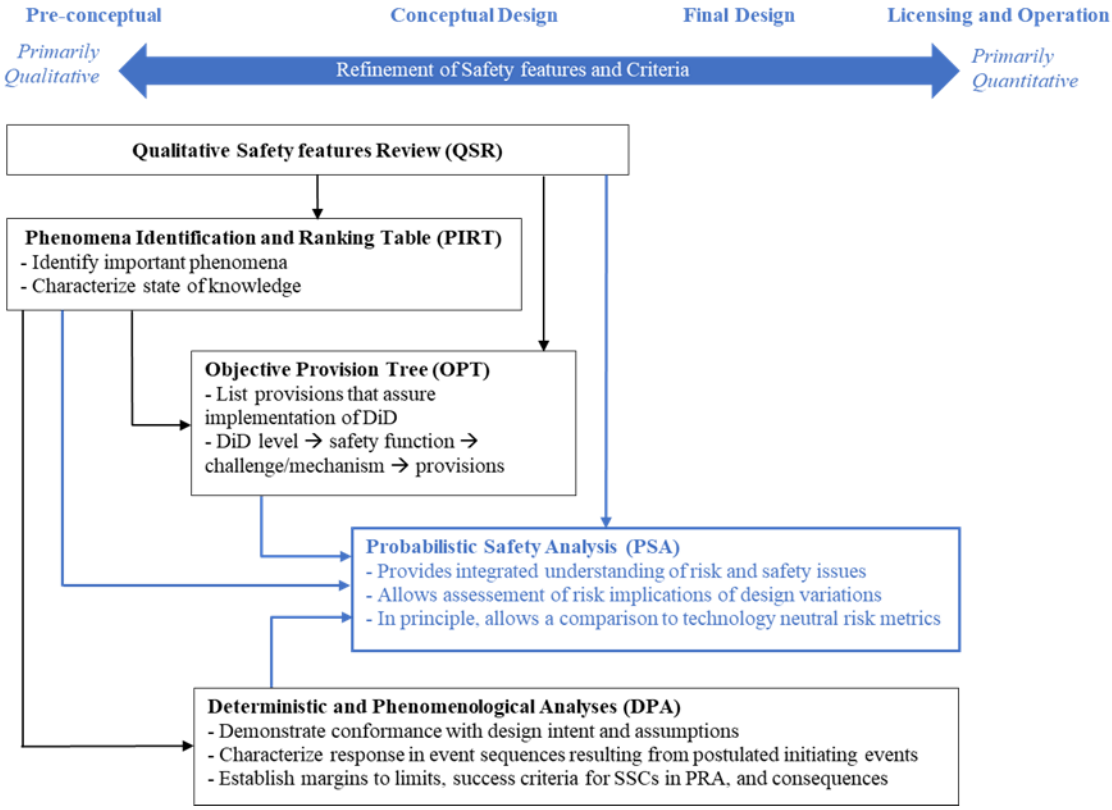

Figure 6: The five main phases over the lifetime of a nuclear power plant from a nuclear safety perspective (adapted from (Establishing the Safety Infrastructure for a Nuclear Power Programme, 2020)).

The K-DEMO studies have explored the application of two ISAM tools: PIRT and OPT.[34] The PIRT tool is a nine-step process to identify, recognize, and qualify the relative importance of all safety-related phenomena or scenarios that could affect systems. The identified phenomena or scenarios are then ranked based on their consequences and the level of knowledge, while including the rationale behind these decisions. Steps 1-5 are typically defined by the facilitator of the PIRT and involve phenomena definition, objectives, background information, potential accident scenarios and the evaluation criteria used to judge their importance. Steps 6-8 comprise information provided by the expert panel in agreement with the facilitator on the identified phenomena (or technical issues), their significance ranking based on the evaluation criteria, as well as information on the knowledge level as assessed by the panel, including the rationale. Table 2 shows the PIRT results for a postulated accident scenario of a rupture of multiple first-wall coolant pipes during plasma burn in the K-DEMO study (Oh et al., 2015).[35]

[34] The application of ISAM tools for K-DEMO has been limited within the scope of the conceptual phase.

[35] The assumptions to perform the PIRT for K-DEMO are: 1) electrical power of 1000 MWe referring to OPR-1000; 2) a tokamak design of the same size as ITER, and 3) the use of water as a coolant. The study investigated safety issues related to three accident scenarios. Here, for illustrative purposes, we display the PIRT results of one accident scenario, as the scope is to illustrate the applicability of the PIRT tool. More details on all three accident scenarios can be found in the (Oh, Kang, Heo, & Kim, 2015). For the European DEMO and taking into consideration the experience gained from ITER, these values may change.

Table 2: PIRT results for a postulated accident scenario involving the rupture of multiple first wall coolant-pipes during plasma burn in K-DEMO (adapted from (Oh et al., 2015)).

SYSTEM	SUBSYSTEM	PHENOMENA	IMPORTANCE (ITER)	IMPORTANCE (K-DEMO)	KNOWLEDGE LEVEL	COMMENT AND/OR RATIONALE
Vacuum vessel	Structure	Structure distortion or damage of plasma facing components by EM load	High	High	High	The EM load in the PFCs (blanket, divertor etc.) affects the structure indirectly. Force is attenuated in the PFCs. The EM load is a major design parameter for the vacuum vessel.
		Wall heat transfer for decay heat removal	Low	Low	High	Most of the heat is produced in the PFCs. It is small to be transferred to the backside of the vacuum vessel.
	Divertor	Structure distortion or damage by EM load	Medium	Medium	High	Structure distortion or damage by the EM load can occur, but each component is designed to withstand it.
		Heat deposition by runaway electron production	Medium	Medium	Medium	Local damage by the heat source generated instantaneously by plasma disruption. In this case, the PFCs can be damaged.
		Wall heat transfer for decay heat removal	Medium	Medium	High	
		ACPs, dust, hydrogen production	Medium	Medium	High	
	Blanket	Blanket Structure distortion or damage by EM load	Medium	Medium	High	Structure distortion or damage by the EM load can occur, but each component is designed to withstand it.
		Heat deposition by runaway electron production	Medium	Medium	Medium	Local damage by the heat source generated instantaneously by plasma disruption. In this case, the PFCs can be damaged.

		Wall heat transfer for decay heat removal	Medium	Medium	High	
		ACPs, dust, hydrogen production	Medium	Medium	High	
	Vacuum system	Pressure increase by loss of coolant	High	High	High	Pressure is returned immediately to vacuum condition by the VV Pressure Suppression System (VVPSS).
		Collection of produced ACPs, dust, tritium	High	High	Medium	
Magnet	Structure	EM load	Medium	Medium	Medium	Quench can occur through an overcurrent generated by an eddy current.

The OPT is a six-level process to ensure design safety through applying the concept of Defence-in-Depth (DiD). These steps involve:

1. the level of DiD (please see more details on the DiD levels in Appendx C);
2. the objectives and barriers to be achieved and protected;
3. the safety function to be maintained (i.e. performed successfully);
4. challenges to cope with;
5. the mechanisms to be prevented or controlled; and
6. the provisions to be implemented to prevent and/or control the mechanisms.

