



Evaluation of regulations and licensing processes

(Deliverable 4.1, Revision A)

January 2024

Revisions

IND REV	RELEASE DATE	PARAGRAPH	SCOPE OF THE REVISION
A	See Cover Page	All	First Issue

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Abbreviations and acronyms

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Acronym	Description
ACR	Quantitative risk analysis
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR	Agreement concerning the International Carriage of Dangerous Goods by Road
AEM	Anion Exchange Membrane
ANDRA	National Radioactive Waste Management Agency
ANPM	National Environmental Protection Agency
ANRE	National Energy and Regulatory Authority
ANVS	Nuclear Regulator in the Netherlands
ARPM	Romanian Environmental Protection Agency
ASAB	Additional Safety Analysis Basis
ASME	American Society of Mechanical Engineers
ASN	Autorité de sûreté nucléaire
ATEX	Equipment intended for use in explosive atmospheres
BAT	Best Available Techniques
BEVI	External Safety of Establishments Decree
BNI	Basic Nuclear Installation
BOE	Spanish Official Gazette
BREF	BAT Reference Documents
BRZO	Major Accidents Risk Decree
C. o. t. E. U	Council of the European Union
CANDU	Canadian Deuterium Uranium
CECOP	Operative Coordination Centre
CEN/CENELEC	European Standardization associations

Acronym	Description
CGEDD	General Council for Environment and Sustainable Development
CHF	Chemically Hazardous Facilities
CNCAN	National Commission for Nuclear Activities Control
CNMC	National Commission on Markets and Competition
CNS	Convention on Nuclear Safety
CRBN	Council on Strengthening Chemical, Biological, Radiological and Nuclear Security in the European Union
CSN	Nuclear Safety Council (Spanish Nuclear Regulatory Body)
DREAL	Directions régionales de l'environnement, de l'aménagement et du logement
DSND	Nuclear safety and radiation protection delegate for defence-related activities and facilities
DSR	Dutch Safety Regulations
EA	Energoatom
EC	European Commission
EDF	Électricité de France
EIA	Environmental Impact Assessment
ENSREG	European Nuclear Safety Regulators Group
EPR	European Pressurized Reactor
ERP	Emergency response plan
ESA	Euratom Supplies Agency
EU	European Union
GR	Group Risk
GRIP	Coordinated Regional Incident Reponse Procedures
GSN	Nuclear Safety Guide
HAZOP	Hazard Analysis
HPP	Hydrogen Production Plant
IAEA	International Atomic Energy Agency
ICPE	Installations Classified for the Protection of Environment
ICRP	International Commission on Radiological Protection
IDSFS	Intermediate Dry Spent Fuel Storage Facility
IED	Industrial Emissions Directive
IJSU	County Inspectorates for Emergency Situations
ILSU	Local Emergency Management Inspectorates
INB	see BNI
INSAG	International Nuclear Safety Advisory Group
INSC	Instrument for Nuclear Safety Cooperation
IPPC	Integrated Pollution Prevention and Control
IRSN	Institute of Radiation protection and Nuclear Safety
ISCIR	State Inspection for Control of Boilers, Pressure Vessels and Hoisting
JRC	Joint Research Centre
KTA	Kerntechnischer Ausschuss

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Acronym	Description
MAPP	Major Accident Prevention Policy
MDETA	Ministry for Development of Economy, Trade and Agriculture
MEPNRU	Ministry of Environmental Protection and Natural Resources of Ukraine
MITECO	Ministry for the Ecological Transition
MIU	Ministry of Infrastructure of Ukraine
MoE	Ministry of Energy
MRA	Manufacturing Risk Assessment
MTES	Ministry for Ecological and Inclusive Transition
NF	Nuclear Facility
NI	Nuclear Installation
NNEG	National Nuclear Energy Generation company
NPNRE	National Plan for Nuclear and Radiological Emergencies
NPP	Nuclear Power Plant
NRC	Nuclear Regulatory Commission
NSDC	National Security and Defense Council
NSN	Nuclear Safety Requirements
OC	Operating Company
OHS	Occupational Health and Safety
OOD	Official Operating Documents
OSCE	The Organization for Security and Co-operation in Europe
OTS	Operating Technical Specification
PEI	Internal Emergency Plans
PEM	Proton Exchange Membrane
PEN	External Emergency Plans
PGS	Publications on Hazardous Substances
PHWR	Pressurized Heavy Water Reactor
PIE	Postulated Initiating Event
PLABEN	Basic Nuclear Emergency Plan
PNIESC	Integrated National Plan in the field of Energy and Climate change
PPI	off site emergency plan
PR	Local Risk
PSA	Probabilistic Safety Analysis
PSAR	Periodic safety assessment report
QRA	Quantitative Risk Assessment
RATEN	State Owned Company for Technologies for Nuclear Energy
RDL	Royal Decree Legislative
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
REVI	External Safety of Establishments Regulation
RHC	Release of hazardous chemicals
RID	Regulations for the International Carriage of Dangerous Goods by Rail
RRZO	Major Accidents Risk Regulation
SAEE	State Agency for Energy Efficiency and Energy Saving of Ukraine

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Acronym	Description
SALEM	Emergency Room
SAR	Safety analysis report
SE	Separate Entity
SES	State Emergency Service of Ukraine
SFB	Spent Fuel Bay
SMR	Steam Methane Reforming
SNN	nuclearelectrica national company
SNRIU	State Nuclear Regulation Inspection of Ukraine
SPZ	Sanitary protection zone
SRS	Safety related systems
TC	Technical committee
TSB	Technical Safety Basis
TSN	Transparency and Security in the Nuclear Field
TSO	Technical Support Organization
WABO	General Provisions Act
WENRA	Western European Nuclear Regulators Association
WGNS	Working group 1 on – Nuclear Safety
WP	Work Package
WRO	Spatial Planning Act

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Preface

This work was produced in a combined effort by various partners, each being responsible for the veracity and quality of their work. The distribution of work was the following:

- Ansaldo: Analysis for France, Analysis for Romania
- ES Group: Analysis for Ukraine, Analysis of European legislation and regulation
- GRS: Analysis of international conventions, Findings
- NRG: Analysis for the Netherlands, Conclusions, Review tasks
- Tecatom: Analysis for Spain, Summary, Review tasks.

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Summary

This document identifies the current regulatory framework that must be fulfilled by nuclear power plants and hydrogen production facilities. Relevant issues that are analyzed are:

- Licensing and permitting processes for HPP and NPP
- regulations related to safety concepts like Defense in Depth and risk assessments,
- regulations related environmental protection and industrial emissions.
- regulations with respect to nearby external hazards and the effect on the initiating events
- regulations with respect to emergency provisions and response organization
- regulation with respect to operation and organization

In section 2 of the document are identified and analyzed the main European Union (EU) Directives in relation with the topics enumerated above. In current EU Directives, Hydrogen production is considered a traditional chemical or industrial process, without regard to the type of Hydrogen production. For that reason, the main EU Directives that applies to HPP in relation with the above issues are:

- the SEVESO Directive [2012/18/EU Seveso](#) [1] on the control of major-accident hazards,
- Directive [2010/75/EU](#) [2] on industrial emissions,
- Directive [2011/92/EU](#) [3] on the assessment of the effects of certain public and private projects on the environment,
- the occupational health and safety framework Directive [89/391/EEC](#) [4] and,
- the ATEX Products directive [2014/34/EU](#) [5] relating to equipment intended for use in potentially explosive atmospheres.

For nuclear power plants the main directive on nuclear safety is [Directive 2009/71/Euratom](#) [6] and its amendment, [Directive 2014/87/Euratom](#) [7]. IAEA safety standards are the framework of practices that Member States should have regard to when implementing the safety Directive and its amendment. IAEA Safety Standards in relation with the topics enumerated above are identified and described in section 3. The case of installing a new HPP sharing resources from an existing NPP will be treated as a design modification that requires a safety assessment. This assessment requires that a systematic evaluation of all features of the facility or activity relevant to safety be carried out.

Sections 4 to 8 provides the analysis of the issues enumerated above for France, Netherlands, Romania, Spain, and Ukraine.

Section 9 collects the main findings and conclusions.

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1 Introduction

The production of hydrogen from nuclear power is a complex and regulated process that requires obtaining specific licenses and permits. The licensing aspects of hydrogen production from nuclear power play a critical role in ensuring that this process is conducted in a safe and responsible manner, and that it meets the necessary standards for quality, safety, and environmental protection.

This deliverable identifies the current regulatory framework that must be fulfilled by nuclear power plants and hydrogen production facilities.

2 Analysis of European legislation and regulation

2.1 Hydrogen production legislation

2.1.1 General description of HPP licensing policy

The production of hydrogen is subject to a significant number of requirements which can be found in EU Directives in various fields, which are not directly to hydrogen production, but they are general for industry especially chemical industry.

The European Commission proposed a fully-fledged legislative framework for the production, consumption, infrastructure development and market rules for a future hydrogen market, as well as binding quotas for renewable hydrogen consumption in industry and transport. But these legislative proposals are still in inter-institutional negotiations.

2.1.2 Safety Concept

This chapter lists the EU directives that must be considered when assessing the health and safety of people working at HPP, safety of the operation of HPP and transport and storage of hydrogen. None of the following directives address the cogeneration of HPP and NPP.

2.1.2.1 Control of major accident hazards.

In relation with the control of major accident hazards the most important directive is [2012/18/EU Seveso](#) [1], which is described later in section 2.1.4.

2.1.2.2 Product Safety

In relation with Product Safety the following directives applies.

ATEX Products Directive [2014/34/EU](#) [5] on the harmonisation of the laws of the Member States relating to equipment and protective systems intended for use in potentially explosive atmospheres.

The used products must meet requirements related to the health or safety of persons and property. According to this directive, devices are divided into groups according to the danger of the environment in which they work. The equipment for production of hydrogen is Equipment group II – Equipment category 3. Equipment in this category is intended for use in areas in which explosive atmospheres caused by gases, vapours, mist, or air/dust mixtures are unlikely to occur or, if they do occur, are likely to do so only infrequently and for a short period only. According to these groups, basic health and safety requirements regarding the design and construction of equipment and protective systems are then established. It also regulates the requirements for assessing the conformity of equipment with technical documentation.

During designing of the HPP it will be necessary to use the products which are certified for use in explosive environment.

Directive [2014/68/EU](#) [8] on the harmonisation of the laws of the Member States relating to the making available on the market of pressure equipment.

This directive applies to pressure vessels and pressure equipment assemblies where a pressure greater than 0.5 bar occurs. It does not apply to long-distance pipelines.

The directive classifies pressure equipment into groups. The pressure vessel for hydrogen is in category 1, because hydrogen is Extremely flammable gas (according regulation 1272/2008/EC) Also establishes basic technical and safety requirements and obligations of manufacturers. The main requirements are: design requirements, calculations requirements, manufacturing requirements, testing requirements, marking requirement, documentation requirements, requirements for conformity assessment procedures.

Directive [2008/68/EC](#) [9] Inland transport of dangerous goods

This directive sets out the requirements and conditions for transporting dangerous goods. This directive excludes the transportation inside of the closed borders area. This directive refers to international agreements for transportation by car(ADR), train(RID) and ship(AND).

This directive will be important if we decide to transport the hydrogen by car or train or ship. And it will be not used when we decide to transport hydrogen via pipeline.

2.1.2.3 Occupational Health and Safety

Council directive [89/391/EEC](#) [4] on the introduction of measures to encourage improvements in the safety and health of workers at work.

This directive defines the duty of employers to take measures necessary for the safety and health protection of employees, including measures for the prevention of occupational risks, for information and training, as well as for the preparation of the necessary organization and resources.

2.1.3 Environmental impact

This chapter lists the EU directives that must be considered in the design, construction, and operation of the HPP in relation with the environment. Most important for the HPP licencing is European directive [2010/75/EU](#) [2].

Directive on industrial emissions. [2010/75/EU](#) [2].

The production of hydrogen is included by this directive in the chemical industry producing inorganic chemical substances. The directive deals with the emissions of the production company, the protection of soil and groundwater. Based on this directive, it is necessary to apply for a permit for the construction of a chemical plant.

It is necessary to ensure that the operation of an installation does not lead to a deterioration of the quality of soil and groundwater. Permit conditions should, therefore, include appropriate measures to prevent emissions to soil and groundwater and regular surveillance of those measures to avoid leaks, spills, incidents, or accidents occurring during the use of equipment and during storage. In order to ensure that the operation of an installation does not deteriorate the quality of soil and groundwater, it is necessary to establish, through a baseline report, the state of soil and groundwater contamination.

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Member States shall take the necessary measures to ensure that an application for a permit includes a description of the following:

- a) the installation and its activities;
- b) the raw and auxiliary materials, other substances and the energy used in or generated by the installation;
- c) the sources of emissions from the installation;
- d) the conditions of the site of the installation;
- e) where applicable, a baseline report;
- f) the nature and quantities of foreseeable emissions from the installation into each medium as well as identification of significant effects of the emissions on the environment;
- g) the proposed technology and other techniques for preventing or, where this is not possible, reducing emissions from the installation;
- h) measures for the prevention, preparation for re-use, recycling and recovery of waste generated by the installation;
- i) further measures planned to comply with the general principles of the basic obligations of the operator as provided for in General principles of the operator's obligations;
- j) measures planned to monitor emissions into the environment;
- k) the main alternatives to the proposed technology, techniques and measures studied by the applicant in outline.

N An application for a permit shall also include a non-technical summary.

ECCN: This Directive contains a list of pollutants. All substances that will be released during hydrogen production must be compared with this table.

AL: N **REACH Regulation [EU 453/2010](#) [10] - Regulation (EC) on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)**

This regulation deals with requirements for the compilation of safety data sheets of dangerous substances and gases. The safety data sheets contain requirements for storage, protection when working with these substances, and protection of the environment. For example: https://produkte.linde-gas.at/sdb_konform/H2_10021694EN.pdf.

This datasheet must be prepared by the equipment manufacturer. It is not necessary to prepare this document for licensing the HPP, but it is necessary for producing and transport.

Directive [2011/92/EU](#) [3] on the assessment of the effects of certain public and private projects on the environment

This directive implies the necessity to prepare an environmental impact assessment report for chemical and other facilities.

Based on this directive, the EU needs to be informed of the intention to build the HPP and that the environmental impacts will be assessed. Because HPP is Integrated chemical plant, namely plant to produce substances on an industrial scale by chemical transformation, where several units which are linked and functionally interconnected, and which are designed for the production of basic inorganic chemicals.

The information for EU should include mainly: characteristic features of targets, localisation of targets, characteristics of the potential impact.

Directive [2008/1/EC](#) [11] concerning integrated pollution prevention and control

This Directive applies to equipment with significant pollution potential. On the basis of this directive, a permit application must be submitted and a permit issued confirming the principles of environmental protection.

Directive [2004/35/CE](#) [12] on environmental liability with regard to the prevention and remedying of environmental damage

In accordance with the 'polluter pays' principle, an operator who causes environmental damage or creates an imminent threat of such damage, should in principle bear the costs of the necessary preventive or remedial measures.

Based on this directive, there could be an obligation to establish some precautionary measures to prevent the risk of environmental damage when our project is being approved. Because: The competent authority may at any time:

- a) require the operator to provide information on any imminent threat of environmental damage or suspected imminent threat;
- b) require the operator to take the necessary preventive measures;

2.1.4 External Hazards and Risks

In this chapter is enumerated EU directives and regulations, which must be taken into account evaluating of risks of operating HPP. Most important for cogenerations of the HPP and NPP will be [2012/18/EU Seveso](#) [1] where can be evaluate of risk and influence of HPP operation and accidents in the area of NPP.

Directive [2012/18/EU Seveso](#) [1] on the control of major-accident hazards involving dangerous substances

To reduce the risk of domino effects, where establishments are sited in such a way or so close together as to increase the likelihood of major accidents, or aggravate their consequences, operators should cooperate in the exchange of appropriate information and in informing the public, including neighbouring establishments that could be affected.

In order to provide greater protection for residential areas, areas of substantial public use and the environment, including areas of particular natural interest or sensitivity, it is necessary for land-use or other relevant policies applied in the Member States to **ensure appropriate distances** between such areas and establishments presenting such hazards and, where existing establishments are concerned, to implement, if necessary, additional technical measures so that the risk to persons or the environment is maintained at an acceptable level.

The producer of hydrogen must elaborate the Safety report. That safety report should contain details of the establishment, the dangerous substances present, the installation or storage facilities, possible major accident scenarios and risk analysis, prevention and intervention measures and the management systems available, to prevent and reduce the risk of major accidents and to enable the necessary steps to be taken to limit the consequences thereof.

One of the biggest risks will be affecting the safety of the nuclear power plant in the event of a hydrogen explosion in the HPP and hydrogen storage areas. The Commission shall assess, where appropriate or in any event on the basis of a notification by a Member State, whether it is impossible in practice for a particular dangerous substance (hydrogen), to cause a release of matter or energy that

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could create a major accident under both normal and abnormal conditions which can reasonably be foreseen. The assessment from the Commission is based on the assumption that hydrogen is explosive when it unexpectedly loses its containment and can cause a major accident. For this assessment it is necessary to deliver to the Commission a complete list of properties (physical, chemical, flammability) of the dangerous substances (hydrogen).

Member States shall ensure that the operator is required to prove to the competent authority, that the operator has taken all necessary measures as specified in this Directive.

The operator must send a notification containing the following information to the competent authority before construction begins:

- the name or business name and full address of the operator of the establishment concerned;
- the registered office of the operator with its full address;
- the name and function of the person in charge of the establishment;
- information enabling identification of the dangerous substances and the category of substances which are or may be present;
- the quantity and physical form of the dangerous substance concerned;
- the activity or proposed activity of the installation or storage facility;
- information on the immediate surroundings of the plant and the factors which the plant and the circumstances of the accident, and the factors likely to cause a major accident or to aggravate its consequences, including available data on neighbouring plants, other establishments outside the scope of this Directive, areas and development activities that could cause or increase the risk of a major accident and the domino effect or exacerbate their consequences.