Oh et al. illustrate in their study the application of the OPT tool on K-DEMO for the DiD levels 2 and 3 for the safety function heat removal[36] (Oh et al., 2015). According to this study, the path of the loss of heat transfer, involving the loss of coolant inventory and flow (forced convection) and ultimate heat sink, appeared to be the most significant. The authors underline that if the heat generated in the fusion reactor and other components is not effectively removed, structures and systems such as the vacuum vessel would be damaged resulting in the release of tritium and activated materials. Therefore, they propose provisions for passive and active safety systems as well as diverse redundant systems to control, protect and mitigate such accidents.

The application of the PIRT and OPT tools of ISAM to K-DEMO demonstrates the applicability of the methodology and its usefulness for recognising and investigating safety issues in the design of fusion power plants. The results could contribute to the conceptual design of the safety features of K-DEMO and assist design engineers and licensers on regulatory requirements by helping identify weaknesses and necessary design provisions.

As discussed, this report aims to support developing a future regulatory framework for fusion power plants. Therefore, it focuses on the safety-related aspects of fusion technology. Nevertheless, nuclear or radioactive material of all types, whether in use, storage or transport, are also subject to security and safeguards concerns. These are briefly outlined in the following chapter.

3.3 THE 3 S'S: SAFETY, SECURITY AND SAFEGUARDS

The nuclear sector is unique compared to other power generation sectors, because besides civilian applications (i.e. energy, medical therapies and diagnostics, food preservation and many others), it also has military applications (i.e. weapons). This uniqueness has led to a misplaced association of nuclear weapons with civilian nuclear applications and mainly power generation. The intersection of military and civilian applications is best observed in the discussion on safety, security and safeguards, sometimes referred to as "3S's" (Murphy & Drupady, 2020).

According to the IAEA glossary (*IAEA Safety Glossary: 2018 Edition*, 2019):

- Nuclear safety is "the achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks."

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[36] The study addressed the DiD levels 2 and 3 for all four safety functions suggested by the panel of experts: plasma control, heat removal, containment integrity, tritium isolation. The study presents the OPT results for one out of the four safety functions mentioned.

- Nuclear security is "the prevention and detection of, and response to, criminal or intentional unauthorized acts involving nuclear material, other radioactive material, associated facilities or associated activities."

International safeguards, as implemented by the IAEA, is about verifying the states compliance with commitments made under safeguards agreements with the IAEA. The IAEA is required under its Statute to:[37]

- "Establish and administer safeguards designed to ensure that special fissionable and other materials, services, equipment, facilities, and information made available by the Agency or at its request or under its supervision or control are not used in such a way as to further any military purpose; and to apply safeguards, at the request of the parties, to any bilateral or multilateral arrangement, or at the request of a State, to any of that State's activities in the field of atomic energy."

Essentially, safety focuses on the normal operation and the prevention and mitigation of possible accidents. Security focuses on preventing, detecting and responding to malicious acts (e.g. theft, sabotage, unauthorised access). Safeguards focus on non-proliferation, involving the timely detection of diversion of nuclear material from the intended peaceful uses (e.g. to manufacture weapons). Consequently, there are overlaps across all 3S's on protecting people, property and the environment from the harmful effects of ionising radiation. All are necessary conditions, while each alone is not sufficient.

In the past, these three communities developed separately. Yet, in recent years, there has been a growing recognition of the need for an integrated, coordinated approach to nuclear safety, security and, to a lesser extent, safeguards. All 3S's should be managed in an integrated way at an early design stage and during construction, commissioning, operation and decommissioning to avoid putting in place conflicting requirements that could undermine the goal to protect society.

There is thus a real opportunity for fusion power plants to develop an integrated 3S's approach. Below are some of the challenges that could be encountered.

- Safety: classifying the design basis accidents for fusion power plants since these have so far been driven by potential hazards associated with NPPs.
- Security: defining the scope of security in the context of fusion technology, e.g. what materials, if any, are worthy of protection against theft. In addition, cybersecurity against potential cyber-attacks is a growing concern, especially when planning future fusion plants for decades ahead.
- Safeguards: defining the physical protection in the context of fusion power plants. This involves understanding how to implement physical protection, in terms of what should be protected and how to do it effectively to prevent the misuse of fertile material (e.g. theft of tritium, or even ingress of fissile material in a fusion facility[38]), as well as what are the necessary processes and systems. Safeguards should identify materials and systems to be covered in the current safeguards arrangement or likely increases of future materials use needing to implement safeguards.

Clarifying all 3S's and the necessary goals and objectives will ultimately enable designers to understand what needs to be delivered and optimised in terms of all requirements on safety, security and safeguards for the protection of the people and the environment.

The following chapter gives an overview of the potential safety-related implications for future fusion power plants identified in the literature. It also outlines relevant policy recommendations for the regulation of future fusion power plants.

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[37] The Statute of the IAEA, Article III.A.5: https://www.iaea.org/about/statute#a1-2

[38] More details about possible scenarios can be found here: (Goldston & Glaser, 2012). It should be recognized that a state must have access to fissile material to take advantage of tritium for military uses.

4. IMPLICATIONS AND RECOMMENDATIONS

First-of-a-kind (FOAK) plants, as will be the case for the first fusion power plants, are the most difficult to regulate because of the lack of reference plants and the limited experience in licensing. Due to these factors, it may be difficult to predict all possible FOAK-related effects. Capitalising on lessons learnt from existing facilities like ITER is therefore vital in helping to identify possible implications and limit uncertainties that can negatively impact the licensing of future fusion power plants. A number of DEMO safety-related implications are described below, as identified in the literature, building on the work of ITER.

4.1 IMPLICATIONS

The identified safety-related implications from the literature are organised below according to accidents, radioactive material release, toxicity and occupational radiation exposure, and radioactive waste.

<u>Accidents</u>

- It remains to be investigated and decided whether the potential DBAs identified for ITER would be identical for DEMO, or whether new accident scenarios should be considered in terms of probability or consequences. These could include accidents involving the tritium breeding blankets and failures in the plasma control or mitigation systems (Perrault, 2016). The limiting conditions for each accident scenario need to be defined to demonstrate that the available safety margins are met.
- The analysis of BDBAs is needed to test the robustness of the defence-in-depth approach, determine the ultimate safety margins and demonstrate no cliff-edge effects. A sensitivity analysis would be helpful to test the key assumptions and understand their robustness for each accident scenario. A comprehensive consideration of DECs and an enhanced confinement is required to meet the 'no off-site emergency response' goal (Wu et al., 2016). The number of necessary confinement barriers will depend upon the risk to the public associated with an accident sequence and its probability of occurrence as well as the need to maintain a balance between facility availability and maintenance schedules (Wu et al., 2016).
- The large gaps in the failure rate data of components must be filled and accident probabilities need to be evaluated: a) hydrogen or dust explosions need to be fully addressed to protect the confinement barriers such as the vacuum vessel and building walls; b) plasma disruptions that could lead to a release of electromagnetic energy need to be better understood (Wu et al., 2016).
- For DEMO, decay heat removal may need to be developed as a safety function[39] (Wu et al., 2016). The design of the tokamak and its cooling systems depends on evaluating the safety issues linked to decay heat removal. It is, therefore, essential to determine from the early design stage whether decay heat removal (from the tokamak) and the residual power evacuation (from the blanket-sectors during transfer and storage) will become safety functions (Perrault, 2016).

<u>Radioactive material release, toxicity and occupational radiation exposure</u>

- For DEMO, it should be ensured that the full range of anticipated contamination levels of water is identified and treatment or disposal paths are implemented (Wu et al., 2016). Since the tritium operational release limits at ITER have not yet been verified, these also remain unknown for DEMO. Moreover, R&D is still necessary to investigate how the fraction of tritium burned in the plasma could be further enhanced to reduce the tritium inventory (Wu et al., 2016).

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[39] A safety function is the action of a collection of equipment to implement automatic mitigation of a particular hazard. Safety functions are specific purposes that must be accomplished to assure the general safety objective. The accomplishment has to be performed in operational states, during and following DBAs and, to the extent practicable, during and following the considered plant conditions beyond DBA.

- It is important that any potential source terms of volatile radioactive fission products as well as toxic products, be thoroughly considered in normal operation and accident scenarios. These could include noble gases and iodine released from the plasma-facing surfaces and the Be dust (when Be is used in the plasma-facing material), Po-210 (activation product of lead from blankets with lithium lead breeder) and mercury (vacuum pumping options include mercury ring pumps).
- The design choices of DEMO need to be optimized and the remote handling technology necessary for maintenance operations further developed to minimize occupational radiation exposure (Wu et al., 2016).

Radioactive waste

- Estimates on the volumes and key characteristics of the low-level and intermediate-level radioactive wastes that are likely to arise from DEMO are needed (including the half-lives and radiation dose rates for each waste stream).
- An improved understanding of tritium retention in materials is needed, as is the development of detritiation systems (Wu et al., 2016).

4.2 RECOMMENDATIONS

Below is a summary of recommendations found in literature that are relevant for developing a regulatory framework for fusion power plants.

Accidents

- A comprehensive safety (and security) framework should be adopted with risk at the centre of the approach. This necessitates a clear description of acceptable and intolerable levels of risk of radiation exposure to workers and the public under normal operation and accident conditions (i.e. the internationally recognised ALARA/ALARP principles). Information on the levels of risk that are judged as intolerable is vital for designers to enable a safety-led design.
- Alongside the regulatory guidelines, a regulatory schedule for fusion power plants is needed to set all agreed hold points, specifying the type of documentation required by the licensee to support safety, security and environmental protection at each hold point.
- The hazard and operability (HAZOP) and FMECA approaches (Pioro, 2016) and the PIRT tool (part of ISAM (GIF/RSW*G/ISAM report,* 2011)) could be considered to support the identification of potential hazards and associated risks..
- The strategy for mitigating the consequences of accidents involving tritium and activated dust should be defined at the earliest design stage of DEMO. If the same inventory limits with ITER are kept, it would be necessary to slow down the process of tritium absorption and dust creation and find ways to detritiate and extract dust from the vacuum vessel quicker during the maintenance periods. On the other hand, if the inventory limits are increased, it would be necessary to re-examine all the accident scenarios involving such inventories, particularly those of hydrogen isotopes and dust explosion that could lead to significant design modifications (Perrault, 2016).
- An integrated approach to safety and security should be adopted for the DEMO conceptual design and subsequently for fusion power plants. This should clarify the safety and security requirements and the implications for the design and operational stage. It is therefore also recommended to develop an organisational structure that can deliver a fully integrated systems engineering approach to the design to ensure a progressive and iterative process that involves: a) definition of requirements and data collection (including lesson learnt from ITER); b) validation and formal approval; c) definition of

concepts and iterative assessment of how requirements are met; d) safety functions and their integration; e) global safety assessment (accidents, releases, doses etc.).

Radioactive material release, toxicity and occupational radiation exposure

- The source terms should be clarified (i.e. maximum dust and tritium inventory in VV) and their data should be regularly reviewed and updated. This is important information for evaluating the environmental releases and impacts during normal operation and accident conditions. The expected routine discharges to the environment (radioactive or chemical) during maintenance activities should be included.
- The aim for DEMO should be to ensure that the risks of ionizing radiation to workers from routine operation and maintenance are ALARA. It is however not certain that using low activation materials in DEMO reactors would suffice to reach the same objective of ALARA exposure currently planned for ITER. It is therefore essential to integrate an optimization approach in the early design stage to respect an objective of an internal dose ALARA and of individual and collective doses equivalent to those of comparable facilities. This is particularly relevant for higher risk zones of exposure to ionizing radiation than ITER (Perrault, 2016).
- All chemical hazards and toxic materials present in DEMO should be specified. If fusion power plants use beryllium, impurities and especially natural uranium need to be measured and minimized to levels ALARA. For DEMO, beryllium zoning should be adopted based on the knowledge learnt from ITER. Estimates on impurities in beryllium are currently evaluated at ITER and best practices are explored, where experience from the fission sector may also be of help.

Radioactive waste

- The focus should be on strategies to effectively assess radioactive waste, control it and keep it as low as reasonably achievable (ALARA). Low-activation materials should be ready for use for DEMO (Wu et al., 2016).
- Decommissioning design guidelines should be developed for DEMO, ensuring that decommissioning requirements are part of the optimized conceptual design.

5. CONCLUSIONS

The European research roadmap to the realisation of fusion energy paves the way for commercial electricity generation from fusion as a potential long-term solution for clean energy. Exploiting fusion energy for commercial power generation will require an appropriate regulatory framework. However, unlike fission, there is no fusion-specific regulatory approach for assessing license applications to construct and operate fusion power plants. This report aimed to address the gap in the regulations and lay the groundwork for developing a regulatory framework tailored to fusion power plants. The steps followed were first reviewing the differences between fusion and fission facilities. Then, a comparison was presented on the applicability of regulatory approaches likely to be part of a regulatory framework for fusion power plants. Since the focus was fusion technology, a detailed analysis of the safety concerns of fission was beyond the scope of this work.

It is clear from the review that the main differences between fusion and fission in terms of safety concerns are summarised as follows:

a. the radioactive source term differs since fusion reactors handle no fissile materials as fuel;
b. in the event of a disturbance, a fusion reaction would intrinsically terminate and, unlike fission, controlling reactivity (i.e. power rising exponentially) would not be necessary; and
c. because of the lack of fissile products, fusion generates no long-lived radioactive waste.

It is important to highlight these differences as any fission-based regulatory framework is going to be driven by the safety issues unique to fission that are inapplicable to fusion. These are the central need to prevent criticality, avoid the release of long-lived radioactivity (e.g. in the event of an accident), manage proliferation risks associated with fissile materials, and safely handle spent fuel.

Nevertheless, as elaborated in this report, there are some common safety aspects between fission and fusion and others specific to fusion, which warrant consideration when regulating fusion power plants. Overall, the safety concerns relevant to fusion are associated with the handling of tritium and its inventory and the generation of activated dust and components (linked to risks of radioactive release, fire or explosion). These, in turn, influence the quantity of low- and intermediate-level radioactive waste, although this would also depend on the materials used. There are also safety concerns associated with the potential use of toxic materials (e.g. beryllium, lithium), material impurities, and the potential release of electromagnetic energy.