Member States shall require the operator to draw up a document in writing setting out the major-accident prevention policy (MAPP) and to ensure that it is properly implemented. The MAPP shall be designed to ensure a high level of protection of human health and the environment. It shall be proportionate to the major-accident hazards. It shall include the operator's overall aims and principles of action, the role and responsibility of management, as well as the commitment towards continuously improving the control of major-accident hazards, and ensuring a high level of protection.

Producer must have a system of safety control which has to contain these main sections:

- organisations and employees
- identification and assessment of significant sources of risk
- operational control
- change control management
- emergency planning
- monitoring of programme performance
- control and evaluation.

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The directive established two tiers based on the amount of hydrogen in each time in one factory: The lower tier (between 5 and 50 ton) and the upper tier (more than 50 ton).

For lower tier only MAPP requirements apply. For upper tier factories, member states shall require to the operator to produce a safety report. This safety report shall demonstrate that all necessary requirements for the prevention of dangerous accidents have been complied during design, operation, maintenance, storage and preparation of internal emergency plans. See Figure 22: Flowchart for the application of Seveso Directive for Hydrogen facilities.

Also, it is necessary to give all required information to competent authority to develop external emergency plans.

Member States shall ensure that their spatial planning policies planning, or other related policies take into account the objectives of the prevention of major accidents and the limitation of the consequences of such accidents the consequences of major accidents for human health and the environment.

Before the operator commences construction or operation, the competent authority shall within a reasonable period of receipt of the report communicate the conclusions of its examination of the safety report to the operator.

Member States shall ensure that the objectives of preventing major accidents and limiting the consequences of such accidents for human health and the environment are taken into account in their land-use policies or other relevant policies.

Member States shall ensure that the public concerned is given an early opportunity to give its opinion on planning for new establishments.

2.1.5 Emergency provisions and response organization

If in the planned HPP will be in upper tier (more than 50 ton of hydrogen in one factory) it is necessary, according to Seveso directive [13], to prepare internal emergency plan and external emergency plans. These plans must contain these main parts:

Internal emergency plans:

- Names or positions of persons authorised to set emergency procedures in motion and the person in charge of and coordinating the on-site mitigatory action;
- Name or position of the person with responsibility for liaising with the authority responsible for the external emergency plan;
- For foreseeable conditions or events which could be significant in bringing about a major accident, a description of the action which should be taken to control the conditions or events and to limit their consequences, including a description of the safety equipment and the resources available;
- Arrangements for limiting the risks to persons on site including how warnings are to be given and the actions persons are expected to take on receipt of a warning;
- Arrangements for providing early warning of the incident to the authority responsible for setting the external emergency plan in motion, the type of information which should be contained in an initial warning and the arrangements for the provision of more detailed information as it becomes available;
- where necessary, arrangements for training staff in the duties they will be expected to perform and, as appropriate, coordinating this with off-site emergency services;

- Arrangements for providing assistance with off-site mitigatory action.

External emergency plans:

- Names or positions of persons authorised to set emergency procedures in motion and of persons authorised to take charge of and coordinate off-site action;
- Arrangements for receiving early warning of incidents, and alert and call-out procedures;
- Arrangements for coordinating resources necessary to implement the external emergency plan;
- Arrangements for providing assistance with on-site mitigatory action; (e) Arrangements for off-site mitigatory action, including responses to major-accident scenarios as set out in the safety report and considering possible domino effects, including those having an impact on the environment;
- Arrangements for providing the public and any neighbouring establishments or sites that fall outside the scope of this Directive with specific information relating to the accident and the behaviour which should be adopted;
- Arrangements for the provision of information to the emergency services of other Member States in the event of a major accident with possible transboundary consequences.

2.1.6 Operation and Organization

According to directive [2010/75/EU](#) [2], licensing requires the operator to ensure that operating conditions are drawn up to limit emissions of pollutants and to prevent pollution incidents.

In directive [2012/18/EU Seveso](#) [1] is set that it is necessary that the producer has a system of safety control system to prevent the risk of a major accident. The main sections which this system should contain is described in chapter 2.1.4.

2.2 Nuclear Power Plant legislation

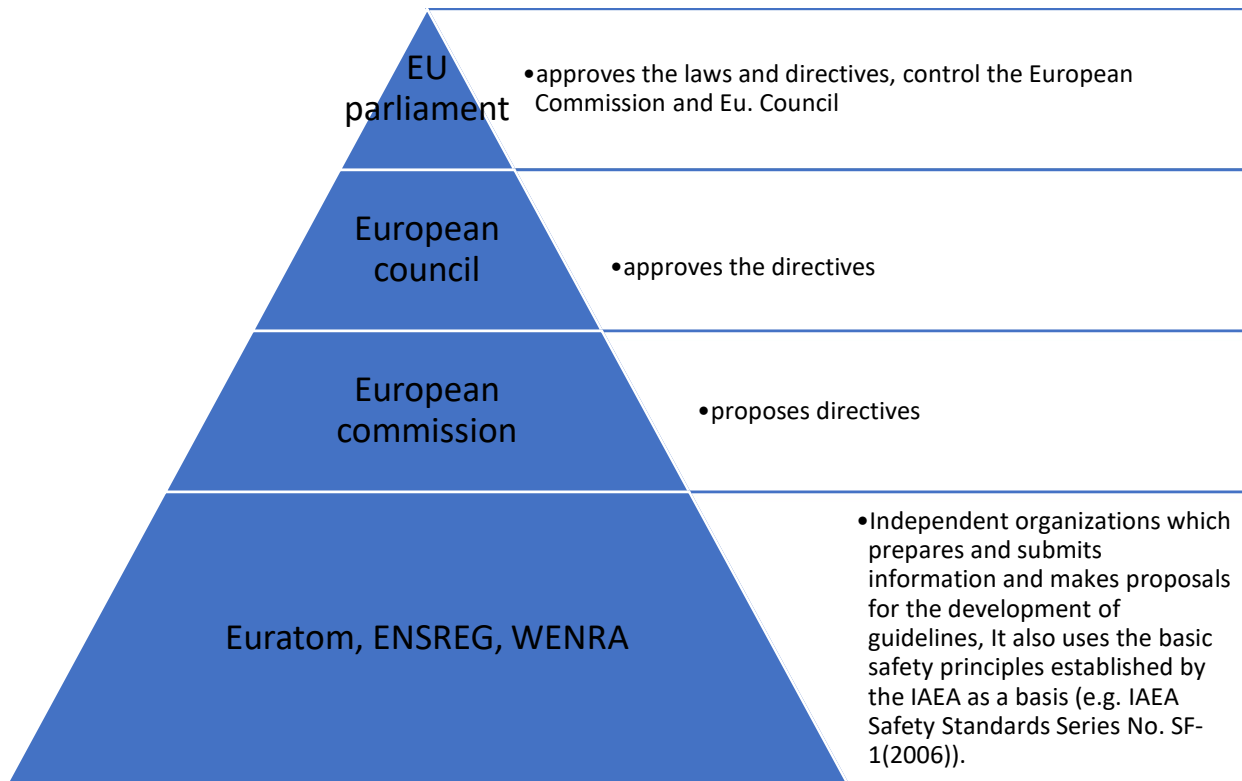
2.2.1 General description of NPP licensing policy

The European Union (EU) has established a comprehensive legal framework for nuclear safety and radiation protection, which is composed of several legislative instruments which are specified in the following chapters.

The European union issues the directives to ensure the basic framework of nuclear safety in Europe. EU also issues Guidelines, communications from commissions and reports from working groups. IAEA (International Atomic Energy Agency) is referenced in its reports as a basic source for documents processing.

The basic principle behind the development of European nuclear legislation can be seen in the following figure.

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Figure 1: European nuclear legislation

Next paragraphs describe the main organizations involve in the nuclear legislation in Europe.

EURATOM

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The European Atomic Energy Community (Euratom) is an international organisation established by the Euratom Treaty on 25 March 1957. Euratom is completely independent of the European Parliament and has no competence to issue European directives. This competence is only at European Commission and European council. Also, Euratom is a member of CNS (Convention on Nuclear Safety) that creates obligations on state parties to implement certain safety rules and standards at all civil facilities related to nuclear energy. These include issues of site selection; design and construction; operation and safety verification; and emergency preparedness.

According to the Treaty, one of the specific tasks of Euratom is to establish uniform safety standards to protect the health of workers and of the general public and ensure that they are applied. Each Member State lays down the appropriate provisions, whether by legislation, regulation or administrative action, to ensure compliance with the basic standards which have been established by the Treaty. In the past the Euratom has their own commission, but in 1967 was all European communities were merged into common institutions. So Euratom only submits proposals for directives to the European Commission, which then forwards them to the European Council for approval.

ENSREG

The European Nuclear Safety Regulators Group (ENSREG) is an independent, expert advisory group created in 2007 following a decision of the European Commission. All EU Member States that operate nuclear installations follow the basic principles set internationally for assuring nuclear safety and the safe management of radioactive waste and spent fuel.



ENSREG's role is to help to establish the conditions for continuous improvement and to reach a common understanding in these areas. As an independent authoritative expert body, ENSREG is working to:

- improve the cooperation and openness between Member States on nuclear safety and radioactive waste issues;
- improve the overall transparency on nuclear safety and radioactive waste issues; and as appropriate, advise the European Commission on additional European rules in the fields of the safety of nuclear installations and the safety of the management of spent fuel and radioactive waste.

ENSREG established four **working groups** to undertake its work programme. For our project is most relevant Working group 1 on – Nuclear Safety (WGNS). This working group organizes workshops to exchange lessons learned and experience, conducts technical discussions, elaborates, and reviews guidelines, provides guidance to facilitate the implementation of EU legislation in the field of nuclear safety and, through all of these, enhances the transparency and mutual understanding in the nuclear safety field at the European scope. Working groups meet as necessary and report back to ENSREG, which meets at least twice a year. ENSREG submits a report to the EU institutions on its activities every three years.

2.2.2 Safety Concept

The European directives about nuclear safety builds on the main nuclear safety international instruments, namely the CNS (The Convention on Nuclear Safety) and the Safety Fundamentals established by the IAEA. For example IAEA Safety Standards Series No. SF-1(2006)).

The first safety directive, [Council Directive 2009/71/Euratom](#) [6] aims at the overall continuous improvement of nuclear safety and its regulation. Moreover, it intends to ensure that Member States provide for appropriate national arrangements for a high level of nuclear safety to protect workers and the general public against the dangers arising from ionising radiations from nuclear installations.

The main obligations arising from this directive [6] fall on the Member States which must “establish and maintain a national legislative, regulatory and organisational framework for nuclear safety of nuclear installations.” The Safety provisions are based on a functional separation of the competent regulatory authority to ensure effective independence (Article 5.2). Member States are also required to ensure that the prime responsibility for nuclear safety of a nuclear installation lies with the license holder (Article 6.1). The latter must under the supervision of the competent regulatory authority regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations (Article 6.2).

Following the Fukushima nuclear accident in 2011, voluntary tests were carried out to verify the safety of the 143 European nuclear power plants within the EU. These so-called “stress tests” were comprehensive and transparent assessments aiming at establishing whether the nuclear power plants could withstand the effects of natural disasters, human failures, or malevolent acts. In view of the lessons learnt from these stress tests and the technical progress achieved through the provisions of the IAEA and by the Western European Nuclear Regulators Association (“WENRA”), [Directive 2009/71/Euratom](#) [6] had to be amended to include a high level community nuclear safety objective covering all stages of the lifecycle of nuclear installations (siting, design, construction, commissioning, operation, decommissioning). In particular, the safety objective calls for safety assessments before the construction of new nuclear power plants and significant safety enhancements for old reactors. The amendment became effective in 2014.

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The amended Nuclear safety Directive, [Directive 2014/87/Euratom](#) [7], introduces the concept of defence-in-depth and a nuclear safety culture as the basis for implementing high level nuclear safety objectives. Defence-in-depth is generally structured in five levels. Should one level fail, the subsequent level comes into play. The objective of the first level of protection is the prevention of abnormal operation and system failures. If the first level fails, abnormal operation is controlled or failures are detected by the second level of protection. Should the second level fail, the third level ensures that safety functions are further performed by activating specific safety systems and other safety features. Should the third level fail, the fourth level limits accident progression through accident management, so as to prevent or mitigate severe accident conditions with external releases of radioactive materials. The last objective (the fifth level of protection) is the mitigation of the radiological consequences of significant external releases through the off-site emergency response.

Council Directive [2009/71/Euratom](#) [6] and its amendment [2014/87/Euratom](#) [7]

These directives set out the basic safety standards for the design, construction, operation, and decommissioning of nuclear installations in the EU.

The establishment of state bodies for nuclear safety, which make supervisory decisions on the basis of effective and transparent requirements regarding nuclear safety, is hereby ordered.

The obligations of the nuclear facility operator are listed here. For example, that nuclear safety is the responsibility of the holder of the license to operate a nuclear power plant.

N
ECCN: The directive requires Member States to ensure that the national framework requires that defence-in-depth shall be applied to ensure that the impact of extreme external natural and unintended man-made hazards is minimised. According to this part, the impact of possible accident at the HPP on the NPP is supposed to be assessed.

N
AL: State supervisory authorities have the following main tasks in the area of supervision:

- a) propose or establish national requirements in the field of nuclear safety or participate in their establishment;
- b) (b) require the permit holder to comply with and demonstrate compliance with national nuclear safety requirements and compliance with the conditions of the relevant permit;
- c) verify this compliance with the requirements by evaluation and inspections;
- d) propose or apply effective and proportionate enforcement measures.'

It is also stipulated here that it is necessary to carry out periodic assessments of nuclear safety.

Council Directive [2013/59/Euratom](#) [14] laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom.

This Directive establishes uniform basic safety standards for the protection of the health of workers, members of the public and patients. It defines precise parameters, leaves little discretionary margin. The Directive applies under normal conditions, but it also refers to planned and emergency exposure situations.

According to article 38 of this directive is set Supervised areas in the NPP. In this area it is necessary taking into account the nature and extent of the radiological risks in the zone under surveillance, radiological surveillance of the site is necessary. If HPP will be at the NPP site it has to be evaluated, if the HPP will be in Supervised area or not. There is possibility that it will be necessary of developing radiation protection plans and strategies for non-standard events, taking in account HPP.

2.2.3 Environmental Impact

The most relevant directive in this area is **Directive [2011/92/EU](#) [15] on the assessment of the effects of certain public and private projects on the environment**

This directive deals with the assessment of the environmental effects of nuclear power plants, factories for the production of chemical substances, and the storage and transport of gases. It provides member states with a procedure for environmental impact assessment.

According to this directive, cumulative effects with other projects should be considered in the assessment. This directive mandates the assessment of environmental impacts even in the case of changes to facilities that have already been assessed. According to these requirements it will be necessary to prepare an assessment of the impact of the new HPP on the surrounding area and also the impact of the cogeneration of HPP and NPP on the surrounding area.

The assessment must include the following key points:

- a) A description of the physical nature of the project as a whole and the land use requirements during construction and operation;
- b) a description of the main characteristics of the production processes, such as the type and quantity of materials used;
- c) an estimate of the type and quantity of waste and emissions.

2.2.4 External hazards and Risks

For external hazards and risks there is no exact legislative for NPP. Potential risks which can breach safety are covered by the [Directive 2014/87/Euratom](#) [7] explained in section 2.2.2

2.2.5 Emergency provisions and response organization

In case of emergency situations, the operator has to have prepared the emergency response plans. This obligation is set out in directive [2013/59/Euratom](#) [14] mentioned in section 2.2.2

There are several requirements for the licensing process that should be included in the application in terms of radiation protection and emergency situations:

- Responsibilities and organisational arrangements for protection and safety.
- Staff competences, including information and training.
- Design features of the facility and of radiation sources.
- Anticipated occupational and public exposures in normal operation.
- Safety assessment of the activities and the facility in order to:
 - identify ways in which potential exposures or accidental and unintended medical exposures could occur;
 - estimate, to the extent practicable, the probabilities and magnitude of potential exposures;
 - assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;
 - define the operational limits and conditions of operation.
- Emergency procedures.
- Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.

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- Management of radioactive waste and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.
- Management of disused sources.
- Quality assurance.

If we decide to build HPP near NPP it may affect emergency procedures and safety assessment and this parts should be changed.

According to the above-mentioned directive it is necessary to prepare of the emergency response plans. Elements to be included in an emergency response plan are:

For emergency preparedness:

- Reference levels for public exposure, taking into account the criteria laid down in Annex I of this directive;
- Reference levels for emergency occupational exposure
- Optimised protection strategies for members of the public who may be exposed, for different postulated events and related scenarios;
- Predefined generic criteria for particular protective measures;
- Default triggers or operational criteria such as observables and indicators of on-scene conditions;
- Arrangements for prompt coordination between organisations having a role in emergency preparedness and response and with all other Member States and with third countries which may be involved or are likely to be affected;
- Arrangements for the emergency response plan to be reviewed and revised to take account of changes or lessons learned from exercises and events.
- Arrangements shall be established in advance to revise these elements, as appropriate during an emergency exposure situation, to accommodate the prevailing conditions as these evolve throughout the response.

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For emergency response:

- The response to an emergency exposure situation shall be undertaken through the timely implementation of preparedness arrangements, including but not limited to:
 - Promptly implementing protective measures, if possible, before any exposure occurs;
 - Assessing the effectiveness of strategies and implemented actions and adjusting them as appropriate to the prevailing situation;
 - Comparing the doses against the applicable reference level, focusing on those groups whose doses exceed the reference level;
 - Implementing further protection strategies, as necessary, based on prevailing conditions and available information.

Every operating NPP developed their own emergency response plan, but if we build HPP near the NPP it will affect the emergency plans and they will have to be adjusted.

2.2.6 Operation and Organization

[Directive 2014/87/Euratom](#) [7] stipulates that nuclear power plants should be designed, built and operated to prevent accidents, mitigate the consequences of accidents if they occur, and to prevent off-site contamination, and that the national regulatory authorities should ensure the application of these objectives in identifying and implementing appropriate safety improvements at existing plants.

Based on the integration level of HPP it will be necessary to evaluate if there will be influence for operation of the plant. Also depending on the level of integration of HPP and NPP, it will be necessary to evaluate changes in radiation protection and organisation of movement at the HPP site.

2.2.7 Relation with International documents of nuclear safety

European nuclear legislative is closely related to materials developed by IAEA. There are some interesting document related to nuclear safety of nuclear facilities. For example council directive 2009/71/Euratom [6] imposes obligations on the Member States to establish and maintain a national framework for nuclear safety. That Directive reflects the provisions of the main international instruments in the field of nuclear safety, namely the Convention on Nuclear Safety, as well as the Safety Fundamentals established by the International Atomic Energy Agency ('IAEA').

3 Analysis of international conventions

3.1 Hydrogen production international conventions

In this this work, no more international conventions regarding Hydrogen production have been identified that those included in section 2.1.

3.2 Nuclear international conventions

3.2.1 Regulatory framework based in IAEA safety standards

As mentioned in 2.2.7 European nuclear legislation is closely related to materials developed by international organizations as the IAEA.

The IAEA provides a regulatory framework which the member states have adopted by consensus. This is given in the form of IAEA safety standards which define the current international state of art in science and technology. They give fundamental principles, requirements, and recommendations to ensure nuclear safety. They serve as a guideline for the development of national nuclear regulatory frameworks. The Safety Standards compromise three different categories: the Safety Fundamentals, Safety Requirements and the Safety Guides. See Figure 2 below.

Safety Fundamentals lay out the fundamental safety objectives and principles of protection and safety. It is established in common understandable language also to non-expert readers. Safety set the requirements that must be met to ensure the protection Especially the IAEA Safety Guides are expressed as 'should' statements. Safety Fundamentals, which establish the fundamental safety objectives and the principles of protection and safety in language that's understandable to non-expert readers; Safety Requirements, which set out the requirements that must be met to ensure the protection of people and the environment, both now and in the future, and help countries establish their national regulatory frameworks; and Safety Guides, which present good and best practices and offer recommendations and guidance on how to comply with the Safety Requirements.

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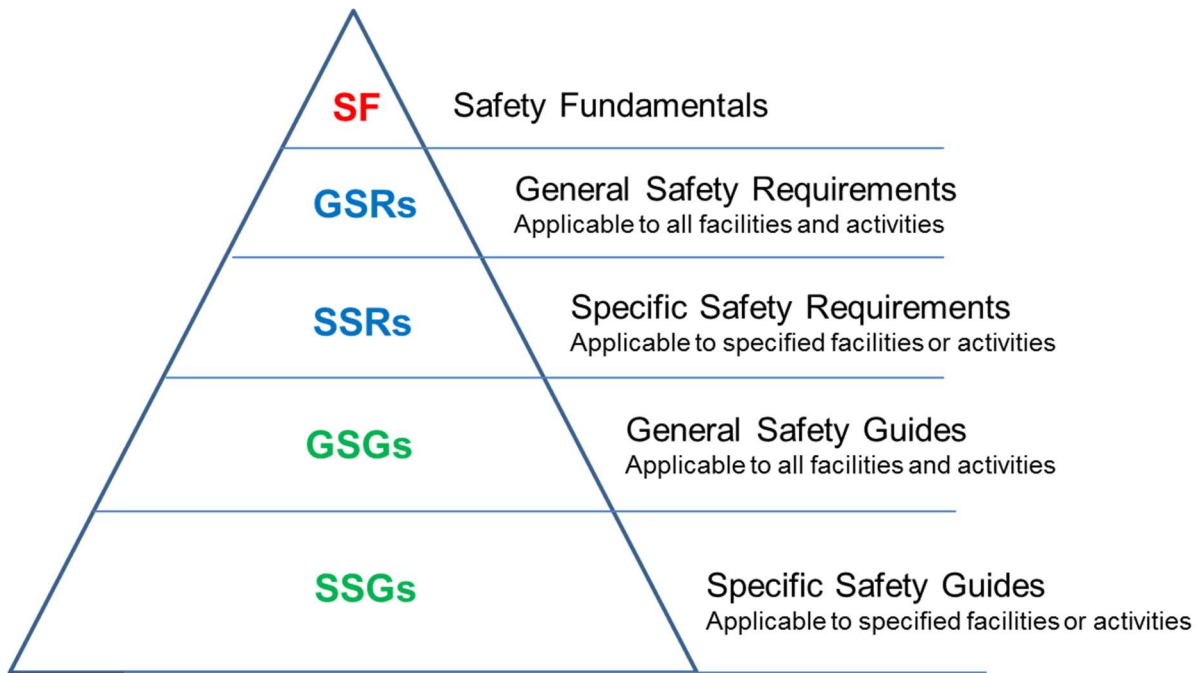


Figure 2: Hierarchy of IAEA Safety Documents

ECCN: N
AL: N
Relevant issues that need to be addressed for the co-generation of hydrogen is indirectly dealt with in some specific safety guides addressing internal hazards [SSG-77](#) [16] , [SSG-64](#) [17].

3.2.2 Safety Concept

The safety concept of a NPP is established in [IAEA Safety Standard No. SSR-2/1 \(Rev.1\)](#) [18] and [No SSR-2/2](#) [19].

No. SSR-2/1 (Rev.1) *Safety of Nuclear Power Plants: Design* [18] provides requirements for the design of NPPs. It goes into detail on the safety objective, safety principles and concepts that provide the basis for deriving the safety requirements that must be met for the design of a nuclear power plant.

In [SSR-2/1 \(Rev.1\)](#) [18] is stated that the Fundamental Safety Principles establish one fundamental safety objective and ten safety principles that provide the basis for requirements and measures for the protection of people and the environment against radiation risks and for the safety of facilities and activities that give rise to radiation risks.

For the operation and activities in a NPP on the highest standard levels, different measures have to be taken to fulfil the following:

- (a) Radiation exposure control of people and radioactive releases to the environment in operational states;
- (b) To restrict the likelihood of events that might lead to a loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source, spent nuclear fuel, radioactive waste or any other source of radiation at a nuclear power plant;
- (c) To mitigate the consequences of such events if they were to occur.

Looking into safety requirements specifically addressing the safety of nuclear hydrogen production the [NP-T-4.2](#) [20] summarizes among other things the integration of nuclear-chemical plants, basic

consideration for a hydrogen systems safety, explosion hazards, interaction between nuclear and chemical systems and the international regulations for handling hazardous materials.

Furthermore, for the integration of nuclear-chemical plants safety concepts must comprise aspects given by the close connection of the two plants and their potential interaction. The safety concepts for hydrogen generating plants contain safety aspects for conventional plants with fundamental differences in safety design philosophies which must be applied for nuclear plants. These differences come from the requirements deriving from the different hazardous substances present. Nuclear power plants are designed to contain the radioactive materials inside the containment in any case. Chemical plants handle combustibles where an accumulation of explosive concentrations should be avoided.

3.2.2.1 Defense in depth concept

For accidents in a NPP and for the mitigation of the consequences of accidents in case of occurrence the concept of defense in depth is applied. The idea of the concept is to have multiple independent layers of defense to allow to compensate for potential mechanical failures as well as human errors. It is not relied exclusively on a single layer regardless of how robust the layer is. Access controls, physical barriers, redundant and diverse key safety functions, and emergency response measures are part of the defense in depth concept. By applying the defense in depth concept for the design of and the operation of a NPP helps to protect against possible operational incidents and accidents and against incidents coming from events outside the plant.

Req. 7 in [SSR-2/1 \(Rev.1\)](#) [18] *Application of defense in depth* provides the practical application of the concept to the design

- In para. 4.11. is stated *The design*:
 - (a) *Shall provide for multiple physical barriers to the release of radioactive material to the environment;*
 - (b) *Shall be conservative, and the construction shall be of high quality, so as to provide assurance that failures and deviations from normal operation are minimized, that accidents are prevented as far as is practicable and that a small deviation in a plant parameter does not lead to a cliff edge effect;*
 - (c) *Shall provide for the control of plant behaviour by means of inherent and engineered features, such that failures and deviations from normal operation requiring actuation of safety systems are minimized or excluded by design, to the extent possible;*
 - (d) *Shall provide for supplementing the control of the plant by means of automatic actuation of safety systems, such that failures and deviations from normal operation that exceed the capability of control systems can be controlled with a high level of confidence, and the need for operator actions in the early phase of these failures or deviations from normal operation is minimized;*
 - (e) *Shall provide for systems, structures and components and procedures to control the course of and, as far as practicable, to limit the consequences of failures and deviations from normal operation that exceed the capability of safety systems;*
 - (f) *Shall provide multiple means for ensuring that each of the fundamental safety functions is performed, thereby ensuring the effectiveness of the barriers and mitigating the consequences of any failure or deviation from normal operation*
- In para. 4.12. is stated that *to ensure that the concept of defence in depth is maintained, the design shall prevent, as far as is practicable*:
 - (a) *Challenges to the integrity of physical barriers;*

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- (b) Failure of one or more barriers;
- (c) Failure of a barrier as a consequence of the failure of another barrier;
- (d) The possibility of harmful consequences of errors in operation and maintenance

3.2.2.2 Safety assessment

Req. 10 in [SSR-2/1 \(Rev.1\)](#) [18] is treating safety assessments. *Comprehensive deterministic safety assessments and probabilistic safety assessments shall be carried out throughout the design process for a nuclear power plant to ensure that all safety requirements on the design of the plant are met throughout all stages of the lifetime of the plant, and to confirm that the design, as delivered, meets requirements for manufacture and for construction, and as built, as operated and as modified.*

Safety assessments are to be used as means to assess the compliance with the safety requirements and the application of the fundamental safety principles for all facilities and activities. They are applied to determine the actions to ensure safety. Safety assessments should be conducted and documented by the operating organization. The safety assessment shall be independently reviewed and submitted to the regulatory authority as part of the licensing or authorization process.

Recommendations for safety assessments of NPP are provided in [IAEA Safety Standard No. GSR part 4 \(Rev.1\)](#) [21]. For safety assessments internal hazards and external hazards and its consequences must be considered.

Especially looking into hazards which could occur because of the hydrogen co-generation the evaluation must be done for internal hazards that can occur onsite due to an event connect to the hydrogen plant. The safety assessment must be done for internal explosions which can lead to missile, internal fires, asphyxiating gases. Projectiles can lead to the damage of other parts which can result in pipe break. Internal fires can cause smoke development which can cause consequential damage.

In [SSG-53](#) [22] section 3.9- 3.23 internal hazards are described. This must be connected to the design guide SSR2/1 [18] where the procedure of safety assessments is summarized.

Stages in the lifetime of a facility or activity for which a safety assessment is carried out, updated and used by the designers, the operating organization and the regulatory body include:

- 1) Site evaluation for the facility or activity;
- 2) Development of the design;
- 3) Construction of the facility or implementation of the activity;
- 4) Commissioning of the facility or activity;
- 5) Commencement of operation of the facility or conduct of the activity;
- 6) Normal operation of the facility or normal conduct of the activity;
- 7) Modification of the design or operation;
- 8) Periodic safety reviews;
- 9) Life extension of the facility beyond its original design life;
- 10) Changes in ownership or management of the facility;
- 11) Decommissioning and dismantling of the facility;
- 12) Closure of a disposal facility for of radioactive waste and the post-closure phase;
- 13) Remediation of a site and release from regulatory control.

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Figure 3 extracted from [IAEA Safety Standard No. GSR part 4 \(Rev.1\)](#) [21] shows the main elements of the process for safety assessment and verification. This process requires that a systematic evaluation of all features of the facility or activity relevant to safety be carried out.

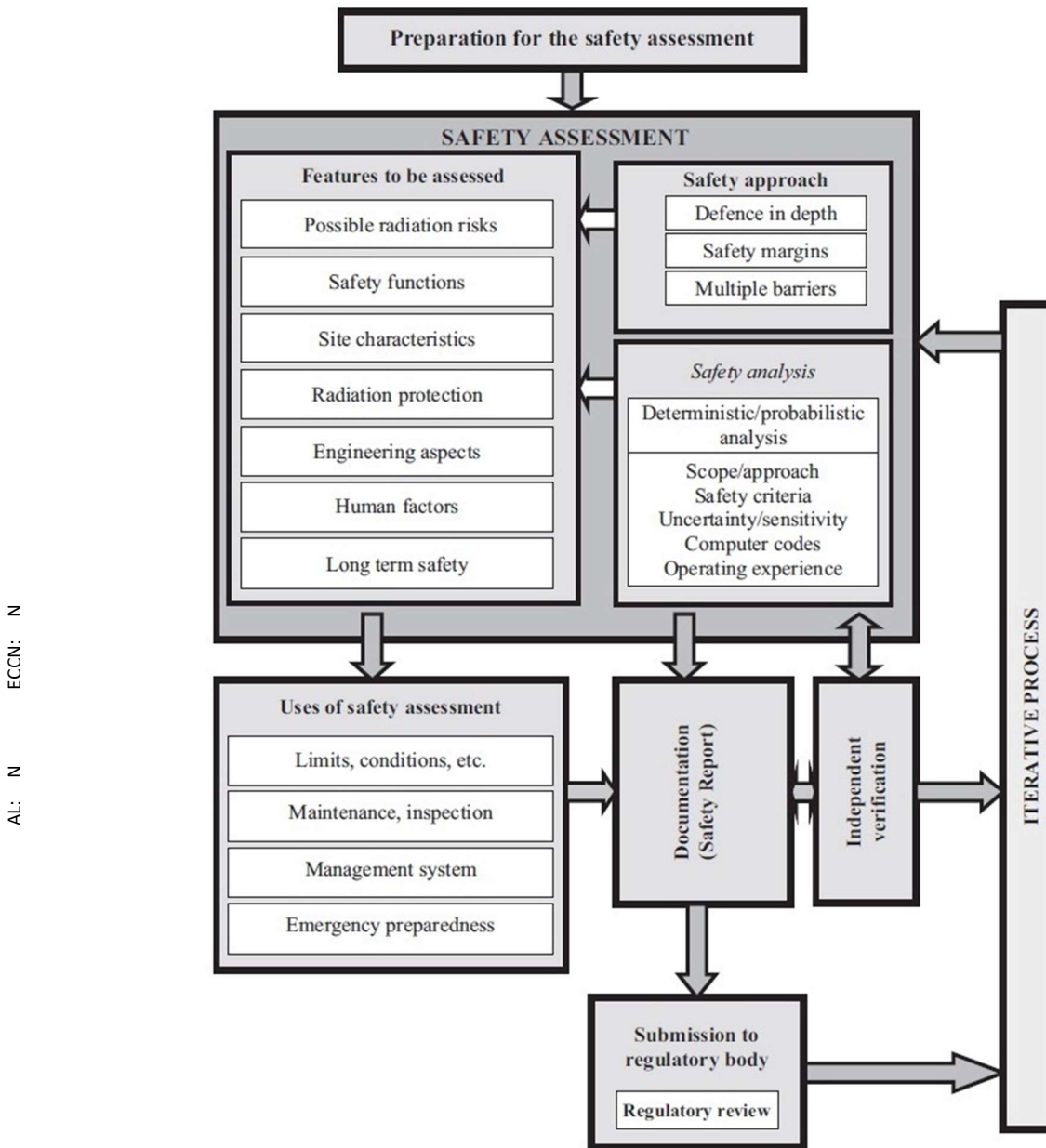


Figure 3 Overview of the safety assessment process

According to requirement 4 of GSR Part 4 [21] (parr. 4.6.): For facilities and activities that continue over long periods of time, the safety assessment shall be updated as necessary through the stages of the lifetime of the facility or activity, so as to take into account possible changes in circumstances, changes in site characteristics, and modifications to the design or operation, and also the effects of ageing.

For safety assessments first phenomena identification and ranking table (PIRT) studies have been done to assess the safety issues which arise from coupling a nuclear plant and a hydrogen facility. This has been done in the USA for a coupled high-temperature gas-cooled reactor (HTGR) with a hydrogen

facility [23]. Since those PIRTs are plant type specific they must be conducted for the nuclear plant type under consideration to evaluate the safety challenges and more specifically the consequences on equipment and people in accident conditions.

3.2.3 Environmental impact

3.2.3.1 Safety and radiation protection requirements

The hazard potential of a nuclear installation depends on its radioactive inventory and that part of this inventory could be released during an accident. Safety and radiation protection measures ensure protection for operating staff, the population and the environment against effects of ionizing radiation during normal operation and in case of an accident.

Different IAEA safety guides and requirements provide recommendations for safety and radiation protection of workers, the public and for protection of the environment:

- [IAEA Safety Standards Series No. GSR Part 3](#) [24], *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*; Effects of atomic radiation, requirements for the protection of people and the environment from harmful effects of ionizing radiation and for the safety of radiation sources is treated in this guide.
- [IAEA Safety Standards Series No. GSG-8](#) [25], *Radiation Protection of the Public and the Environment*. It provides guidance on the framework for protection of the public and the environment. It gives recommendations on the application of the radiation protection principles of justification, of optimization of protection and safety, and of dose limits. The protection of the public and the environment in all exposure situations — planned, emergency and existing is included.
- [IAEA Safety Standards Series No. GSG-9](#), *Regulatory Control of Radioactive Discharges to the Environment*; It provides guidance to governments, regulatory bodies, applicants for a licence and operating organizations on how to control radiation exposures of the public resulting from discharges from normal operations. It provides guidance on application of the principles of radiation protection and the safety objectives associated with the control of discharges and on the process for authorization of discharges.
- [IAEA Safety Standards Series No. GSG-10](#), *Prospective Radiological Environmental Impact Assessment for Facilities and Activities*; It describes a framework and methodologies for prospective radiological environmental impact assessment. It provides *the assessment of the exposure of the public*.
- [IAEA Safety Standard No. SSR-2/1 \(Rev.1\)](#) [18], *Safety of Nuclear Power Plants: Design*; It provides requirements applicable to the design of nuclear power plants. Safety objectives as well as safety principles and concepts in accordance with safety requirements that must be met for the design of a nuclear power plant are established.
- [Document Preparation Profile DS524 | IAEA](#), [26] *Radiation Protection Aspects of Design for Nuclear Power Plants*; It gives recommendations on radiation protection aspects in the design of new nuclear power plants in accordance with requirements established in SSR 2/1.
- [IAEA Safety Standard No. GSR part 4 \(Rev.1\)](#) [21] *Safety Assessment for Facilities and Activities*; It provides requirements for safety assessments for facilities. Special focus lays on the defence in depth and quantitative analyses. Requirements for a consistent and coherent basis for safety assessments is established.