Consequently, some fission safety concepts are relevant to fusion, such as the defence-in-depth principle, as well as the accident prevention and mitigation goals for radiation protection and technical safety. Fusion power plants, however, should allow evolving these goals and simplify the regulation, particularly by a) eliminating the need for offsite emergency response, i.e. no public evacuation and sheltering, as in the case of ITER, which would facilitate public acceptance, b) minimising as low as reasonably achievable the activity and volume of radioactive waste so that waste is not a burden on future generations. Similarly, although there is no need for a safety function to control reactivity, the community should consider the two safety functions for radiation protection purposes (i.e. the confinement of radioactive material and the limitation of radiation exposure). In addition, decay heat removal is expected to become a safety function for future fusion power plants (due to a larger amount of activated material compared to ITER). Fire protection and prevention of explosions, however, will, likely remain non-safety support functions. Lastly, for the multiple physical barriers providing the above safety functions, fusion reactors may probably need to follow a similar approach to fission power plants rather than ITER's approach. There are mainly two reasons for that. First, many in-vessel components at ITER are not credited with a safety function because of their experimental nature. These components should however be reliable in future fusion power plants, which would enable them to be credited with a safety function and thus simplify the first confinement barrier. Second, considering the expected higher tritium inventory in fusion power plants compared to ITER, the cryostat system and the tokamak building may have to be strengthened to serve as confinement barriers.

In terms of the regulatory regime, so far states have adopted different approaches for regulating the safety concerns of fission power plants. These approaches can be primarily divided into two categories: prescriptive and goal-setting (also called performance-based). Both approaches have their advantages and disadvantages. The main difference is that a prescriptive regime establishes several detailed legal requirements that need addressing to reach the safety goals, whereas a goal-setting regime focuses on establishing specific safety goals and targets, while accepting that there are likely multiple ways to reach these goals. According to IAEA, a regulatory framework should maintain a balance between prescriptive approaches and more flexible, goal-setting approaches. This balance would depend on the state's legal system and its impact on resources. Nevertheless, governments shall ensure that a graded approach is adopted to the regulatory control of radiation exposure based on the principle of proportionality. This means that implementing regulatory requirements shall be commensurate with the risks to radiation exposure, while avoiding unnecessary regulatory burdens and costs.

Similarly, the approach adopted for the safety assessment that is part of the regulatory provisions for licensing varies among states. Some states have developed a highly prescriptive approach, while others have a more goal-setting, performance-based approach. In general, prescriptive regulations are likely to be more deterministic, whereas goal-setting regulations, more risk-informed, since performance indicators are often risk-related metrics. Given that both deterministic and probabilistic analyses have advantages and disadvantages, integrating them in a systematic and balanced way would allow obtaining useful insights from both approaches. This would help inform decision-makers in a holistic way on the safety issues of nuclear facilities. Such an integrated approach has been proposed by the GIF RSWG charter (in 2011 and 2014), called 'Integrated Safety Assessment Methodology' (ISAM). Its applicability to fusion has been partly investigated by the Korean DEMO project. The study demonstrated the potential of the ISAM approach in investigating and recognising safety issues and necessary design provisions for fusion facilities. It showed that ISAM could ultimately contribute to the conceptual design and regulatory guidance for fusion power plants. Such integrated approaches could be particularly relevant to first-of-a-kind facilities, as is the case for fusion power plants. The reason is the large uncertainties are expected because of the lack of reference fusion power plants and data, but also because of the limited experience in licensing such plants and the difficulty in forecasting technology development.

In conclusion, even though there are safety concepts from fission relevant to fusion, implementing them requires adaption to reflect the differences between the two technologies. Adopting a fission-based regulatory approach could be overly conservative in addressing certain fission-specific safety aspects and consequently disproportionate towards the risks to people and the environment. This approach could result in a significant burden on the regulatory process and negatively affect investments. On the other hand, the potential for offsite radioactive release from fusion power stations (mainly due to tritium) would require different regulations from current fusion experimental facilities, which are classified as irradiation installations.[40] Therefore, the following attributes are proposed for a fusion regulatory framework:

- A thoughtful approach to the regulatory regime, including the regulatory schedule and hold points, is warranted. The regulatory approach should be tailored to the safety concerns of future fusion power stations by being **consistent and proportionate to their hazard potential.**
- The regulatory framework needs to be **flexible and adaptable** to account for existing and future technological variations of fusion technology and the high uncertainty associated with future technology

[40] Installations used for medical, industrial, research and other purposes and any places where radiation generators are installed (*IAEA Safety Glossary: 2018 Edition*, 2019).

development. Capitalising on lessons learnt from existing facilities like ITER is vital to identify possible implications and limit uncertainties that can negatively affect the licensing of future fusion power plants.

- The framework must be transparent to support an appropriate regulatory control and licensing process. It would engender the confidence of investors and operators in controlling costs and the trust of the public and decision-makers in the safety of fusion. **Transparency and trust** will, in turn, enable the progress of fusion technology, promote knowledge creation and the development of science and innovation for the benefit of society.

A few points are emerging from the above conclusions that could be further explored in the future:

- There is a need to explore ways to **promote regulatory cooperation and collaboration across states** to harmonise regulatory frameworks and the terms used, e.g. for waste classification. The aim is to reduce regulatory burden and promote, and enhance safety evaluations globally in terms of efficiency, capacity and capability. These could be done with comparisons and exchanging experiences by, for example, benchmarking datasets to codes and standards, setting quantitative requirements on a technology-specific basis, etc. Among the challenges that could be encountered against efforts to promote regulatory cooperation are a) investments would be necessary to establish a degree of cross-border cooperation; and b) a level of confidence and trust would be needed to set common standards.
- It would also be necessary to make efforts to **distinguish between the concepts of asset safety and public and environmental safety.** That involves clarifying the requirements for protecting investors' assets and the safety requirements for the public and the environment.
- Finally, there needs to be a clear distinction between what a tolerable level of risk is and what an acceptable level of risk is: "*It must be recognised that a tolerable level of risk for the public to take is not necessarily the same as an acceptable level of risk*." (European Nuclear Society's High Scientific Council, 2020) "*Tolerability does not mean acceptability. It refers to a willingness to live with a risk so as to secure certain benefits and in the confidence that it is being properly controlled… For a risk to be 'acceptable' on the other hand means that for purposes of life or work, we are prepared to take it pretty well as it is.*" (Health and Safety Executive (HSE), 1988; Lukacs & Williams, 2020). Discussing acceptable risk represents a passive approach to risk where if no action is taken the probability of the risk occurring, or its then potential impact, are not significant. Tolerable risk is a risk undertaken only if a benefit is desired, and the benefit should exceed the cost of reducing this risk. For instance, "*in the context of climate change, the risks associated with nuclear power could be tolerated in order to secure the benefit of nuclear power in the fight against the greater risk from climate change and limiting the rise in global temperatures to sustainable levels. Therefore, when asking the question "how safe is safe enough" in relation to nuclear power, it is important to view the risks associated with NPPs in the context of the risks to people's health, living standards and lifestyles, and the degradation of the natural world, associated with failure to achieve the 2050 climate change targets if nuclear power was not part of the energy mix*." (European Nuclear Society's High Scientific Council, 2020).