Radiation protection shall follow three principles which are stated in [IAEA Safety Standards Series No. GSG-8](#) [25]:

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- justification,
- optimization of protection and safety and
- application of dose limit

These principles are explained in detail in [IAEA GSR Part 3](#) [24] among other requirements:

- The application of the principles of radiation protection
- Establishment of a legal and regulatory framework
- Responsibilities of the regulatory body
- Responsibilities for protection and safety
- Management for protection and safety

[IAEA SSR-2/1 \(Rev.1\)](#) [18] also establishes requirements for radiation protection:

- Requirement 5 *Radiation protection in design states:*
The design of a nuclear power plant shall be such as to ensure that radiation doses to workers at the plant and to members of the public do not exceed the dose limits, that they are kept as low as reasonably achievable in operational states for the entire lifetime of the plant, and that they remain below acceptable limits and as low as reasonably achievable in, and following, accident conditions.
- Requirement 81 *Design for radiation protection states:*
Provision shall be made for ensuring that doses to operating personnel at the nuclear power plant will be maintained below the dose limits and will be kept as low as reasonably achievable, and that the relevant dose constraints will be taken into consideration."

3.2.3.2 Safety assessment in the design

For the safety assessment in the design different requirements on the suitability of the site and environment characteristics regarding a possible influence on the transfer in case of radioactive release from the NPP to the environment shall be met.

In [DS524](#) [26] is summarized that *Safety guides SSG-68, SSG-67, SSG-9 (Rev. 1), NS-G-2.13, NS-G-3.2 and GSG-10 provide recommendations for the assessment or reassessment (for safety reviews) of the suitability of a site and also for analysis of secondary and cascading effects of external hazards for designing or assessing the effective radiation protection measures and arrangements.*

These cascading effects of external hazards should be considered in the case of the nuclear powered hydrogen cogeneration.

3.2.3.3 Application of dose limits

According to [GSR Part 3](#) [24] dose limits for occupational exposure and public exposure are established by the government or the regulatory body. Relevant dose constraints for occupational exposure are established and used by licensees, and those for public exposure are established or approved by the government or regulatory body. For internal exposures, such as those that result from the inhalation and ingestion of radioactive substances, the dose limits apply to the committed dose

More detailed information on radiation protection, dose rate limits are established in [DS524](#) [26]:

- General aspects of radiation protection in design
 - o Sources of radiation
- Control of sources of radiation and estimation of dose rate
 - o Estimation of dose rates during normal operation
 - o Source categories for normal operation

- Sources and propagation of radiation
- Specific design features of radiation protection for normal operation
 - Protection of the public during normal operation
 - Discharge criteria
 - Specific design features of radiation protection for accident conditions
- Design for radiation monitoring for normal operation and accident conditions

3.2.4 Internal and external hazards and Risks

Internal and external hazards must be considered in the design of items important to safety in a nuclear power plant. It is necessary to provide appropriate features to prevent internal and external hazards and to mitigate possible effects to ensure that safety is not compromised.

Internal hazards are defined as those hazards to safety of the NPP that originate within the site boundary. They are linked to the failure of facilities and actions controlled by the operating organization.

External hazards are hazards coming from events outside of the plant site and are not under the control of the operating organization, but which might affect the safety of the NPP.

The IAEA Safety Standard [SSG-64](#) [17] gives combinations of hazards and design concepts for protection against internal hazards in nuclear power plants in accordance with the requirements provided in [SSR-2/1 \(Rev.1\)](#) [18]. Internal hazards like fires, explosions, missiles, pipe breaks, flooding, collapse of structures and falling objects with a focus on heavy load drop, electromagnetic interference and release of hazardous substances originating from within the site boundary are discussed.

For general design recommendation for protection against internal hazards several steps need to be considered:

- Identification and characterization of internal hazards and hazard combinations
- Prevention of internal hazards
- Mitigation of the effects of internal hazards
- Definition of assessment, verification, and success criteria
- Aspects of design for protection against internal hazards

The following internal hazards are discussed in [SSG-64](#) [17], which are relevant in the context of the co-generation of hydrogen.

- Internal fire
- Internal explosions
- Internal missiles
- Pipe breaks (pipe whip and jet effect and flooding)

For each hazards the following is established in detail:

- Identification and characterization of each hazard
- Prevention of the above-mentioned hazard
- Mitigation of the consequences of the hazard

More detailed information can be found in section 4 *Recommendation for specific internal hazards* in [SSG-64](#) [17].

The IAEA Safety Standard [SSG-77](#) [16] summarizes the protection and management of internal and external hazards in the operation of nuclear power plants. It gives recommendations gained from the understanding of operational aspects of hazards and combinations of hazards.

3.2.4.1 Potential Hazardous events of nuclear-powered hydrogen cogeneration

In [NP-T-4.2](#) [20] is summarized that *the primary goal is the safe use of hydrogen and the control of its risks associated with its use*. This applies for the design of a nuclear reactor for process heat as well as for the design of the nuclear reactor using the electricity for the hydrogen generation. Primary hazards inflicted using hydrogen systems are i. a. combustion, hydrogen embrittlement and exposure. According to [NP-T-4.2](#) [20] potential hazardous events are:

- Fire and explosion of flammable mixtures
- Release of toxic material.

In the [IAEA Safety Guide 50-SG-S5](#) [27] external man-induced events in relation to nuclear power plant siting are evaluated which can be of use to derive guidelines for safe design and measures for the interaction of the NPP and the chemical plant. The approach in the Safety Guide is to identify potential man-induced events and develop design basis parameters. In the end it is shown either that the hazardous potential is not great enough to be considered or that the evaluated effects are acceptable for the provision of design basis parameters. The Safety Guides establishes categories of events. In Table 1 sources and their associated events are identified.

Table 1 Source and initial event identification

Facilities and transportation systems to be investigated	Relevant features of the facilities and traffic	Initial event
Oil refinery, chemical plant, storage depot, pipelines, mining or quarrying operations, forests, other nuclear facilities, etc.	Quantity and nature of substances	Explosion Fire
	Flowsheet of process in which hazardous materials are involved	Release of explosive, flammable, corrosive, toxic or radioactive clouds
	Meteorological and topographical features of the region	Ground collapse, subsidence
	Existing protective measures in the installation	
Railway trains and wagons, road vehicle, ship, barges, etc.	Frequency of passage	Explosion
	Type and quantity of hazardous material associated with each movement	Fire Release of explosive, flammable, corrosive or toxic clouds
	Features of the vehicles (including protective measures)	

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Meteorological and topographical features of the region

The excerpt of the table in [50-SG-S5](#) [27] takes the cases relevant for the consideration for the co-generation of hydrogen. The formulation of man-induced design basis events on the regional knowledge and the design of the proposed plants depends. Following the derivation of initial events, the impact of different secondary effects occurring from events like fire or explosion are summarized in Table 2. These secondary effects can be applied on hydrogen plant as well.

Table 2 Impact on NNP and consequences

Impact on the plant	Parameters	Consequences of impact
(1) Pressure wave	Overpressure at the plant as a function of time	Collapse of parts of structure or disruption of systems and components
(2) Missile	Mass	Penetration, perforation, or spalling of structures, or disruption of systems and components
	Velocity	
	Shape	Collapse of parts of structure or disruption of systems and components
	Size	
	Kind of material	
	Structural features	
	Impact angle	
(3) Heat	Flux	Disruption of systems or components Ignition of fire combustibles
(4) Smoke and dust	Composition	Blockage intake filters
	Concentration and quantity as a function of time	Habitability of control room and other important plant rooms and affected areas
(5) Flammable and explosive gas	Concentration and quantity as a function of time	Permeation of the plant and fire or explosion inside plant
		Explosion or fire on site
(6) Corrosive, toxic, and radioactive gas and aerosols	Concentration and quantity as a function of time	Permeation of the plant
	Corrosive, toxic limits	Habitability of control room and affected plant areas
		Corrosion and disruption of systems or components
(7) Ground shaking	Response spectrum	Mechanical damage

AL: N
ECCN: N

(8) Flooding	Level of water Velocity of impacting water	Damage to structures, systems and components
(9) Subsidence	Settlement, differential displacement, settlement rate	Collapse of structures or disruption of systems and components

Coming to the sources associated with industrial and commercial facilities in [50-SG-S5](#) [27] it is stated that *hazards presented to a nuclear power plant from a stationary source such as industrial plants, storage depots and pipelines arise from explosion, fires and the formation of gas and dust clouds*. For the assessment the following information is needed:

- Types of hazardous material
- Quantities in store
- Types of process (flowsheets)
- Dimensions of major vessels
- Stores or other forms of containment
- Pipeline characteristics
- Isolating characteristics
- Operating conditions
- Active and passive safety systems
- Accident and failure data
- Possible interaction of materials in different stores
- Data on meteorology of the region, local meteorological features and topography of the area (between source and NPP)

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In a next step it is recommended to analyze the identified events to their potential for effects important to safety. Parameters evaluated in [50-SG-S5](#) [27] are:

- Nature and maximum amounts of materials that may explode
- Distance of closest approach to items important to safety.

Evaluating design basis explosions TNT equivalents are usually used to estimate the shock waves and the resulting safe distances for given weights of explosive chemicals and for given pressure resistances of relevant structures. By the explosion generated missiles should be considered, too.

For the design basis explosions, the following parameters should be determined:

- Pressure waves: maximum overpressure incident and reflected and time variation
- Generated missiles: size, impact velocity
- Ground shock

The release of hazardous fluids resulting in the formation gas and vapor clouds and drifts. A drifting cloud can affect the NPP in the following form:

- Externally to the plant: potential hazard similar to fire and explosion
- Permeation of the plant: Potential hazard to staff and important safety systems (toxic gases, corrosive gases)

Common method of defense to ensure protection is by distance.

Precautionary measures against possible occurring fire induced events such as the reduction of the amount of combustible gases close to the NPP, protection barriers, redundancy of safety systems, physical separation by distance, separate fire compartments and fire detection and extinguishing systems are recommended.

Recommendations in [NP-T-4.2](#) [20] include that load-bearing concrete structures that withstand a 3 h standard fire should have a thickness of 0.15 m. The temperature of reinforced bars and structural steel for short term fires of less than 6 h is not allowed over 500°C. Explosion and events connected to gas cloud explosion like fire, loss of off-site power, smoke, ground motion and missiles the plant structure must be assessed. As a result, the capacity of the NPP containment to resist blast overpressure needs to be evaluated. The pressure- distance relationship developed for TNT can be used. In [NP-T-4.2](#) [20] is stated that reinforced concrete walls with minimum 0.5 m thickness can normally withstand substantial overpressure. Protective measures for explosion are similar to those for fire. In a first step all available information should be evaluated, and a screening procedure should be carried out. In the literature can be found that this can be done by using a screening distance value (SDV) for sources beyond that they become significant. As limiting values, a screening probability level (SPL) can be used, too. Another procedure can be an approach based on expert judgment. For human induced hazards the SDV and SPL must be chosen conservatively small to keep the risk acceptable low. In [NP-T-4.2](#) [20] is summarized that Member States apply SVDs in the range of 5-10 km for explosions and 1-2 km for fires.

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3.2.4.2 Risks and evaluation methods

As indicated in Figure 3 above, the safety analysis can include both deterministic and probabilistic analysis. According to [GSR part 4 \(Rev.1\)](#) [21], requirement 5 *Preparation for the safety assessment*: “The first stage of carrying out the safety assessment shall be to ensure that the necessary resources, information, data, analytical tools as well as safety criteria are identified and are available.

The safety criteria defined in national regulations or approved by the regulatory body to be used for judging whether the safety of the facility or activity is adequate have been identified. This could include applicable industrial standards and associated criteria.

3.2.5 Emergency provisions and response organization

In IAEA Safety Standard No [SSG-77](#) [16] is stated that hazard management must be implemented with the nuclear and radiation safety programme of the NPP. The management as well as the decision making for hazard management shall be in harmonization with the guidance and actions comprised in the NPP’s emergency preparedness and response and the accident management programme.

[SSG-77](#) [16] recommends that strategies for coping with the impact of hazards must be established as part of the hazard management. Strategies shall cover the infrastructure of the region (e. g. roads, railways, electric grid interfaces, communications, sources of water, proximity to waterways, regional population centre and local industry). External resources and organisations like:

- Emergency services
- Local government
- Response organisations

shall be identified. Early warning protocols must be installed and trained with external organizations as well as external communication should be tested.

[GSR-7](#) [28] provides requirements for the preparedness and response for a nuclear or radiological emergency.

Different national organisations like operating and response organisations at local, regional and national levels may be involved. Also, international organisations might be involved. The involved organisations might be the same for a nuclear or radiological emergency as for a conventional emergency. Specialised agencies and technical experts could be required additionally.

The goals of the emergency response are stated as the following in [GSR-7](#) [28]:

- (a) *To regain control of the situation and to mitigate consequences;*
- (b) *To save lives;*
- (c) *To avoid or to minimize severe deterministic effects;*
- (d) *To render first aid, to provide critical medical treatment and to manage the treatment of radiation injuries;*
- (e) *To reduce the risk of stochastic effects;*
- (f) *To keep the public informed and to maintain public trust;*
- (g) *To mitigate, to the extent practicable, non-radiological consequences;*
- (h) *To protect, to the extent practicable, property and the environment;*
- (i) *To prepare, to the extent practicable, for the resumption of normal social and economic activity*

Requirement 5 in [GSR-7](#) says that *the government shall ensure that protection strategies are developed, justified and optimized at the preparedness stage for taking protective actions and other response actions effectively in a nuclear or radiological emergency.*

Functions that are essential for the emergency response in a nuclear or radiological emergency are established in Section 5 of [GSR-7](#) [28].

In Section 6 of [GSR-7](#) [28] requirements of the infrastructure are summarized.

4 Analysis for France

4.1 Nuclear Power Plant in France

4.1.1 Introduction

France is the world's second largest nuclear power producer. The French reactors are generating about 70% of its total electricity generation. In 2021, nuclear power plants accounted for 360.7 TWh. The operating fleet comprises 56 PWRs (Figure 5): 32 reactors at 900 MW(e), 20 reactors at 1300 MW(e), and 4 reactors at 1450 MW(e). All the existing operating civil nuclear power reactors are operated by Électricité de France S.A (EDF), two units have been closed in 2020 at Fessenheim. One European Pressurized Reactor (EPR) is under construction at the Flamanville site.

The following sections aims to supply an overview on the legal framework, main actors in the licensing process, safety dossier contents, nuclear safety approach, emergency provisions, operation and organization for nuclear installations in France. Furthermore the main findings related to the integration of HPP within a NPP are provided.

4.1.2 General description of NPP licencing policy

In France public security, health and safety, protection of nature and environment are “interests” mentioned in Environment Code (article L 593-1), Transparency and Security in the Nuclear Field (TSN)

Act (I of Article 28) and in Order of 7 February 2012 setting the general rules relative to basic nuclear installations (article 1.3).

French regulatory architecture is shown in Figure 6. The Autorité de sûreté nucléaire (ASN) is the French Nuclear safety authority.

The legislative domain is constituted by laws; decrees, orders and ASN regulatory decisions belong to legally binding domain; guidelines, issued to explain how to implement the corresponding regulations, are not binding. Ministerial Decrees and orders are under the responsibility of the government. ASN proposes or gives advice on ministerial decisions. ASN issues regulatory decisions that are to be endorsed by the government, technical rules and prescriptions

Table 1 below outlines the main French laws, orders, decrees and regulations for the following:

- Basic Nuclear installation (BNI/INB) (including NPP),
- Installations classified for the protection of the environment (ICPE),
- Nuclear pressure equipment,
- Radiation Protection,
- Radioactive waste management.

The main French laws, order, decrees and regulation applicable to Basic Nuclear Installation are described in detail in the following sections with particular attention to the aspects related to safety and licensing.

4.1.2.1 ACT No. 2006-686 of 13 June 2006 on Transparency and Security in the Nuclear Field (TSN) Act

This Act establishes the Nuclear Safety Authority (Autorité de sûreté nucléaire) ASN as an independent authority and provides a legislative framework for basic nuclear installations (INB). It is composed of an independent college of 5 commissioners, a General Directorate and eleven decentralized divisions. Whenever it deems it necessary, ASN calls upon its technical support organisations, primarily the IRSN, for advice as well as. For major issues (such as license application), ASN requests the opinion of the competent advisory expert group to which the IRSN presents its analyses; for other secondary matters, safety analyses are the subject of an opinion to be sent directly to ASN by the IRSN. As for license application, a government decree finalises, based on ASN and other organisations advice the licensing process. Furthermore, the act ensures Transparency in the nuclear field providing the set of provisions adopted to ensure the public's right to reliable and accessible information on nuclear security. The licencing process of a French nuclear installation is depicted in Figure 4 extracted by the document [29].

Periodic reports concerning a basic nuclear installation are required by article 21 of the Act, in particular, according to Article 23, an annual report needed to be provided, containing for example nature and measurements of radioactive and non-radioactive release into the environment, nature and quantity of the waste stored, incident and accident occurred within the boundary of the installation.

Findings

The integration of HPP in a NPP is not mentioned in TSN Act. Anyway according to Article 29 of TSN ACT, this integration could imply a change in the licensee boundary ad a significant change in the installation.

The Nuclear Safety Authority (Autorité de sûreté nucléaire) ASN is the independent authority that provides a legislative framework for basic nuclear installations (INB) integrated with HPP. HPP is a considered as Installation Classified for the Protection of the Environment (ICPE), as explained in 4.2.3, Hydrogen and hydrogen production are respectively substance and activities ICPE classified. Inside

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INB/BNIs (basic nuclear installations including also NPP), the French nuclear regulator ASN (presented in Section 4.1.3.3) manages the ICPE. Outside the INB/BNI, DREAL (presented in Section 4.1.3.4) manages ICPE.