6. ACKNOWLEDGEMENTS

This work has been conducted in the Fusion Sector of the Euratom Research Unit, Clean Planet Directorate, Directorate-General for Research and Innovation at the European Commission. The authors would like to gratefully acknowledge the support and feedback from the colleagues of the Euratom Research Unit, the Head of Unit Elena Righi Steele, and the Deputy Head of Unit Domenico Rossetti di Valdalbero. The authors would like to thank colleagues from the ITER Unit of the Directorate-General for Energy, the ITER Organisation, the IAEA and the UKAEA for the input and documents that helped complete this work.

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8. TERMS AND ACRONYMS

ACPs	Activated Corrosion Products.
ALARA	As low as reasonably achievable.
ALARP	As low as reasonably practicable.
BDBA	Beyond design basis accidents.
DBA	Design basis accidents.
DEC	Design extension conditions.
DEMO	A proposed demonstration fusion power station.
DiD	Defence in Depth.
DPA	Deterministic and Phenomenological Analyses.
EC	European Commission.
EEE	Electrical and electronic equipment.
EM	Electromagnetic.
EU	European Union.
Euratom	European Atomic Energy Community or EAEC.
FMECA	Failure Modes, Effects and Criticality Analysis.
Gen-II	A second-generation nuclear fission reactor, referring to the class of commercial reactors built until the end of 1990s.
Gen-III	A third-generation nuclear fission reactor, a development of Generation II nuclear reactor designs incorporating evolutionary improvements, e.g. improved fuel technology, superior thermal efficiency, significantly enhanced safety systems (including passive nuclear safety), and standardized designs for reduced maintenance and capital costs. The first Gen-III reactor began operation in 1996.
Gen-IV	A fourth-generation nuclear fission reactor, whose designs are still in development as of 2020.
HAZOP	Hazard And Operability Studies.
IAEA	International Atomic Energy Agency.
ISAM	Integrated Safety Assessment Methodology
ITER	Latin word for 'the Way', an international fusion research and engineering megaproject
MS	Member State of the European Union.
OPT	Objective Provision Tree.
PFCs	Plasma Facing Components.
PIRT	Phenomena Identification and Ranking Table.
PRA	Probabilistic Risk Assessment, see PSA.
PSA	Probabilistic Safety Assessment or Analysis, also known as Probabilistic Risk Assessment (PRA).
PWR	Pressurised water reactor, a type of light-water nuclear fission reactor; it has several newer Generation III reactor evolutionary designs including the European Pressurised Reactor (EPR).
QSR	Qualitative Safety features Review.
SSCs	Systems, Structures and Components.
VV	Vacuum Vessel.

9. APPENDICES

APPENDIX A: SAFETY FUNDAMENTALS

According to the most recent glossary by the International Atomic Energy Agency (IAEA), nuclear safety is defined as *(IAEA Safety Glossary: 2018 Edition, 2019):*

"The achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks."

Nuclear safety is about the **fundamental safety objective** to protect people and the environment from harmful effects of ionising radiation within the plant and any release of radioactive material away from the plant. This objective applies to ***all plant stages*** in the lifetime of a nuclear power plant: planning, siting, design, manufacture, construction, commissioning and operation, and decommissioning. It also applies to ***all plant states***: operational states (i.e. normal operation and anticipated operational occurrences) and accident conditions.

A set of **fundamental safety principles** (see the detailed list on these ten principles in *(Fundamental Safety Principles*, 2006)) covers the aspects of safety responsibility, justification, leadership and management, as well as protection, prevention, risk limitation, including emergency preparedness and response. These ten principles form the basis for developing the safety requirements and implementing measures to achieve the fundamental safety objective.

According to the fundamental safety principles, the prime responsibility for safety against activities that give rise to radiation risks rests with the ***licensee***. That involves managing safety and ensuring that safety requirements are met throughout the lifetime of facilities (see 'Principle 1: Responsibility for safety' in *(Fundamental Safety Principles*, 2006)). However, ***governments*** have the responsibility for establishing and sustaining a regulatory framework and an ***independent regulatory body*** to protect society and the environment against radiation risks (see 'Principle 2: Role of government' in (*Fundamental Safety Principles*, 2006)). Regulating nuclear and radiation safety is a national responsibility. Yet, radiation risks may transcend national borders and states are expected to fulfil their national and international undertakings and obligations. Cross-border cooperation is therefore essential to foster a safety culture and assure confidence in safety globally.

The IAEA international nuclear-safety related conventions[41], codes of conduct[42] and safety standards[43] promote international cooperation by supporting States to meet their obligations under the general principles of international law, such as those of environmental protection, and facilitating cross-border commerce and trade.

Appendix A.1: EU Legislation

In the EU, a set of instruments exist for supporting Member States (MS) to achieve the safety requirements and implementation measures. The Treaties of Rome, signed in 1957, established the European Economic Community and the European Atomic Energy Union, known as the Euratom Treaty, enforced since 1958. The Euratom Treaty seeks to create the conditions necessary *"for the development of a powerful nuclear industry which will provide extensive energy resources, lead to the modernisation of technical processes and contribute, through its many other applications, to the prosperity of their peoples", as well as for the "safety necessary to eliminate hazards to the life and health of the public".* (Consolidated version of the Treaty

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[41] List of International Conventions: https://www.iaea.org/topics/nuclear-safety-conventions.
[42] Details on the IAEA codes of conduct: https://www.iaea.org/topics/codes-of-conduct
[43] Consisting of the safety fundamentals, requirements and guides: https://www.iaea.org/resources/safety-standards/search

establishing the European Atomic Energy Community, 2016). The Euratom Treaty forms the basis for the EU legislative and non-legislative acts on:

1. **Nuclear safety:** The EU significantly enhanced its leadership in nuclear safety worldwide with the amended Nuclear Safety Directive (Council Directive 2014/87/Euratom, 2014). The Directive reflects the provisions of the main international instruments for nuclear safety, namely the IAEA Convention on Nuclear Safety41 and the Safety Fundamentals (Fundamental Safety Principles, 2006). The EU directive applies to *'any civilian nuclear installation subject to a licence'*, which includes *'a nuclear power plant, enrichment plant, nuclear fuel fabrication plant, reprocessing plant, research reactor facility, spent fuel storage facility and storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations'.* It requires that EU countries give the highest priority to nuclear safety *'covering all stages of the lifecycle of nuclear installations (siting, design, construction, commissioning, operation, decommissioning)'*, strengthen the role of national regulatory authorities, create a system of peer reviews and a safety re-evaluation every 10 years and enhance transparency on nuclear safety matters. The directive highlights the concept of Defence-in-Depth as the basis for implementing high-level nuclear safety objectives and the critical importance of the containment function, which is the last barrier to protect people and the environment against radioactive releases resulting from an accident.

2. **Radiation protection:** The Euratom Community has established the Basic Safety Standards Directive (Council Directive 2013/59/Euratom, 2013) to protect workers, members of the public, and patients against the dangers of ionising radiation under any planned, existing or emergency exposure situation that entails risk, including industrial practices and natural radiation sources, the nuclear industry and medical applications. In addition, the directive sets specific arrangements for monitoring radioactive substances in potable water and parametric values for radon, tritium and the indicative dose received from natural or anthropogenic sources of radiation (Council Directive 2013/51/Euratom, 2013). Finally, the Community has also set the maximum permitted levels of radioactive contamination of food and feed that may be placed on the market following a nuclear accident or any other radiological emergency (Council Regulation (Euratom) 2016/52, 2016).

3. **Radioactive waste and spent fuel:** The EU's Radioactive Waste and Spent Fuel Management Directive (Council Directive 2011/70/Euratom, 2011) requires EU countries to establish and maintain a national legislative, regulatory and organisational framework, including an independent regulatory body and financing mechanisms for managing radioactive waste and spent fuel. As of August 2015, member states need to submit a national report to the Commission on the implementation of the directive every three years. All MS generate radioactive waste either from generating electricity or non-power uses of radioactive materials for medical, research, industrial and agricultural purposes, whereas 21 of them manage spent fuel on their territory (*Commission Communication COM(2019) 632*, 2019). The Community has also set a system (Council Directive 2006/117/Euratom, 2006) for supervising and controlling transboundary shipments of radioactive waste and spent fuel exceeding set quantities and concentrations (Council Directive 2013/59/Euratom, 2013). These exclude disused sources, radioactive materials recovered through reprocessing for further use, waste that contains only naturally occurring radioactive material and radioactive waste or other material shipped for processing or waste recovery.

4. **Decommissioning of nuclear facilities:** The Euratom Directives on Nuclear Safety (Council Directive 2014/87/Euratom, 2014) and Radioactive Waste and Spent Fuel Management (Council Directive 2011/70/Euratom, 2011) described above also establish the national responsibility on decommissioning nuclear facilities as well as the closure and post-closure phase of disposal facilities.

5. **Safeguards to avoid misuse:** Nuclear safeguards (Commission Regulation (Euratom) No 302/2005, 2005) guarantee that nuclear materials are not diverted from the intended purposes declared. The Regulation applies to '*any person or undertaking setting up or operating an installation for the production, separation, reprocessing, storage or other use of source material or special fissile material'* and *'shall declare to the Commission the basic technical characteristics of the installation'*. *'It shall not apply to holders of end products used for non-nuclear purposes which incorporate nuclear materials that are in practice irrecoverable.*' Annual reports of physical inventories shall be transmitted to the Commission together with a special report in case of unusual occurrences or loss or delay during transfer. A Commission recommendation provides reference characteristics for operators of nuclear installations for implementing a nuclear material accountancy and control system (*Commission Recommendation C(2009) 785*, 2009).

In addition, the following EU Directives could be relevant for fusion installations:[44]

6. **Electromagnetic fields:** The EU Directive (Directive 2013/35/EU, 2013) sets the minimum health and safety requirements for the protection of workers from health and safety risks arising or likely to arise from exposure to electromagnetic fields during work. The directive covers all known short-term direct biophysical effects and indirect effects caused by electromagnetic fields. It does not cover suggested long-term effects and the risks resulting from contact with live conductors.

7. **Substances in electrical and electronic equipment**: The EU Directive (Directive 2011/65/EU, 2011) sets rules on restricting the use of hazardous substances in electrical and electronic equipment (EEE) to contribute to the protection of human health and the environment, as well as on the environmentally sound recovery and disposal of waste EEE. The directive does not apply to equipment necessary for protecting the security of MS, space equipment, large-scale stationary industrial tools or fixed installations, means of transport, non-road mobile machinery, active implantable medical devices, photovoltaic panels and equipment specifically designed for research and development purposes.

Appendix A.2: Safety Concerns

The main safety concerns in nuclear installations are accidents, potential radioactive material release, occupational radiation exposure and radioactive waste.

Accidents

An accident is an unintended event, operating error, equipment failure or another mishap, with potential consequences that are not negligible in terms of radiation exposure or nuclear safety (*Classification of Radioactive Waste*, 2009; Council Directive 2014/87/Euratom, 2014; *IAEA Safety Glossary: 2018 Edition,* 2019). Accident conditions are deviations from the normal operation that are less frequent and more severe than anticipated operational occurrences. They can be categorised as follows (Figure 7):

- <u>Design Basis Accidents (DBA):</u> a postulated accident leading to conditions against which a facility is designed based on established design criteria and a conservative methodology, keeping releases of radioactive material within authorised limits. The purpose of the DBAs is to design conservative boundary conditions for the nuclear power plant, with no or minor radiological consequences that do not necessitate any off-site protective actions.

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[44] Note that the '*Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work*' shall not apply to workers exposed only to radiation covered by the Treaty establishing the European Atomic Energy Community. Also, the '*Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work*' applies without prejudice to the provisions for chemical agents to which measures for radiation protection apply according to Directives adopted under the Treaty establishing the European Atomic Energy Community).

- Beyond Design Basis Accidents (BDBA): a postulated accident leading to more severe conditions than a DBA. BDBAs are further subdivided into Design Extension Conditions (DEC) and practically eliminated conditions.
- Design Extension Conditions (DEC): Postulated accident conditions that are not considered in the DBAs, but are considered in the design process of the facility following a best estimate methodology. For DECs, releases of radioactive material are kept within acceptable limits (e.g. based on engineering judgement, deterministic and probabilistic safety assessments). Design extension conditions could include severe accidents.
- Severe conditions: An accident more severe than a DBA and involving significant core degradation.
- Practically eliminated conditions: Severe accident conditions that are not considered in the design process of the facility because they were considered either physically impossible to occur or with a high degree of confidence to be extremely unlikely to arise.

<table>
<tr><th colspan="2">Operational states</th><th colspan="4">Accident conditions</th></tr>
<tr><td rowspan="4">Normal Operation</td><td rowspan="4">Anticipated operational occurrences</td><td rowspan="4">Design basis accidents</td><td colspan="3">Beyond design basis accidents</td></tr>
<tr><td colspan="2">Design extension conditions</td><td>Practically eliminated conditions</td></tr>
<tr><td>No severe accidents</td><td colspan="2">Severe accidents</td></tr>
<tr><td>without significant fuel degradation</td><td colspan="2">with core degradation</td></tr>
<tr><td colspan="3">Considered in design according to established criteria</td><td colspan="2">Considered in design process according to best estimate methodology</td><td>Not considered in design process</td></tr>
</table>

Figure 7: Plant states (adapted from (CNSC, REGDOC-2.5.2, 2014; IAEA Safety Glossary: 2018 Edition, 2019)).