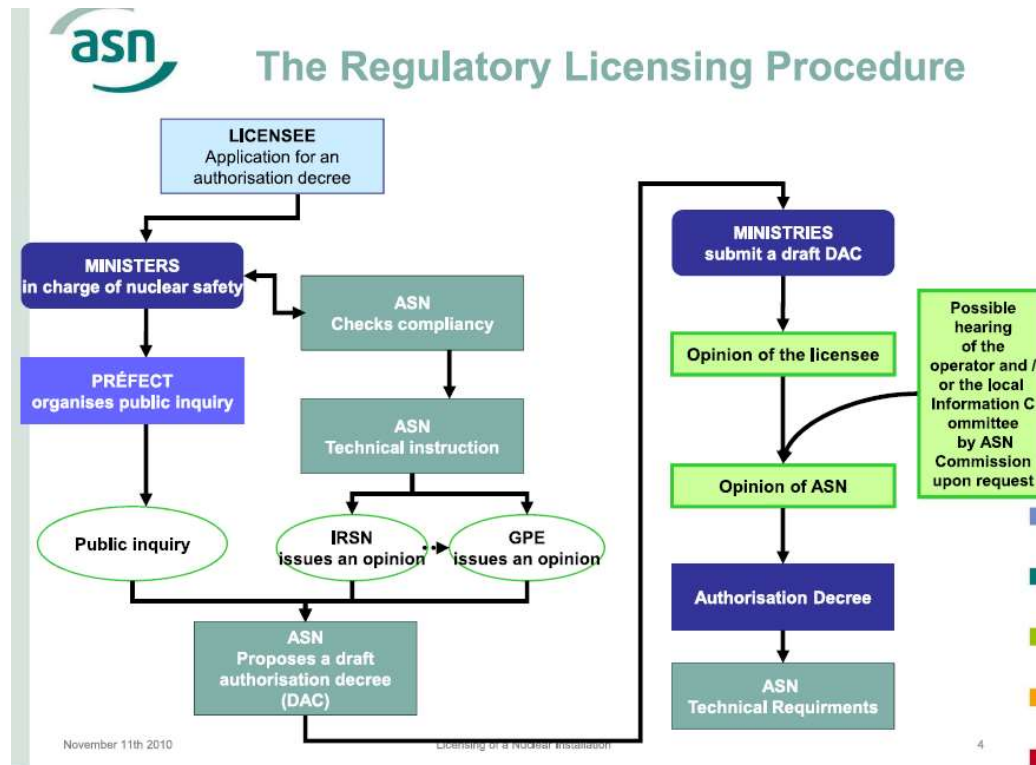


Figure 4 The regulatory Licensing Procedure [29]

4.1.2.2 French environment code

The main environmental law principles are provided in the 2004 Environmental Charter which is part of the French Constitution.

The French Environment Code (*Environment Code*) provides most of the acts and decrees related to the environment, such as [30] :

- Rules concerning the preservation of natural resources.
- The monitoring of hazardous activities.
- Environmental assessment and public information on projects.

The code includes the main laws (article L) and the main decrees and orders (articles R and D).

The rules provided in Environmental Code are demanded for each installation/facility/plant that may have an impact on the environment due to its activity/processes and products/substances used/handled. These installations, defined "Installations classified for the protection of the environment" – ICPE installations, are classified according to a specific nomenclature according to the installation is subject to authorisation (articles L.512-1 to L.512-6 of the Environmental Code), approval (articles L.512-7 of the Environmental Code) or declaration (articles L.512-8 to L.512-13). The authorization scheme adopted in France is assessed in Section 4.2.4.1. The classification depends on the level of the risk of the activities/processes carried out within the facilities and the amount of hazardous substances manipulated/stored/produced.

The documents to be prepared for each authorization scheme are listed in Section 4.2.4.1.

Basic nuclear installations that include NPPs are subject to specific rules as for example those provided in article L 593- 7 of the Environment Code. According to article L 593-7, the creation of a basic nuclear installation is subject to authorization. This authorisation may be obtained if the operator provides evidences that the technical or organizational measures adopted or conceived at the design, construction and operation stages, as well as the general principles proposed for decommissioning, are suitable to prevent or limit the risks or drawbacks that the facility presents for the protection of interests mentioned in Article L. 593-1 (public security, health and safety, protection of nature and the environment). The applicant shall provide a “dossier” including, in particular, a preliminary version of the safety report, which specifies the risks to which the planned installation may expose the interests mentioned in Article L. 593-1, as well as an analysis of the measures taken to prevent these risks and a description of the measures to limit the probability of accidents and their effects. Furthermore, to obtain the authorisation, the operator needs to demonstrate to have technical and financial capacities to carry out his project in compliance with these interests, in particular to cover the costs of dismantling the installation and restoring, monitoring and maintaining its location.

4.1.2.3 Order of 7 February 2012 setting the general rules relative to basic nuclear installations such as nuclear reactors

The Order sets the general rules relative to basic nuclear installations. The Order applies to all the element important for the protection of the interests mentioned in article L. 593-1 of the environment code (public security, health and safety, protection of nature and the environment), and the activities important for the protection of these interests.

Element important for protection of the interests can be subdivided in the following categories:

- element important components required to place the basic nuclear installation site in a safe state and maintain it in that state;
- element important components used to prevent, detect or limit the consequences of incidents or accidents but which are not required for placing the facility in a safe state and maintaining it in that state;
- element important components required to prevent or limit the impact on interests to be protected, associated in particular with the management of water sources and effluents (sampling, collection, release), as well as atmospheric releases (INB, ICPE).

Element important for protection need to be properly defined, tested, fabricated and qualified, in order to comply with the associated functions and to preserve their capacity to fulfil its requirements. Furthermore, a specific demonstration that that the safety functions of the Element important for protection of interests are ensured in normal, degraded and accidental conditions is required.

The order defines “Activity important for protection” each activity important for protection of the interests mentioned in L. 593-1 of the environment code (public security, health and safety, protection of nature and the environment), or activities participating in the technical or organisational provisions mentioned in the second paragraph of article L. 593-7 of the environment code, or that could affect them. These activities occur through the entire lifecycle of the element important for the protection and include for example design, purchase, fabrication, manufacturing, construction, assembly, delivery (including transport) and storage, installation, testing, commissioning, operation, maintenance.

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For each lifecycle of the nuclear installation specific Activities Important for the protection can be identified following the criteria below listed, if at least one of the below provided criterium is satisfied the activity can be considered as Important for the protection:

- Activity having an impact on the element important for the protection, its characteristics and capacity to fulfill its requirement;
- Activity related to a safety function of element important for the protection;
- Activity that can change the results of a safety analysis;
- Activity that have an impact on the authorization/licensing documents.

The compliance with the INB-order must be demonstrated in the chain of external contractors, if any. In application of article II.2.5.4 of the Order 7th February 2012, contracted activities for supervision purposes are also subject to a supervision done by the Nuclear Operator.

4.1.2.4 Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations and the supervision of the transport of radioactive materials with respect to nuclear safety

This decree, concerning the basic nuclear installations, sets the consultative committee for basic nuclear installations that reports to the ministers responsible for nuclear safety, establishes that the ministers responsible for nuclear safety submit to the consultative committee for basic nuclear installations, for its opinion, all draft decrees concerning authorization applications for the creation, modification, shutdown and decommissioning, or shutdown and transition to the surveillance phase of basic nuclear installations. Furthermore, specifies that the general rules provided by article 30 of the Act of 13 June 2006 (TSN Act) are set by order of the ministers responsible for nuclear safety. The operator/licencee submit to the French Regulator (ASN: Autorité de Sûreté Nucléaire) the Safety Case/Dossier containing the documents indicated in the French Decree 2007-1557 of 2 November 2007. The safety dossier represent the totality of documentation to justify safety during the design, construction, commissioning, operation and decommissioning phases of the installation.

According to French Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations, a Safety Case/Dossier must be prepared to obtain the Authorization decrees:

- to create/ build a basic nuclear installation (art.8)
- to commission a basic nuclear installation (art.20)
- to final shutdown and decommission of a basic nuclear installation (art. 37)
- to declassify the installation (art. 40)

Furthermore, specific documents must be prepared by the applicant/operator in case of modification of the authorization decree for a basic nuclear installation.

4.1.2.4.1 Safety dossier to create/build a basic nuclear installation (art.8)

To create/ build a basic nuclear installation, according to art.8 of Decree 2007-1557 of 2 November 2007), the following documents/data need to be provided:

1. The name, forenames and status of the operator and his domicile or, if the applicant is a corporate person, then its corporate name or description, head offices and status of the signatory of the application;
2. A document describing the nature of the installation, its technical characteristics, the operating principles, the operations to be performed in it and the various phases involved in its construction;

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3. A 1/25,000 scale map locating the planned installation;
4. A 1/10,000 scale site plan indicating the proposed perimeter of the installation and, within a one-kilometre strip around this perimeter, the buildings with their current uses, the railways, public highways, water supply points, canals and watercourses and gas and electricity transmission networks;
5. A detailed drawing of the installation at a minimum scale of 1/2500;
6. The impact assessment specified in article L. 12 2-1 of the Environmental Code, the content of which, notwithstanding the requirements of article R. 122-3, is defined in article 9;
7. The preliminary safety case, the content of which is specified in article 10 and assessed in Section 4.1.4;
8. The risk control study, the content of which is clarified by article 11;
9. If the operator requests public protection restrictions pursuant to article 31 of the Act of 13 June 2006, the description of these restrictions;
10. The decommissioning plan, which presents the methodological principles and the steps envisaged for decommissioning of the installation and rehabilitation and subsequent supervision of the site. The plan in particular justifies the dismantling time envisaged between the final shutdown of the installation and its decommissioning. It can refer to a document drawn up by the operator for all its nuclear installations and enclosed with the file;
11. For a radioactive waste disposal installation, the decommissioning plan is replaced by a document presenting the envisaged procedures for final shutdown and subsequent supervision of it. This document comprises an initial analysis of the safety of the installation after final shutdown and transition to the surveillance phase;
12. If the plan for creation of the basic nuclear installation is the subject of a public debate pursuant to article L. 121-8 of the Environmental Code or a consultation pursuant to I of article L. 121-9 of the same code, the report and results of this public debate or the minutes of this consultation.

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4.1.2.4.2 Safety dossier to commission a basic nuclear installation (art.20)

Prior to commissioning of the installation, the operator has to submit to the Safety Authority the following documents/data need to be provided:

1. The safety case comprising the updated preliminary safety case and the data provided for assessment of installation conformity with the requirements of the authorisation decree and the construction requirements defined pursuant to article 18;
2. The general operating rules the operator intends to implement, as of commissioning of the installation, for protection of the interests mentioned in I of article 28 of the Act of 13 June 2006;
3. A waste management plan, specifying the operator's objectives for limiting the volume and radiological, chemical and biological toxicity of the waste produced in its installations and, by reuse and reprocessing of the waste thus produced, for reducing the size of the repository reserved for ultimate waste. This study takes account of all installation waste management

channels up until disposal. It can cover the waste produced by all the installations and equipment located within the perimeter;

4. The on-site emergency plan mentioned in article L. 1333-6 of the Public Health Code, which is mandatory for basic nuclear installations, together with the opinion of the health, safety and working conditions committee, obtained in accordance with article L. 236-2 of the Labour Code. The on-site emergency plan, on the basis of the sizing study included in the safety case, defines the organisational measures, the response methods and the necessary resources implemented by the operator in the event of an emergency situation, to protect the personnel, the public and the environment from ionising radiation, and preserve or restore the safety of the installation. If an off-site emergency plan was drawn up, the on-site emergency plan specifies the details of how the operator is to carry out the measures incumbent upon it under the off-site emergency plan. The on-site emergency plan takes into account the steps to be taken by the operator in the event of an accident, as defined in the safety case. At the initiative of the operator or at the request of the Nuclear Safety Authority, the on-site emergency plan may be common to several neighbouring Basic Nuclear Installations with the same operator. As applicable, it takes the place of the on-site operations plan required by 18 article R. 512-29 of the Environmental Code for installations classified on environmental protection grounds located within the perimeter of the Basic Nuclear Installation.

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5. Except for a radioactive waste repository, an up date as necessary of the decommissioning plan mentioned in 10° of I of article 8.

6. An update of the environment impact assessment.

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After checking that the installation complies with the objectives and rules defined by chapter I of title IV of the Act of 13 June 2006 and its implementing provisions, the Nuclear Safety Authority authorises commissioning of the installation. It may make this authorisation dependent on the operator taking account of its previous observations to the operator concerning the application file, and aimed at protecting the interests mentioned in I of article 28 of the Act of 13 June 2006. The Nuclear Safety Authority may postpone its decision to authorise commissioning until introduction of the public protection restrictions mentioned in article 31 of the Act of 13 June 2006. It informs the operator accordingly before expiry of the time period specified in article 4 of this decree.

At the end of the commissioning the operator is required to submit to the Nuclear Safety Authority the following documents:

- A summary report on the installation start-up tests;
- A summary of the operating experience matured
- Updating of the documents above mentioned (from 1 to 6)

It can also define intermediate steps in the start-up process and make performance of these steps dependent on the supply of information by the operator to the Nuclear Safety Authority or on approval from this authority.

4.1.2.4.3 Safety dossier for significant modification of the installation (art.31)

In case of a significant modification of a basic nuclear installation specific documents need to be prepared by the licensee in accordance with Article 31 of French Decree 2007-1557 of 2 November 2007.

The following constitute a significant modification of a basic nuclear installation as defined by II of article 29 of the Act of 13 June 2006:

1. A change in its nature or a rise in its maximum capacity;
2. A modification of the elements essential for protection of the interests mentioned in I of article 28 of the Act of 13 June 2006 (public security, health and safety, protection of nature and environment) , which appear in the authorisation decree pursuant to article 16;
3. An addition of a new basic nuclear installation within the perimeter of the existing installation.

The operator which wishes to make a significant modification to its installation sends an authorisation application to the ministers responsible for nuclear safety in the conditions defined in articles 7 and 8.

The dossier accompanying the application concerns the installation as it would be after the envisaged modification and specifies the impact of this modification on the various aspects of the current authorisation.

The application is examined and is the subject of a decision in accordance with the procedures defined in chapter II of title III.

In the case mentioned in 3° above, the authorised modification requires a commissioning authorisation issued in accordance with the procedures defined in article 20.

Furthermore the Article 32 specifies the following:

- Other than in the cases described in articles 29 to 31, the requirements of the authorisation decree for a basic nuclear installation can be modified in the following conditions:
 - o If the modification is requested by the operator, it submits its application, along with a file, to the ministers responsible for nuclear safety. This file proves that the requested modification is compatible with the interests mentioned in I of article 28 of the Act of 13 June 2006. It states which file documents specified in articles 7¹ and 8 are affected by this modification and supplies an updated version of these documents. The documents requested by Article 8 are listed in Section 4.1.2.4.1. The operator sends a copy of the application, along with the file, to the Nuclear Safety Authority. The ministers responsible for nuclear safety transmit a copy to the Minister for Civil Security and a copy to the Minister for Health.
 - o If the modification is requested by the Nuclear Safety Authority, it sends a fully justified application to the ministers responsible for nuclear safety and informs the operator accordingly.
 - o If the modification is envisaged at the initiative of the ministers responsible for nuclear safety, they inform the operator and the Nuclear Safety Authority accordingly.

4.1.3 Regulatory Authorities

Environmental regulatory authorities intervene on both a national and local scale.

¹ According to Article 7, the application for the decree authorising the creation of a basic nuclear installation is filed with the ministers responsible for nuclear safety by the person in charge of operating the installation.

4.1.3.1 Ministry for Ecological and Inclusive Transition (Ministère de la transition écologique et solidaire) (MTES)

As provided in [31], at national level, the Ministry for Ecological and Inclusive Transition (*Ministère de la transition écologique et solidaire*) (MTES) enforces environmental policies through five General Directorates respectively dedicated to:

- Energy and Climate.
- Infrastructure, transport and sea.
- Planning, housing and nature.
- Prevention of technological risks.
- Civil aviation.

The MTES is also the ministry for 70 public institutions, including the National Agency for Management of Radioactive Waste (*Agence nationale pour la gestion des déchets radioactifs*) (ANDRA). Other ministries also have jurisdiction over specific environmental issues (such as the Ministry of Economy for certain mining permits).

4.1.3.2 General Council for Environment and Sustainable Development (Conseil général de l'environnement et du développement durable) (CGEDD)

The General Council for Environment and Sustainable Development (*Conseil général de l'environnement et du développement durable*) (CGEDD) within the MTES advises the government on environmental matters. The CGEDD also sits as a special body (Environmental Authority) (*Autorité environnementale*) (AE) dedicated to carrying out its legal duties concerning the assessment of the effects of certain public and private projects on the environment. The AE Environmental Authority (*Autorité Environnementale*) is the advisory body regarding projects that are likely to affect the environment. Its role is to give an opinion on the quality of the environmental impact assessment; this is further discussed in Environmental Permit. French administrative courts stated that the Environmental Authority shall remain totally independent and be different from the authority in charge of delivering the permit. In this context, a decree was adopted in July 2020, making the prefect of a region the official authority in charge of case-by-case decisions (ie, when the environmental impact assessment is not automatically applicable).

4.1.3.3 Nuclear Safety Authority (Autorité de sûreté nucléaire) (ASN)

ASN is the independent administrative Nuclear Safety Authority (*Autorité de sûreté nucléaire*) enforces nuclear law, it also tackle environmental issues. ASN is tasked, on behalf of the State, with regulating nuclear safety and radiation protection in order to protect workers, patients, the public and the environment from the risks involved in nuclear activities. ASN also contributes to informing the citizens.

4.1.3.4 Directions régionales de l'environnement, de l'aménagement et du logement) (DREAL)

At a local level, Regional Directorates for Environment, Land Planning and Housing (*Directions régionales de l'environnement, de l'aménagement et du logement*) (DREAL), implement the environmental policies in each French region, under the authority of the local representative of the state, the prefect (*préfet*).

As far as local authorities are concerned, mayors can also exercise administrative enforcement powers in relation to environmental law. They specifically have jurisdiction to enforce waste law in situations such as the unauthorised dumping of toxic waste (*Article L.541-3, Environment Code*).