According to the latest IAEA safety standards on the design of nuclear plants (Safety of Nuclear Power Plants: Design, 2016), combinations of events should be considered in the DBAs or DECs, when engineering judgement and safety assessments indicate that they could lead to anticipated operational occurrences or accident conditions (depending mainly on their likelihood of occurrence). Consequences of other events, such as a flood following an earthquake, shall be part of the original postulated initiating event.[45]

The primary means of preventing and mitigating the consequences of accidents is **Defence-in-Depth (DiD)** that concerns designing and using multiple and independent levels of protection (or lines of defence) to compensate for the failure of one or more defences, while ensuring that the risks are kept acceptable. *"Defence in depth is implemented primarily through the combination of a number of consecutive and independent levels of protection that would have to fail before harmful effects could be caused to people or to the environment. If one level of protection or barrier were to fail, the subsequent level or barrier would be available. When properly implemented, defence in depth ensures that no single technical, human or organizational failure could lead to harmful effects, and that the combinations of failures that could give rise to significant harmful effects are of very low probability. The independent effectiveness of the different levels of defence is a necessary element of defence in depth."* (*Fundamental Safety Principles*, 2006). Defence-in-depth is structured in five levels, where if one were to fail, the subsequent level would come into play and so

[45] A postulated initiating event (PIE) is a postulated event identified in design as capable of leading to anticipated operational occurrences or accident conditions (*IAEA Safety Glossary: 2018 Edition*, 2019).

on. Appendix C describes the levels of defence-in-depth in existing nuclear power plants, the objectives of each level of protection and the essential means of achieving them for all plant states.

Radioactive Material Release and Occupational Radiation Exposure

An EU country shall establish the legal requirements and appropriate regulatory control for a system of protection against a potential radioactive material release and occupational radiation exposure for the workers, members of the public, and patients. These should be based on the principles of *justification, optimisation and dose limitation* (Council Directive 2013/59/Euratom, 2013):

- Justification: Decisions introducing or altering an exposure pathway for existing situations or emergency exposures shall be justified, meaning that they increase the individual or societal benefit.
- Optimisation: Radiation protection of individuals that are subject to public or occupational exposure shall be optimised to keep the magnitude of individual doses, the likelihood of exposure and the number of individuals exposed **as low as reasonably achievable (ALARA),** while considering the current state of technical knowledge and economic and societal factors (with regards medical exposure, Article 56 shall apply)
- Dose limitation: In planned exposure situations, the sum of doses to an individual shall not exceed the dose limits for occupational exposure or public exposure. Reference dose limits are found in Article 9-12 and Annex I of the directive (dose limits shall not apply to medical exposure).

The IAEA general safety requirements (*Preparedness and Response for a Nuclear or Radiological Emergency*, 2015) provide guidance values for restricting workers exposure in a radiological emergency, together with examples of protective and other response actions (although these would depend on the nature of the accident, weather conditions, available resources, and site-specific factors, such as population, housing and industry characteristics). Generic criteria for use in emergency preparedness and response are also provided.

Radioactive waste

Radioactive waste is radioactive material in gaseous, liquid or solid form with no foreseen further use. It is regulated as radioactive waste by a competent regulatory authority under a national legislative and regulatory framework (Council Directive 2011/70/Euratom, 2011; *IAEA Safety Glossary*: 2018 Edition, 2019). Spent fuel, which is nuclear fuel that has been irradiated in and permanently removed from a reactor core, if not considered for reprocessing, can be destined for disposal if regarded as radioactive waste.

Radioactive waste is commonly classified according to its radioactivity level and decay time, which form the basis for selecting the optimal method for waste treatment, storage and disposal. Classification schemes differ widely from country to country, even within the EU (*Commission Communication COM(2019) 632*, 2019). This leads to a range of terminologies that pose challenges in establishing consistent and coherent waste management policies and implementing strategies, making communication on waste management practices difficult both nationally and internationally.[46]

The IAEA safety guide on the radioactive waste classification (Classification of Radioactive Waste, 2009) provides a comprehensive range of waste classes together with general boundary conditions among them and an illustration of the use of the classification scheme to assist in determining disposal options:

1. Exempt waste (EW): waste that meets the criteria for exemption or exclusion from regulatory control as radioactive waste.

[46] Recently, the Commission has carried out a study on benchmarking of national inventories to identify common aspects with respect to waste classification, best practices and challenges for the collection and management of data, as well as for the estimation of current and future inventories, including identification and treatment of uncertainties: https://op.europa.eu/s/oLsR.

2. Very short-lived waste (VSLW): Waste that can be stored for decay over a limited period of up to a few years and subsequently exempted or excluded from regulatory control.

3. Very low-level waste (VLLW): Waste that does not necessarily meet the criteria of EW, but does not need a high level of isolation and containment and is suitable for disposal in a near-surface landfill facility with limited regulatory control.

4. Low-level waste (LLW): Waste that is above established regulatory-control levels, but with limited amounts of long-lived radionuclides; requires robust isolation and containment for periods of up to a few hundred years and is suitable for disposal in engineered near-surface facilities.

5. Intermediate-level waste (ILW): Waste that may contain long-lived radionuclides that require a greater degree of isolation and containment than near-surface disposal, but needs no, or limited, provision for heat dissipation; requires disposal at greater depths, of the order of tens to a few hundred metres.

6. High-level waste (HLW): Waste with large amounts of long-lived radionuclides or with levels of activity concentration high enough to generate significant quantities of heat during radioactive decay; the generally recognised disposal option is in deep, stable geological formations usually several hundred metres or more below the surface.

Appendix A.3: Safety Objective, Goals and Functions

The three targets of any safety framework are the public, the workers and the environment. Any national nuclear safety framework is to ensure that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the **objective** to control the radiation exposure of people and the release of radioactive material to the environment, prevent accidents and, should an accident occur, mitigate its consequences and avoiding (Council Directive 2014/87/Euratom, 2014; *Fundamental Safety Principles*, 2006):

a. Early radioactive releases that would require off-site emergency measures but with insufficient time to implement them;
b. Large radioactive releases that would require protective measures that could not be limited in area or time.

Three interdependent safety goals have been defined for nuclear fission power plants i.e. Gen-II/PWR (Figure 8) *(Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev. 1*, 1999):

- General safety goal: Establish and maintain an effective defence against a radiological hazard in nuclear power plants.

- Radiation protection goal: Ensure that radiation exposure within the plant and any release of radioactive material from the plant is ALARA and below prescribed limits during normal operation, and ensure the mitigation of radiation exposure due to accidents.

- Technical safety goal: Prevent with high confidence accidents in nuclear plants and ensure that, for all accidents, even those of very low probability, radiological consequences, if any, would be minor; ensure that the likelihood of severe accidents with serious radiological consequences is extremely small.