4.1.3.5 National Radioactive Waste Management Agency (ANDRA)

According to [32], Andra, the National Radioactive Waste Management Agency is a specific public agency, has the responsibility for the long-term management of radioactive waste produced in France (but excluding foreign waste or waste originating from foreign spent fuel processing). This agency operates waste repositories, defines the acceptance criteria for waste packages in these repositories

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and controls the quality of their production. The agency is also in charge of designing, siting, and constructing new disposal facilities. It keeps up to date the National inventory of radioactive waste and recoverable materials in France (this inventory includes the so-called “committed” or forecast waste with projection over the coming years with contrasting scenarios) with an edition issued on a three-year basis

4.1.3.6 Nuclear safety and radiation protection delegate for defence-related activities and facilities (DSND) and Defence Nuclear Safety Authority

As indicated in [32], the nuclear safety and radiation protection delegate for defence-related activities and facilities (DSND) was created at the Ministry of Defence to study nuclear safety policy applicable to defence-related installations and activities. Taking account of the specific aspects of defence-related activities, they draw up nuclear safety regulations and propose the technical provisions regarding protection against ionising radiation. The DSND monitors application of the regulations and reviews any authorisation application for creation, commissioning, modification, shutdown and decommissioning. The DSND proposes safety measures to prevent accidents and mitigate their consequences. The DSND takes part in public information in the fields within their scope of competence and on the activities and installations under their control, in compliance with national defence requirements and notably via information committees (CI). In issuing their opinion, they draw on expert groups, including the IRSN and independent commissions. The DSND is assisted by personnel placed at their disposal, within an entity called the Defence Nuclear Safety Authority placed under their responsibility.

4.1.3.7 Nuclear Safety and Radiation Protection Mission

As provided in [33], the Nuclear Safety and Radiation Protection Mission is the ministerial department, placed under the authority of the Minister for ecological and solidarity-based transition, and the Minister for health, which, on their behalf, deals with nuclear safety and radiation protection subjects within the competence of the Government, except for defence-related activities and installations and the protection of workers against ionising radiation. These missions are defined in Article 8.1.3 of the Order of 9 July 2008.

The department thus:

- coordinates and follows the files falling within the competence of the Ministers responsible for nuclear safety and radiation protection (coordination of BNI procedures, preparation of regulations in collaboration with ASN, etc.);
- participates in the development of the national emergency organisation (accidents affecting nuclear installations or radioactive material transports, radiological emergency situations, acts of terrorism, etc.) in collaboration with the services of the ministry responsible for civil protection;

4.1.3.8 ICPE inspectorate and mines inspectorate

According to [34], the ICPE inspectorate checks compliance with the technical requirements binding on the licensee. This means that its work focuses both on the equipment of the installations and the persons responsible for operating it, as well on the working methods and the organisation. It also intervenes in the event of complaints, accidents or incidents. If the inspectorate observes that the binding requirements are not appropriate, it can propose that the Prefect imposes additional requirements through an order. If the licensee does not comply with the compulsory measures, it could incur administrative penalties (compliance notice, deposition of sums, automatic enforcement, daily penalty payment, administrative fine, suspension of

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license, closure) and criminal penalties. The law provides for severe penalties in the event of any breach of these provisions.

4.1.3.9 Other public body

IRSN (Institute of Radiation protection and Nuclear Safety (IRSN) was created in February 22th by law 2001–398 of 9 May 2001, and by the implementing order of 22 February 2002. IRSN is the public expert body in charge of the scientific assessment related to nuclear and radiological risks. IRSN gives expertise and contribution to public policies and technical support to public authorities (ASN, ministries...); provides also services to industry and other organisations and Training in radiation protection of health professionals and persons occupationally exposed

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Figure 5 – Map of France's nuclear power facilities (source: IAEA).

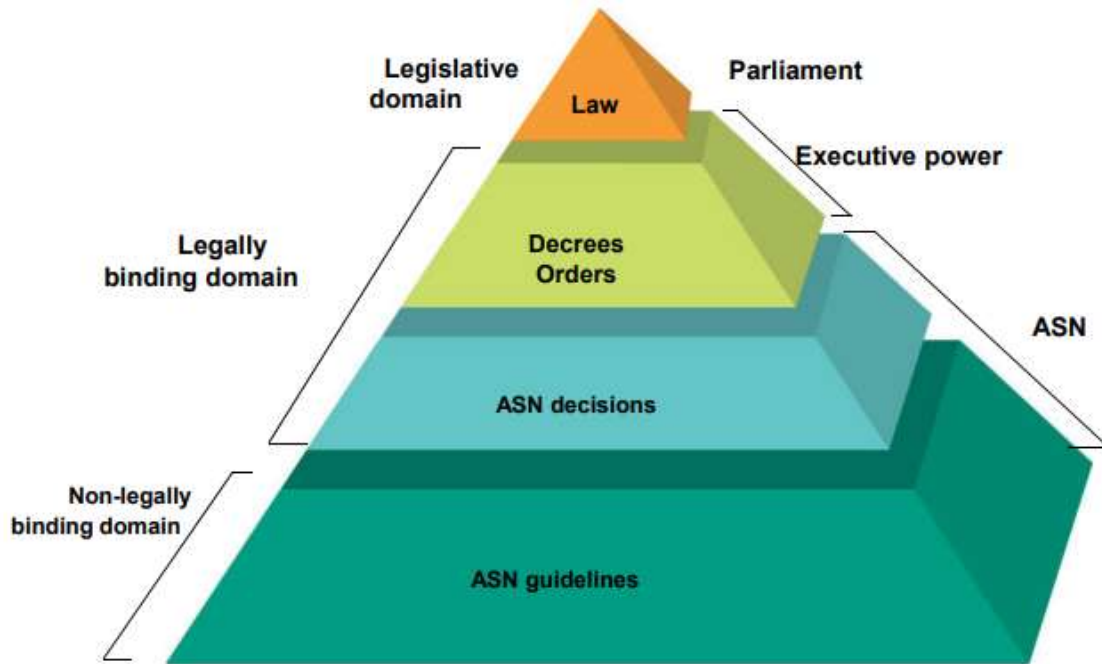


Figure 6 – Regulatory architecture for NPPs in France (Ref. [IAEA](#)).

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4.1.4 Safety Concept for NPP

In France the installations in which radioactive elements are used are classified in three main categories.

- ✓ basic nuclear installations (*installations nucléaires de base – INB*) regulated under Decree 2007-1557;
- ✓ installations classified for environmental protection purposes (*installations classées pour la protection de l'environnement - ICPE*) ;
- ✓ defence-related nuclear installations and activities (*installations et activités nucléaires intéressant la défense – IANID*).

In 2006, Act No. 2006-686 of 13 June 2006 on nuclear transparency and safety (TSN Act) establishes the Nuclear Safety Authority (*Autorité de sûreté nucléaire*) ASN as an independent authority and provides a legislative framework for basic nuclear installations (INB). The operator of the NPPs in France is required to carry out regular safety assessments to identify potential hazards and risks and to ensure that appropriate measures are in place to control these risks.

The preliminary safety report, mentioned in article 10 of French Decree 2007-1557 of 2 November 2007 concerning basic nuclear installations, is the key safety document that aims to demonstrate that the safety functions associated to the element important for the protection of interests (i.e confinement of radioactive and hazardous materials, control of reactor reactivity, heat decay removal, limitation of exposure to ionizing radiation and hazardous materials) are ensured in normal, incidental and accidental conditions. Scope of the safety assessment is to identify potential incident-accident events, causes of postulated events, potential consequences and the levels of defence in depth implemented in the plant (prevention, controls/detection and mitigation).

The French nuclear safety approach, in fact, is based on the defense-in-depth principle: this principle needs to be implemented in the safety demonstration of the NPP. This principle consists in the implementation of successive and independent lines of defense against the risks identified including the cliff-edge effect. These lines include prevention means as well as detection and mitigation provisions including zonings.

The defense-in-depth principle, which can presently be formulated in the following terms:

- a. The first level is to provide sufficient safety margins at the design, construction and operation stages in order to guarantee a good behavior of the plant in normal operation;
- b. the second level requires to implement the protection systems with the necessary redundancy, so that they are able in all anticipated transients and incidents to bring back the plant into its normal operating domain;
- c. the third level consists of an analysis of plant behavior in the event of accidents, which are supposed to cover all accidental sequences resulting from possible failures

This analysis must demonstrate that the action of safeguard systems is able to limit the consequences to the plant and to the environment below given limits; it must be done with conservative assumptions, both for the accidental scenarios and for the evaluation of plant behavior.

4.1.5 Environmental Protection and Industrial Emissions for NPP

The following regulations and guidelines apply to nuclear power plants in France regarding environmental protection and industrial emissions:

- Environmental Code: The [French Environmental Code](#) sets out the regulatory framework for environmental protection in France, including emissions control for industrial facilities such as nuclear power plants.
- Industrial Emissions Directive (IED): The IED is a European Union directive that sets out rules for preventing and controlling industrial emissions, including emissions from nuclear power plants. France is a member of the EU and therefore, nuclear power plants in France must comply with the IED.
- Environmental permit: Nuclear power plants in France must obtain an environmental permit from the [Ministry of Ecological Transition](#). The permit outlines the environmental conditions that the plant must comply with.
- Environmental monitoring: Nuclear power plants in France must conduct environmental monitoring to assess the impact of plant operations on the environment. This includes [monitoring](#) of air, water, and soil quality, as well as radiation levels in the environment.

More details are given in Section 4.2.3.

4.1.6 External hazards and Risks for NPP

The list of hazards within the design basis are provided in the sections below reported.

4.1.6.1 External hazards

1. Aircraft crash.
2. Earthquake.
3. Lightning and electromagnetic interference.
4. Exceptional mass of snow .
5. Extreme weather or climate conditions involving extreme external temperatures and relative humidity, ice/frost, extreme winds and tornados.

6. Fire.
7. External Explosion (no missile effect nor pressure wave impacting the element important for the protection components) including room conditions/ element important for the protection equipment constraints ensured for the minimum duration in case of external explosion damaging HVAC.
8. External Flooding or drought.
9. Malevolence acts.
10. Plausible combinations of hazards:
 - i. earthquake + Internal Fire.
 - ii. earthquake+flooding
 - iii. Water table + external flooding;
 - iv. External explosion + External fire;
 - v. Accidental temperature + External Fire.
11. Loss/Malfunctioning of utilities including for example:
 - Loss/Malfunction of External Electrical Power Systems (loss of Site Power)
 - Loss/Malfunction of HVAC Systems
 - Loss/Malfunction of I&C
 - Loss/Malfunction of Fire Protection Systems
 - Loss/Malfunction of other Building Systems

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4.1.7 Emergency provisions and response organization for NPP

France has a comprehensive emergency provisions and response organization in place for nuclear power plants. The organization involves several levels of government, as well as the nuclear power plant operator and local emergency services.

As provided in [33] the organisation of the response by the public authorities in a nuclear or radiological emergency situation is a particular case of the government's organisation for dealing with major emergencies, as presented in circular 5567/SG from the Prime Minister dated 2nd January 2012. This circular describes the role and the responsibilities:

- at government level (ministries and interministerial crisis committee);
 - at defence and security zone level (zone operations centre);
 - at département level (departmental operations centre);
- of the various stakeholders and regional agencies taking part in the response to a major emergency.

The emergency organization for accident situation is shown in Figure 7.

The management of a radiological emergency situation is covered by the "national response plan for a major nuclear or radiological accident" of February 2014 and by the interministerial directive of 7 April 2005 concerning the organisation of the public authorities in the event of a nuclear or radiological emergency. International notification of the emergency situation is the subject of the interministerial directive of 30 May 2005 relative to the application of the international convention on the early notification of a nuclear or radiological accident and the decision of the council of the European Communities concerning the community procedures for the rapid exchange of information in the event of a nuclear or radiological emergency situation. Information exchange protocols are in place with France's neighbors liable to be affected by a nuclear or radiological emergency situation in a

facility close to a border.

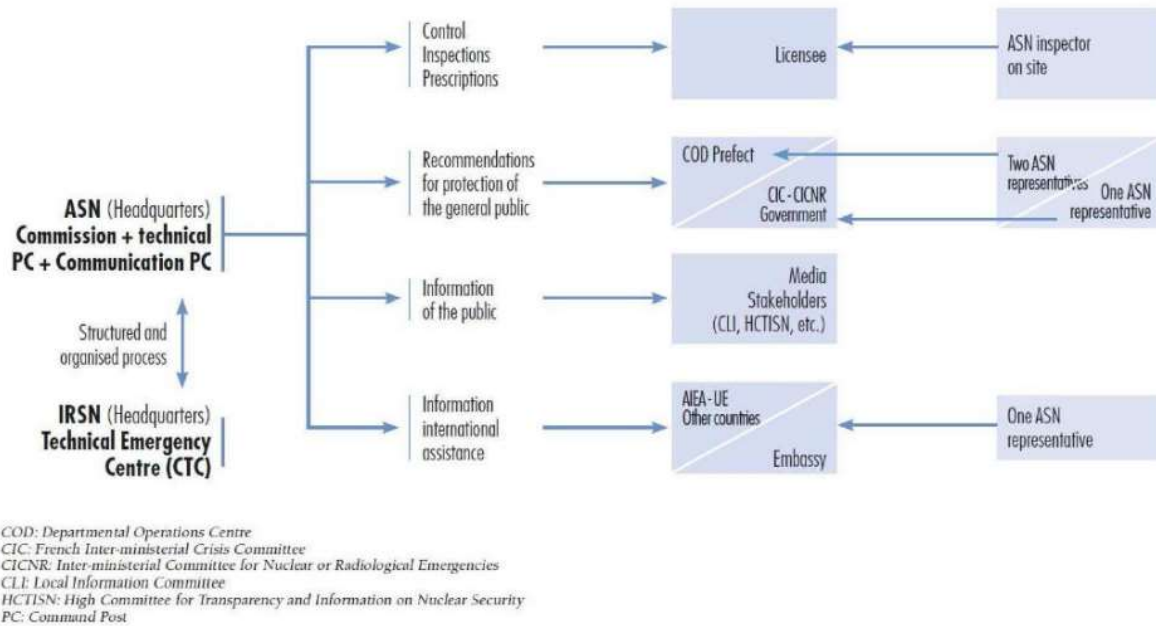


Figure 7 Emergency organisation for accident situations [33]

4.1.8 Organisation at the local level

According to [33], in a nuclear or radiological emergency situation liable to have an impact outside a BNI, the Prefect of the département where this facility is situated takes charge of the emergency response operations. He or she implements the provisions of the off-site emergency plan (PPI) and orders population protection measures. To ensure local management of the emergency, he or she activates and utilises the emergency management centre (departmental operations centre), which comprises representatives from all the response services (police, gendarmerie, civil protection), the decentralised regional agencies of ASN and IRSN. He or she is also responsible for communication with the media and informing the general public and elected representatives. The licensee of the BNI affected by the accident must deploy an organisation and means for controlling the accident, assessing it and mitigating the consequences, for protecting the persons on the site and alerting and regularly informing the public authorities. These arrangements are determined beforehand in the on-site emergency plan that the licensee is required to prepare.

4.1.9 Organisation at the national level

As provided in [33], organisation at the national level in the event of a major crisis requiring the coordination of numerous actors, a governmental crisis organisation is set up, under the supervision of the Prime Minister, with the activation of the interministerial crisis committee.

The purpose of this committee is to establish the strategic decisions and ensure their implementation at interministerial level.

It comprises:

- all the ministries involved,;
- the nuclear safety authority (ASN) and its technical support organisation (IRSN)

- the licensee;
- the administrations or public institutions providing assistance, such as Météo-France.

In a radiological emergency situation, each ministry has the responsibility to prepare and implement the national level measures within their field of competence.

The ministries involved also work together with ASN in order to advise the Prefect on the protection measures to be implemented and provide the Prefect with the information required to assess the state of the facility, the entity of the consequences of the incident or accident and its possible developments.

4.1.9.1 Emergency plans

The licensee of a INB/BNI is obliged by the regulations to draw up a nuclear or radiological emergency response plan [33]. This plan is called the on-site emergency plan and its purpose is:

- to return the facility to a stable, controlled state;
- to prevent, mitigate or delay the consequences of the accident outside the facility;
- to alert the response services outside the facility and facilitate their on-site response actions;
- to alert and protect the persons on the site;
- to alert the public authorities;
- to take the steps provided for in the off-site emergency plan which are under the responsibility of the licensee.

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As provided in [35] , the emergency plans in case of accidents occurring in a INB/BNI define the measures necessary to protect workers, public and the environment, and to control any potential accident.

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The on-site emergency plan, prepared by the licensee, is designed to return the facility to a safe condition and mitigate the consequences of an accident. It defines the organizational actions and the resources to be implemented on the site. It also defines the modalities for informing the public authorities quickly. The licensee's obligations in terms of preparedness and management of emergency situations are determined by the Order of 7 February 2012 setting the general rules for INBs/BNIs (Title VII) [Error! No se encuentra el origen de la referencia..]. These obligations are completed by the ASN resolution n -2017-DC-0592.

This national emergency system comprises specialized teams and equipment capable of intervening at an accidented site within 24 hours.

4.1.9.2 Off-site emergency plan

For certain INB/BNIs, such as NPPs or research reactors, the public authorities in the département are obliged by the regulations to draft and adopt a contingency plan for the population living within a specified area around the facility [33]. This plan is called the “off-site emergency plan” (PPI) and its purpose is to protect populations in the short term from the threat of radioactive releases and provide the licensee with outside emergency response resources. It defines the duties of the various services concerned, the ways of broadcasting the alert and the material and human resources.

As provided in [35], the off-site emergency plan (PPI) is established by the prefect of the department concerned. PPIs are established to protect the populations, property and the environment, and to cope with the specific risks associated with the existence of structures and facilities whose perimeter is localized and fixed. They implement the orientations of civil protection policy in terms of mobilization of resources, information, alert, exercises and training.

As provided in [36], in 2016, the French government increased the range of the off-site emergency plans from 10 km to 20 km around NPPs, in agreement with the Herca-Wenra European approach. This will allow for better preparation of the populations involved and for better coordination with neighboring countries. In addition, stable iodine tablets are pre-distributed in this perimeter. As provided in [36], according to the current studies and international standards, an accident comparable to Fukushima would require protective actions such as evacuation up to 20 km and sheltering up to 100 km. These actions would be combined with the intake of stable iodine. The Herca-Wenra European approach propose to adopt the following measures:

- evacuation up to 5 km around nuclear power plants, and sheltering and iodine thyroid blocking up to 20 km;
- a general strategy should be defined in order to be able to extend evacuation up to 20 km, and sheltering and iodine thyroid blocking up to 100 km;

4.1.9.3 National "major nuclear or radiological accident" plan

As discussed in [33], at the Government level, the national "major nuclear or radiological accident" plan published in February 2014 covers the major radiological emergency situations concerning BNIs or the transport of radioactive materials. It provides the national emergency management organization and the strategies to adopt for the ministerial authorities. This plan is implemented at national level (defence and security zones and départements) and supplements the off-site emergency plans.

4.1.9.3.1 National response organization

As indicated in [33], in an emergency situation, the responsibilities of ASN, with the support of IRSN, are as follows:

- To ensure steps taken by the licensee are pertinent and robust;
- To advise the Government and its local representatives;
- To contribute to the dissemination of information;
- To act as competent authority within the framework of the international Conventions on Early Notification and Assistance.

In the event of a severe accident, an Interministerial Crisis Committee is involved and is ready to take part of the intervention. The relevant ministries, together with ASN give advise to the prefect at the local level and to the Government, via the committee, on protective measures to be taken. They provide the information to assess the state of the facility, the severity of the consequences of the incident or accident, its possible development, and the measures required to protect the general public and the environment.

In an emergency situation, several parties have the authority to make decisions in the local response organization:

- The holder of the license (licensee) of the nuclear facility involved in the incident/accidents manages the response organization and the resources defined in its on-site emergency plan.
- The nuclear safety authority (ASN) monitors the licensee's actions and ensure that the nuclear safety and radiation protection requirements are duly taken into account. In an emergency situation, aided by IRSN's assessments, it can at any time ask the licensee to perform assessments and take the necessary actions.
- The prefect of the department in which the nuclear installation is sited takes the necessary decisions to protect the population, the environment and the facilities potentially impacted

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by the accident. The prefect is thus responsible for coordinating the resources both public and private, human and material deployed in the plan and keeps the population and the mayors informed of events. The regional division of ASN supports the prefect in drafting the plans and managing the situation.

In the event of a severe accident [35] , a number of preventive measures can be envisaged by the prefect in order to protect the general public:

- Sheltering and listening: the individuals involved, alerted by a siren, take shelter at home or in a building, with all openings carefully closed, and wait for instructions from the prefect broadcast by radio.
- Administration of stable iodine tablets: When ordered by the prefect, the individuals potentially exposed to radioactive release iodine need to take the prescribed dose of potassium iodide tablets urgently.
- Evacuation: In the event of an imminent risk of large-scale radioactive releases, the prefect may order evacuation.
- The populations involved need to leave their homes and go to the nearest assembly point.

As provided in [35], in the event of the release of radioactive substances into the environment, specific measures have been established to manage the post-accident phase; they are based on the definition of area zoning to be implemented as of the end of the releases on exiting the emergency phase and including:

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- an evacuation zone, defined according to the ambient radioactivity (external exposure) within which the residents must be evacuated for a period of time which will depend on the situation;
- a zone, including the first zone, within which action is required to reduce both the exposure of the populations to ambient radioactivity and the consumption of contaminated foodstuffs, as far as is reasonably possible (for example a ban on consumption of produce from the garden, restrictions on access to wooded areas, ventilation and cleaning of homes, etc.);
- a last zone, larger than the first two, which is intended more for the economic management of the regions, within which specific surveillance of foodstuffs and agricultural produce will be implemented

According [], the dose levels established for the implementation of population protection measures in a radiological emergency situation are defined by Article D 1333-84 of the Public Health []; in particular the following reference values have been established:

- an effective dose of 10 mSv for the sheltering recommendation;
- an effective dose of 50 mSv for the evacuation recommendation;
- an equivalent dose to the thyroid of 50 mSv for the recommendation to administer stable iodine tables in situations liable to cause emissions of radioactive iodine.

4.1.10 Operation and organization for NPP

The operation of nuclear power plants in France is highly regulated, with strict safety protocols in place.

During its operation, a reactor is subject to oversight by ASN and to comprehensive safety reviews every 10 years, the French Nuclear Safety Authority (ASN) is responsible for regulating the nuclear industry in France and ensuring the safety of nuclear facilities. The ASN carries out regular inspections and audits of nuclear power plants and has the authority to impose sanctions or shut down facilities if necessary.

In terms of organization, EDF is responsible for the operation, maintenance, and safety of its nuclear power plants. The company has a comprehensive safety program in place, which includes regular maintenance and testing, emergency response plans, and training for all personnel. EDF also has a waste management system in place to handle and store radioactive waste safely.

EDF is also responsible for the decommissioning of nuclear power plants that have reached the end of their operational life. The company has established a decommissioning fund to finance the decommissioning process and the management of radioactive waste.

The French Decree 2007-1557 of 2 November 2007, discussed in Section 4.1.2.4, provides also indications concerning authorization applications for the creation, operation modification, shutdown and decommissioning of basic nuclear installations. In particular it provides the main rules and obligations for creation, operation and modification of NBI in accordance with the decree.

4.2 Hydrogen Production Plant in France

In France, Law No 2015-992 of 17 August 2015, relating to the Energy Transition for a Green Growth provided in its Article 121 that the Government shall establish a “development plan for the storage of renewable energies using decarbonated hydrogen” aiming, firstly, at encouraging hydrogen mobility through the development of fuel cells and hydrogen distribution infrastructures, and secondly, at adapting regulations to allow the power-to-gas business.

On 1 June 2018, the Minister for Energy presented the hydrogen plan, which has three main objectives:

- “greening” hydrogen for industrial use;
- using hydrogen for mobility to complement the battery sector; and
- stabilising energy networks.

The Parliament also empowered the Government to take measures through law-decrees in order to “define the terminology of the different types of hydrogen according to the energy source used for its production”, “to allow the production, transport, storage and traceability of hydrogen”, and “to define a support framework applicable to low-carbon hydrogen”.

The Law-Decree No 2021-167 of 17 February 2021 relating to hydrogen was published in the Journal Officiel on 18 February 2021. It created a Book VIII in the Energy Code, entitled “Provisions relating to hydrogen”. As provided in [], hydrogen-specific laws and regulations are expected to be introduced in France over the coming months, these shall include several clarifications on the legal framework for hydrogen.

In addition, the Multiannual Energy Program, published on 23 April 2020, approved by Decree No 2020-456 of 21 April 2020, with deadlines in 2023 and 2028, foresees an increase in the financial support for the hydrogen sector. The Government is determined to promote the development of green hydrogen in France. For instance, it has not waited for the publication of the Law-Decree to

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encourage motorway concessionaires to install hydrogen refuelling stations as soon as the car fleet has reached a certain threshold of hydrogen vehicles.

4.2.1 Introduction

This section aims to supply an overview of the HPP licensing policy, the ICPE regulations and applicable rules, the authorization documents, the management of risks and the emergency provisions for HPP in France.

4.2.2 General description of HPP Licensing policy

In France, every industrial activity, which can have an impact on the environment due to its processes or substances handled/used has to respect specific rules set out in French Environmental Code. Installations classified for the protection of the environment (ICPE) can have impacts (water, air, soil pollution, etc.) and present dangers (fire, explosion, etc.) on the environment. For these reasons, they are subject to specific regulations (ICPE regulations).

The requirements of ICPE regulations have been defined in accordance with the nature and importance of the associated hazard for a certain number of activities and chemical compounds. These different elements are classified in a document called ICPE nomenclature, in which each activity or substance concerned is classified and each class defines different authorization schemes based on the risk level according to the quantity of stored products, volume of activity etc. ICPE regulations adopt the following classification authorization scheme that are explained in Section 4.2.4.1

- D (Declaration)
- Dc (Declaration) with periodic checks
- R (Registration/Enregistrement «E»)
- A (Authorization)

The list of dangerous substances/activities that are classified under ICPE are provided in Book V of the French Environmental Code (Appendix to Article R-511-9).

According to ICPE regulation, in particular as provided in Book V of the French Environmental Code (Appendix to Article R 511-9), the substances and the activities are classified in the four main categories provided in Table 4. Table 5 provides the list of substances/activities belonging to each category of interests for a HPPs provided that hydrogen is one of the substances classified: in particular Hydrogen is mentioned among the Hazardous substances and mixtures (Seveso 3) with ICPE Heading 4xxx and among the activities that imply the production of inorganic chemicals (such as hydrogen in industrial quantities by chemical or biological transformation) with the ICPE heading 3420.

The same Table 5 provides also an example of substances and activities that are of interests also for a NPP with reference for example to radioactive substances and hydrogen released into the batteries charging stations.

Following the adoption of Law No. 2019-1147 of November 8, 2019 on energy and climate, article L. 100-4 of the Energy Code on national energy policy was amended to include the objective of “developing low-carbon and renewable hydrogen and its industrial, energy and mobility uses.” The Law also empowers the government to take any measure by ordinance that would “define a support and traceability framework for renewable and low-carbon hydrogen.” This is the purpose of Ordinance No. 2021-167 of February 17, 2021 on hydrogen.



The Ordinance creates a new Book VIII in the Energy Code and defines three types of hydrogen according to their production methods. It also sets up a public support mechanism for hydrogen production and creates a mechanism for guarantees of origin and traceability to certify the type of hydrogen produced. Finally, a new regime for self-consumption of hydrogen has been introduced. This legal document contains the different modifications and additional arrangements brought to different articles and chapters of the French Code of Energy in order to integrate and to take into account the development of the use of renewable hydrogen as an energy vector, and thus its production, various characteristics of its transport and distribution (traceability for example), administrative and control aspects. The Ordinance will be supplemented by decrees and application orders.

The main French laws, order, decrees and regulation applicable to HPP are listed in Table 3.

Table 3 French laws, orders, decrees and regulations for HPP

French laws, orders, decrees and regulations for HPP	
	French Environmental Code (Appendix to Article R.511-9) ¡Error! No se encuentra el origen de la referencia.
	Circular of 14 May 2012 on the assessment of substantial changes under Article R. 512-33 of the Environment Code [37]
	Decree No. 2020-1168 dated 24 September 2020 relating to the rules applicable to installations in which dangerous substances are present in quantities such that they can be the cause of major accidents [38]
	Decree n ° 2020-1169 of September 24, 2020 amending the nomenclature of classified installations for the protection of the environment and the nomenclature annexed to article R. 122 -2 of the environmental code [39]
	Decree No. 2020-828 dated 30 June 2020 modifying the nomenclature and the water police procedure [40]
	Decree No. 2020-559 dated 12 May 2020 modifying the nomenclature of installations classified for the protection of the environment [41]
	Law No. 2019-1147 of November 8, 2019 on energy and climate, article L. 100-4 of the Energy Code [42]
	<u>Law No 2015-992 of 17 August 2015</u> [43]
	<u>Decree No 2020-456 of 21 April 2020</u> [44]
	<u>Law-Decree No 2021-167 of 17 February 2021</u> [45]

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4.2.3 Regulatory Authorities

Environmental regulatory authorities intervene on both a national and local scale.

4.2.3.1 Ministry for Ecological and Inclusive Transition (Ministère de la transition écologique et solidaire) (MTES)

As provided in [31], at national level, the Ministry for Ecological and Inclusive Transition (*Ministère de la transition écologique et solidaire*) (MTES) enforces environmental policies through five General Directorates respectively dedicated to:

- Energy and Climate.
- Infrastructure, transport and sea.
- Planning, housing and nature.
- Prevention of technological risks.
- Civil aviation.

4.2.3.2 General Council for Environment and Sustainable Development (Conseil général de l'environnement et du développement durable) (CGEDD)

The General Council for Environment and Sustainable Development (*Conseil général de l'environnement et du développement durable*) (CGEDD) within the MTES advises the government on environmental matters. The CGEDD also sits as a special body (Environmental Authority) (*Autorité*

environnementale) (AE) dedicated to carrying out its legal duties concerning the assessment of the effects of certain public and private projects on the environment. Its role is to give an opinion on the quality of the environmental impact assessment; this is further discussed in Environmental Permit. French administrative courts stated that the Environmental Authority shall remain totally independent and be different from the authority in charge of delivering the permit. In this context, a decree was adopted in July 2020, making the prefect of a region the official authority in charge of case-by-case decisions (ie, when the environmental impact assessment is not automatically applicable).

4.2.3.3 Directions régionales de l'environnement, de l'aménagement et du logement (DREAL)

At a local level, Regional Directorates for Environment, Land Planning and Housing (*Directions régionales de l'environnement, de l'aménagement et du logement*) (DREAL), implement the environmental policies in each French region, under the authority of the local representative of the state, the prefect (*préfet*).

As far as local authorities are concerned, mayors can also exercise administrative enforcement powers in relation to environmental law. They specifically have jurisdiction to enforce waste law in situations such as the unauthorised dumping of toxic waste (*Article L.541-3, Environment Code*).

4.2.3.4 ICPE inspectorate and mines inspectorate

According to [34], the ICPE inspectorate checks compliance with the technical requirements binding on the licensee. This means that its work focuses both on the equipment of the installations and the persons responsible for operating it, as well on the working methods and the organisation. It also intervenes in the event of complaints, accidents or incidents. If the inspectorate observes that the binding requirements are not appropriate, it can propose that the Prefect imposes additional requirements through an order. If the licensee does not comply with the compulsory measures, it could incur administrative penalties (compliance notice, deposition of sums, automatic enforcement, daily penalty payment, administrative fine, suspension of license, closure) and criminal penalties. The law provides for severe penalties in the event of any breach of these provisions.

4.2.4 ICPE Regulations

The identification and quantification of the substances classified under the ICPE regulations are elements needed to

- To compare the resulting data with the ICPE thresholds;
- To identify the requirements applicable, as provided within the ICPE regulations;
- To identify the classification/authorization scheme;
- To identify the related documentation to produce.

Inside INB/BNIs (basic nuclear installations including also NPP), the French nuclear regulator ASN (presented in Section 4.1.3.3) manages the ICPE. The list of equipment, located in with the INB site, necessary for the operations of the INB, that are classified for ICPE is provided as Annex of the Environmental Study, that is submitted to the French Regulator to obtain the Authorization Decree. Outside the INB/BNI, DREAL (presented in Section 4.1.3.4) manages ICPE.

Table 4 Main Categories of substances/activities classified under ICPE

ICPE Heading	Categories of substances/activities
1xxx	1) Substances
2xxx	2) Activities

ICPE Heading	Categories of substances/activities
3xxx	3) IED (Industrial Emissions Directives) activities
4xxx	4) Hazardous substances and mixtures (Seveso 3)

Table 5 ICPE Categories of substances/activities of interest for HPPs and NPPs

ICPE Heading	Categories of substances
1xxx	1) Substances
17xx	Radioactive substances
2xxx	2) Activities
29xx -	Miscellaneous
2925	<i>Battery charging</i>
	Accumulator (Charging workshop of) 1. When the loading produces hydrogen, the maximum direct current power usable for this operation (1) being greater than 50 kW Scheme <<D>> 2. When the loading does not produce hydrogen, the maximum current power usable for this operation (1) being greater than 600 kW, with the exception of charging infrastructure for electric vehicles open to the public defined by decree n°. 2017-26 of January 12, 2017 relating to charging infrastructure for electric vehicles and carrying various measures of transposition of Directive 2014/94 / EU of the European Parliament and of the Council of October 22, 2014 on the deployment of an infrastructure for alternative fuels. Scheme <<D>> (1) Cumulative deliverable load power of all workshop infrastructures.
3xxx	3) IED (Industrial Emissions Directives) activities
3420	Manufacture in industrial quantities through chemical or biological transformation of inorganic chemicals, such as: a) Gases, such as hydrogen chloride, hydrogen fluoride, , hydrogen [...].....
4xxx	4) Hazardous substances and mixtures (Directive 2012/18/UE Seveso 3)
4000	Hazardous substances and mixtures (definition and classification thereof)
4715	Hydrogen

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4.2.4.1 Authorization schemes

As provided in [!Error! No se encuentra el origen de la referencia.], ICPE regulations identify the following classification scheme basis on the type/quantity of dangerous substances stored/used within the facilities and the type of activities carried out within the facilities.

ICPE regulations adopt the following classification scheme

- D (Declaration)
- Dc (Declaration) with periodic checks
- R (Registration/Enregistrement «E»)
- A (Authorization)

Table 6 provides the authorization scheme for HPP integrated within a NPP, the thresholds and the Display radius expressed in kilometres provided for in Article L. 512-11 of the Environmental Code (applicable only for Scheme A). In the following sections each authorization scheme is presented.

The authorization, known as an environmental authorization or environmental permit, is issued under the conditions provided for in the single chapter of Title VIII of Book I.

4.2.4.1.1 Declaration- Scheme <<D>>

This scheme involves the least polluting and least dangerous activities. If in the facility are carried out activities or within the facility are stored substances/chemicals in quantity lower than «Declaration Status», the facility is Not Subjected (NS) to ICPE Regulation and the owner doesn't follow any particular rules (has to be confident that the thresholds are not exceeded). Only a simply declaration document need to be submit to the Prefect [!Error! No se encuentra el origen de la referencia..

4.2.4.1.2 Declaration with periodic checks-Scheme <<DC>>

This scheme concerns the facilities that are under the declarative scheme and that require to have periodic inspections carried out to ensure compliance. The inspections/checks are the responsibility of the site operator that could also involve an external registered survey company [!].

4.2.4.1.3 Registration Enregistrement-Scheme <<E>>

This scheme is an intermediate scheme between declaration and authorisation – and is a 'simplified authorisation' scheme. The site operator issues a dossier (with the departmental Prefecture concerned by the site) which clearly lays out the site's compliance with all ministerial decrees concerning minimizing environmental impact [!].