Goals	General nuclear safety goal	Radiation protection goal	Technical safety goal
Management principles	Safety culture	Responsibility of operating organization	Regulatory control and verification
Defence-in-depth principles	Defence in depth	Accident prevention	Accident mitigation

Figure 8: Safety goals, management principles and defence-in-depth for nuclear plants (adapted from (Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev. 1, 1999)

As mentioned above, defence-in-depth is amongst the fundamental concepts underlying the overall safety strategy of nuclear power plants. It helps preserve the basic safety functions for all plant states and ensure that radioactive materials do not reach people or the environment. Defence-in-depth is implemented primarily through a series of barriers, which are *'a physical obstruction that prevents or inhibits the movement of people, radionuclides or some other phenomenon (e.g. fire), or provides shielding against radiation' (IAEA Safety Glossary: 2018 Edition,* 2019).Barriers are physical, providing for the confinement of radioactive material at successive locations, serving safety or operational purposes. In principle, these barriers would never be jeopardized and power operation is only allowed if this multi-barrier system is not violated and is capable of functioning as designed. Design provisions help prevent undue challenges to the integrity of the physical barriers, prevent their failure if jeopardized, and prevent consequential damage of a series of barriers. Safety system design should ensure to the extent practicable that the *different safety systems protecting the physical barriers are functionally independent under accident conditions.*

The three fundamental safety **functions** in nuclear fission power plants (i.e. Gen-II, Gen-III, Gen-IV) are (*Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev. 1*, 1999; *Safety of Nuclear Power Plants: Design*, 2016):

1. Control of reactivity: controlling the reactor power;
2. Decay heat removal (i.e. cooling the fuel): removal of heat from the reactor and the spent fuel store;
3. Confinement of radioactive material: shielding against radiation and control of planned radioactive releases, as well as limitation of accidental radioactive releases, within appropriate physical barriers.

The **physical barriers** that provide the above safety functions in existing fission reactors (i.e. Gen-II, Gen-III and Gen-III+) are:

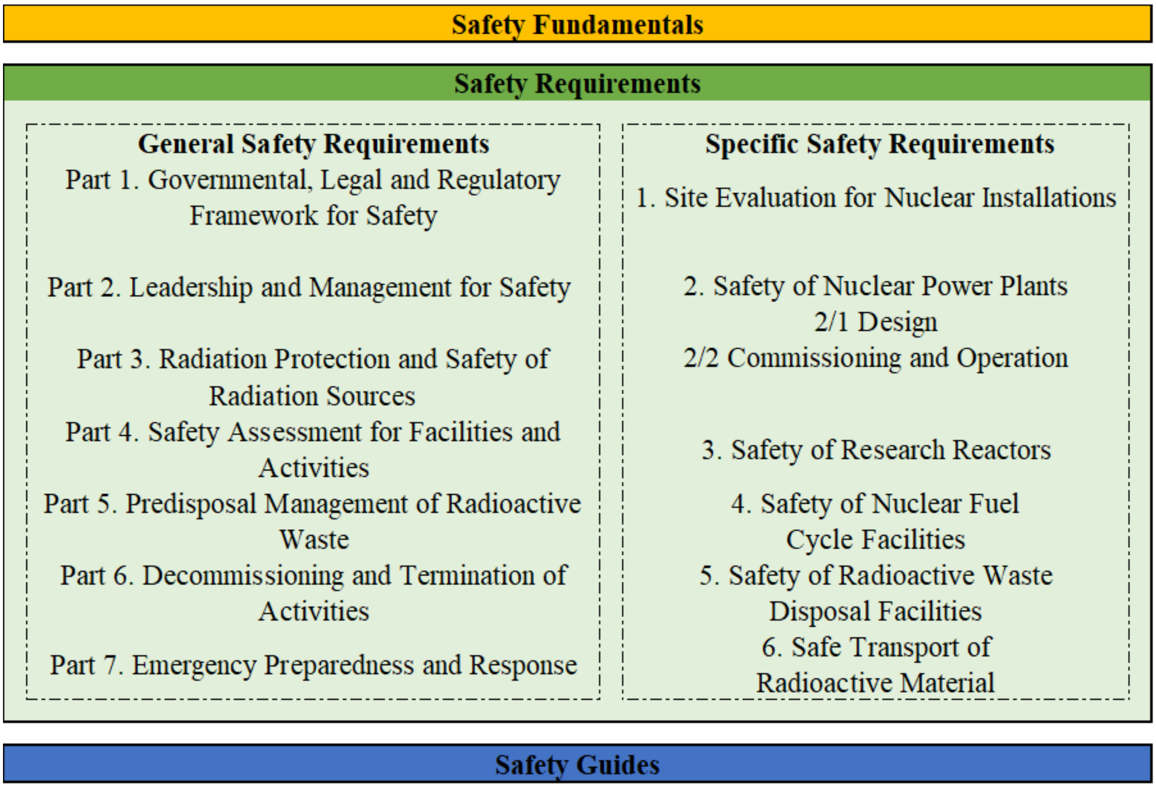
1. The fuel assembly (i.e. fuel matrix and fuel cladding): the fuel is in the form of solid ceramic uranium pellets and radioactive fission products remain largely bound inside these pellets as the fuel burns. The pellets are packed inside sealed zirconium alloy tubes to form fuel rods;
2. The pressure boundary: the reactor vessel body confining the fuel assembly, coolant, and fittings that support the coolant flow and support structures, i.e. the large steel pressure vessel and primary piping systems;
3. The containment structure: a robust pre-stressed or reinforced concrete containment structure.

These barriers may change for future power plants as the likelihood and consequences of barrier failures are reduced (*Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev. 1*, 1999).

APPENDIX B: IAEA SAFETY STANDARDS

The IAEA Safety Standards for protecting people and the environment from harmful effects of ionizing radiation are organised in three categories (adapted from (*Classification of Radioactive Waste*, 2009):

a. **Safety fundamentals,** presenting the fundamental safety objective and principles and providing the basis for the safety requirements;
b. **Safety requirements,** setting the requirements to establish, in a harmonized manner, a national regulatory framework that ensures the protection of people and the environment; and
c. **Safety guides,** providing recommendations and guidance for complying with the safety requirements, presenting international good practices and reflecting the best practices to help users achieve high levels of safety.



APPENDIX C: DEFENCE IN DEPTH

The table below shows the levels of defence-in-depth in existing nuclear power plants, the objectives of each level of protection and the essential means of achieving them for all plant states (adapted from (Basic Safety Principles for Nuclear Power Plants 75-INSAG-3 Rev. 1, 1999; Defence in Depth in Nuclear Safety, 1996).

LEVELS OF DEFENCE IN DEPTH	OBJECTIVE	ESSENTIAL MEANS	PLANT STATES
Level 1	Prevention of abnormal operation and failures	Conservative design and high quality in construction and operation	Normal operation
Level 2	Control of abnormal operation and detection of failures	Control, limiting and protection systems and other surveillance features	Anticipated operational occurrences
Level 3	Control of accidents within the design basis	Engineered safety features and accident procedures	Design Basis Accidents
Level 4	Control of severe plant conditions, including prevention of accident progression and mitigation of the consequences of severe accidents	Complementary measures and accident management	Beyond design basis accidents
Level 4	Mitigation of radiological consequences of significant releases of radioactive materials	Off-site emergency response	Post-accident conditions

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The European research roadmap to fusion energy paves the way for commercial electricity generation from fusion as a potential long-term solution for clean energy. The commercial exploitation of fusion electricity will require states to establish and maintain a suitable national regulatory framework for safety to assess licensing applications to construct and operate fusion power plants. Yet, unlike fission power plants, there is to date no specific legal framework for regulating fusion power plants. This report aims to lay the groundwork towards a regulatory framework tailored to fusion power plants. It provides a review of the key regulatory approaches as well as safety-related aspects that are likely to be part of a future regulatory framework for fusion power plants.

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