4.2.4.1.4 Authorization-Scheme (A)

This scheme covers those installations with the most potentially polluting risks. The site operator must expressly request authorization prior to any start-up of operations, clearly demonstrating its acceptance of the risk - the Prefect may grant or refuse such a request to start operations. The authorization dossier requires a greater level of detailed information than that required for registration, adding detailed site Environmental Health and Safety measures. In the mainframe of the "Authorization process" it is important to demonstrate the existence of action plans and specific measures for protecting the health and safety of all site personnel.

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Table 6 Authorization Scheme substances/activities of interest for HPPs and NPPs

ICPE Heading	Description	Scheme	Display radius expressed in kilometres provided for in Article L. 512-11 of the Environmental Code (applicable only for Scheme A).	Threshold	Reference Decree
1716	Radioactive substances	D	n/a	Depend on cases	
2925	Battery charging	D	n/a	> 50 kW	Arrêté du 29/05/00
3420	Manufacture in industrial quantities through chemical or biological transformation of inorganic chemicals, such as: a) Gases, such as hydrogen chloride, hydrogen fluoride, , hydrogen [...].	A	3	For the explanation of the term "industrial quantities" See Note 1 ²	Décret 02/05/13
4715	Hydrogen (CAS No. 133-74-0). The quantity likely to be present in the facility is: 1 Above or equal to 1 t	A	2	≥1 ton	Arrêté du 12/02/98 Arrêté du 26/11/15
4715	Hydrogen (CAS No. 133-74-0). The quantity likely to be present in the facility is: Above or equal to 100 kg but below 1 t <i>Low threshold quantity as defined in Article R. 511-10: 5 t</i> <i>High threshold quantity as defined in Article R. 511-10: 50 t</i>	D	n/a	≥ 100 kg < 1ton	Arrêté du 12/02/98 Arrêté du 26/11/15

AL: N
ECCN: N

² As [explained](#) "production on an industrial scale contains no quantitative capacity thresholds. The scale of chemical manufacture can vary from a few grams (of a highly specialised product), to many tonnes (of a bulk chemical product); yet both may correspond to "industrial scale" for that particular activity. Various criteria should be taken into account to decide whether production is "on an industrial scale", the fact that the activity is carried out for "commercial purposes" may be a strong indicator of "industrial scale", "Commercial purposes" implies that the activity is being undertaken principally as a remunerated business activity..

4.2.4.2 Extracts from Environment Code-Regulatory Part

Art. R. 511-9

Column A of the appendix to this Article constitutes the nomenclature of the facilities classified for environmental protection.

Art. R. 511-10

I. - The dangerous substances and mixtures mentioned in I of Article L. 515-32 are dangerous and assimilated substances and mixtures as defined in the heading 4000 (*rubrique 4000 in French*) of the nomenclature appended to Article R. 511-9, which are covered by columns between 4100 and 4799, and those numbered 2760-4 and 2792. Inside these headings, quantities known as high threshold quantities (*seuil haut*), are defined and, for some of them, low threshold quantities (*seuil bas*).

II. - The facilities mentioned in I of Article L. 515-32 are the low threshold facilities and the high threshold facilities defined in III. The installations mentioned in Article L. 515-36 are the only upper threshold installations.

III. - High threshold installations are those meeting the direct high threshold exceedance rule or the high threshold accumulation rule defined in Article R.511-11.

Low threshold installations are those, other than high threshold installations, meeting the direct low threshold overrun rule or the low threshold accumulation rule defined in Article R. 511-11.

Art. R. 511.11

I. - A facility complies respectively with the "low direct threshold exceedance rule" or the "high direct threshold exceedance rule" when, for at least one of the items mentioned in the first paragraph of I of Article R. 511-10, the hazardous substances or mixtures it covers are likely to be present in the facility in quantities greater than or equal to the lower threshold quantity or the upper threshold quantity mentioned under this heading. For a heading between 4100 and 4699, all hazardous substances or mixtures presenting the hazard class, category, including waste covered by headings 2700 to 2799 and substances covered by headings 4800 to 4899, but excluding hazardous substances or mixtures specifically described in headings 4700 to 4799, 2760-4 and 2792, shall be counted. For the application of the low threshold direct overrun rule, headings which do not mention a low threshold quantity are not considered.

II. - Installations of the same establishment under the same operator on the same site in the sense of Article R. 512-13 respectively meet the "low threshold accumulation rule" or the "high threshold accumulation rule" when at least one of the sums S_a , S_b or S_c defined below is greater than or equal to 1 :

- (a) Health hazards: the sum S_a is calculated, for all hazardous substances or mixtures with classes, categories and hazard statements under headings 4100 to 4199 (including, where appropriate, hazardous substances or mixtures specifically mentioned under headings 4700 to 4899 and waste under headings 2700 to 2799), according to the formula:

$$S_a = \sum \frac{q_x}{Q_{x,a}}$$

where "qx" means the amount of the hazardous substance or mixture "x" that may be present in the establishment, and "Qx, a" means the lower threshold amount or the upper threshold amount specified in headings 2760-3, 2792 or 4700 to 4799 if the hazardous substance or mixture is included in any of those headings, or otherwise the lower threshold amount or the upper threshold amount specified in headings 4100 to 4199. If the hazardous substance or mixture is subject to more than one heading numbered 4100 to 4199, the lower of the low or high threshold quantities mentioned in those headings shall be used.

AL: N
ECCN: N

- (b) Physical hazards: the sum S_b is calculated for all dangerous substances or mixtures with classes, categories and hazard statements according to headings 4200 to 4499 (including, where applicable, dangerous substances or mixtures named in headings 4700 to 4899 and waste mentioned in headings 2700 to 2799), according to the formula:

$$S_b = \sum \frac{q_x}{Q_{x,b}}$$

where "qx" means the amount of the hazardous substance or mixture "x" which may be present in the establishment, and "Qx, b" the threshold quantity or the upper threshold quantity mentioned in headings 2760-3, 2792 or numbered 4700 to 4799 applicable, if the dangerous substance or mixture is covered by any of these columns, or otherwise the lower threshold quantity or the upper threshold quantity mentioned in the applicable heading numbered 4200 to 4499. If the hazardous substance or mixture is subject to more than one heading numbered 4200 to 4499, the lower of the low or high threshold quantities mentioned in those headings shall be used.

- (c) Environmental hazards: the sum S_c is calculated for all hazardous substances or mixtures with classes, categories and hazard statements in headings 4500 to 4599 (including, where applicable, the hazardous substances or mixtures specifically mentioned in headings 4700 to 4899 and the waste mentioned in headings 2700 to 2799) according to the formula:

$$S_c = \sum \frac{q_x}{Q_{x,c}}$$

where "qx" means the amount of hazardous substance or mixture "x" which may be present in the establishment, and "Qx, c" the lower threshold quantity or the upper threshold quantity mentioned in headings 2760-3, 2792 or 4700 to 4799 applicable, if the dangerous substance or mixture is covered by any of these columns, or otherwise the lower threshold quantity or the upper threshold quantity mentioned in the applicable heading numbered 4500 to 4599. If the hazardous substance or mixture is subject to more than one heading numbered 4500 to 4599, the lower of the low or high threshold quantities mentioned in those headings shall be used.

- (d) For the application of the low threshold cumulation rule, dangerous substances and mixtures named in headings 4700 to 4799 for which no low threshold quantity is mentioned in the sums S_a , S_b or S_c shall not be considered.
- (e) Dangerous substances present in an establishment in quantities less than or equal to 2 % only of the relevant threshold quantity shall not be included in the "qx" quantities if their location within the establishment is such that the substances cannot trigger a major accident elsewhere in the establishment.

Art. R. 511-12

A dangerous substance or mixture participates in the classification of a facility with respect to the nomenclature mentioned in Article R. 511-9, in order of priority, in one of headings 2700 to 2799, 4700 to 4799, 4800 to 4899, if the substance or mixture is covered by one of these headings or, failing

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that, in the heading with the lowest upper threshold quantity among those numbered 4100 to 4699 concerning the dangerous substance or mixture.

If the upper threshold quantities of the headings numbered 4100 to 4699 for the dangerous substance or mixture are equal, the installation shall be classified in that of these headings having, in case of equality, in order of

priority:

- the lowest low threshold quantity;
- the lowest authorisation threshold;
- the lowest registration threshold;
- the lowest declaration threshold

Article L512-11

The so-called Seveso low threshold installations are subject to additional obligations ([articles L.515-32 to L.515-42](#)).

Article L515-33

The licensee draws up a written document defining its major accident prevention policy.

This policy is designed to ensure a high level of protection of public health and the environment and is proportionate to the risks of major accidents. It includes the operator's overall objectives and principles of action, the role and organization of managers within management, as well as the commitment to continuously improve the control of major accident hazards.

This policy is updated and reviewed periodically.

Article L515-37

I. – When an application for authorization concerns a classified installation to be set up on a new site, the public utility easements provided for in Article L. 515-8 may be instituted.

The first paragraph of this I is also applicable due to the additional risks created by a new installation on an existing site or by the modification mentioned in the first paragraph of Article L. 181-14.

II. – These easements take into account the probability and intensity of technological hazards and may, within the same perimeter, be applied in a modulated manner depending on the areas concerned.

III. – In the event of the establishment or modification of the public utility easements mentioned in Article L. 515-8, the duration of the public inquiry is extended to six weeks. During this period, a public meeting is organized by the investigating commissioner.

IV. – The easements and their perimeter are determined by the competent authority for the issuance of the authorization for the classified installation.

Article L515-39

The hazard study mentioned in article L. 181-25 is periodically reviewed and updated.

Article L515-40

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The operator implements a safety management system.

This safety management system is proportionate to the dangers linked to major accidents and to the complexity of the organization or the activities of the establishment. The operator keeps this system up to date.

Article L515-41

The operator draws up an internal operation plan with a view to:

- 1° Contain and control incidents in such a way as to minimize their effects and limit the damage caused to public health, the environment and property;
- 2° Implement the necessary measures to protect public health and the environment against the effects of major accidents.

The draft plan is subject to consultation with the staff working in the establishment within the meaning of the labor code, including subcontracted staff, within the framework of the expanded health, safety and working conditions committee provided for in article L. 4523-11 of the labor code.

The operator keeps this plan up to date.

4.2.4.3 Décret n° 2014-285 du 03/03/14 modifiant la nomenclature des installations classées pour la protection de l'environnement

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ECCN: According to Article 4 of the Décret n° 2014-285 du 3 mars 2014, article 4), the Hydrogen is identified as substance having the following CAS number 133-74-0. The authorization scheme depends on the quantity likely to be present in the installation being

Table 7 The authorization scheme for HPP

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Quantity of Hydrogen	Declaration scheme
Greater or equal to 1 t	(A-2)
Greater or equal to 100 kg and lower than 1 t	(D)

Within the meaning of the l'article R. 511-10 of the Environmental Code (provided in 4.2.4.2) the low threshold quantity is fixed at **5 t**. High threshold quantity is fixed at 50 t.

4.2.5 Safety concept for HPP

Hydrogen storage is regulated. The relevant rules depend on the quantities of hydrogen being stored. The hydrogen storage is ICPE classified (4715). The authorization schemes are the following

- Authorization-Scheme (A) when the quantity of hydrogen stored is equal to or greater than 1 ton;
- Declaration -Scheme (D) when the quantity of hydrogen stored is greater than or equal to 100 kg, but less than 1 ton

Under these thresholds, no permit is required.

4.2.5.1.1 Requirements as per Arrêté du 12/02/98

Section 2.1 - Siting-Layout Requirements

The following specific requirements need to be followed:

- for liquid hydrogen: the installation must be located at least 20 metres from the property line. It is forbidden to store or use liquid hydrogen in buildings.
- for gaseous hydrogen: the installation must be located at a distance of at least :
 - if it is located in the open air, at least 8 metres from property lines or any building,
 - if the room containing the installation is enclosed, 5 metres from the property line or any building.

The distances of 8 to 5 metres between the building and the storage of hydrogen gas containers are not required if they are separated by a solid wall without openings, made of non-combustible materials and with a 2-hour fire rating, with a minimum height of 3 metres and extended from the storage by a shed made of non-combustible materials with a 1-hour fire rating, with a minimum width of 3 metres projected on a horizontal plane. This wall must be extended on either side and on the side of the storage by return walls without openings, made of non-combustible materials and fireproof to 1 hour, 3 metres high and at least 2 metres long.

Section 2.4 - Fire behaviour of buildings

The premises housing the hydrogen gas installations must have the following minimum fire reaction and resistance characteristics

- 2-hour fire-resistant walls and high floors,
- non-combustible light roofing,
- interior doors with a 2-hour fire rating and fitted with a door closer or self-closing device,
- door leading to the outside, flameproof to 2 hours,
- M0 class materials (non-combustible).

Closed premises must be equipped at the top with devices allowing the evacuation of hydrogen, smoke and combustion gases released in the event of a fire (skylights on the roof, opening doors on the façade or any other equivalent device). The manual opening controls are located near the accesses. The smoke extraction system must be adapted to the particular risks of the installation.

Section 2.5 - Accessibility

The installation must be accessible to allow the intervention of the fire and rescue services. It is served, on at least one side, by a machine track or by a ladder track if the high floor of this installation is at a height of more than 8 metres in relation to this track.

In the case of a closed room, one of the sides is equipped with an opening allowing the passage of equipped rescuers.

Section 2.8 - Equipment earthing



Metal equipment (tanks, vessels, pipes) must be earthed in accordance with the applicable regulations and standards, particularly in view of the flammable nature of hydrogen.

Section 2.9 - Retention of work areas and premises

Section 4. Risks

4.2 - Fire-fighting equipment

4.2.1 - Requirements specific to liquid hydrogen

The installation must be equipped with fire-fighting equipment appropriate to the risks and in compliance with the standards in force, in particular

- a standardised 100 mm diameter fire hydrant with the necessary equipment to set up a large nozzle and two small ones,
- 1 x 50 kg powder extinguisher on wheels,
- 2 x 9 kg powder extinguishers,
- 1 x 6 kg CO² extinguisher.

This equipment must be placed near the installation, maintained in good condition and checked at least once a year. The personnel must be trained in the use of fire-fighting equipment. In the event of fire in the vicinity of the installation, measures must be taken to protect the installation.

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4.2.2 - Requirements specific to hydrogen gas

The installation must be equipped with fire-fighting equipment appropriate to the risks and in compliance with the standards in force, in particular

- 1 x 50 kg powder extinguisher on wheels ;
- 1 x 40 mm water tap, equipped with a nozzle that can be brought into service instantly.

This equipment must be located near the installation, maintained in good condition and checked at least once a year. Staff must be trained in the use of fire-fighting equipment. In the event of fire in the vicinity of the installation, measures must be taken to protect the installation.

4.4 - Electrical safety equipment

In the parts of the installation referred to in point 4.3 "explosive atmospheres", the electrical installations must be reduced to what is strictly necessary for operating purposes. They must consist entirely of equipment suitable for use in explosive atmospheres. However, in those parts of the installation where explosive atmospheres may occur episodically with low frequency and short duration, the electrical installations may consist of electrical equipment of good industrial quality which, in normal service, does not generate arcs or sparks or hot surfaces likely to cause an explosion. The pipes must not be a possible cause of ignition and must be adequately protected against impact, against the spread of flames and against the action of products present in the part of the installation in question.

4.5 - Prohibition of fires

In the parts of the installation, referred to in point 4.3, where there is a risk of fire or explosion, it is forbidden to bring fire in any form whatsoever, except for the carrying out of work which has been subject to a "fire permit". This prohibition must be clearly displayed.

4.7- Safety instructions

Without prejudice to the provisions of the Labour Code, instructions specifying the methods of application of the provisions of this decree must be drawn up, kept up to date and posted in the places frequented by the personnel. These instructions must in particular indicate

- the ban on bringing fire in any form into the parts of the installation referred to in point 4.3 "fire" and "explosive atmospheres",
- the requirement for a "permit to work" for the parts of the installation referred to in point 4.3
- the measures to be taken in the event of a leak from a container or pipe containing hydrogen, including the conditions of release laid down in point 5.7,
- the measures to be taken in the event of a container heating up,
- the means of extinction to be used in the event of a fire,
- the warning procedure with the telephone numbers of the person in charge of the establishment, the fire and rescue services, etc,
- the emergency shutdown and safety procedures for the installation (electricity, fluid networks).

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4.9 - Gas detection

Gas detectors are installed in the parts of the installation referred to in point 4.3 that present risks in the event of the release and significant accumulation of gas. These areas are equipped with detection systems whose sensitivity levels are adapted to the situation.

AL: N

Other Requirements to follow to reduce the environmental impact for HPP are discussed in 4.2.6

4.2.5.2 Décret n° 2013-375 du 02/05/13 modifiant la nomenclature des installations classées

The production of inorganic chemicals such as hydrogen in industrial quantities by chemical or biological transformation is an activity ICPE classified (3420) subject to authorization with reference to the quantities produced .As provided in [], this authorization is released after having demonstrated that the risks to the environment are mitigated, specific measures to prevent pollution of, and protect, water are implemented and greenhouse gas emission are limited.

4.2.5.3 Hydrogen Storage

Hydrogen storage is regulated. The relevant rules depend on the quantities of hydrogen being stored. The hydrogen storage is ICPE classified (4715). The authorization schemes are the following

- Authorization-Scheme (A) when the quantity of hydrogen stored is equal to or greater than 1 ton;

- Declaration -Scheme (D) when the quantity of hydrogen stored is greater than or equal to 100 kg, but less than 1 ton

Under these thresholds, no permit is required.

4.2.5.4 Hydrogen Transportation

Transportation is subject to different regulations according to the modality adopted. Two different modalities of transportation has been identified: transportation via the pipelines of a dedicated transportation network or through the existing natural gas transportation network. In case of use of a dedicated pipeline, specific regulations need to be developed by the government. If the pipeline used for hydrogen transportation is part of the existing natural gas transportation network (this applies only to renewable hydrogen), the hydrogen transportation is regulated by the same regulations applied for natural gas. In particular the following rules are applied:

- The right of access to natural gas transportation facilities must be ensured by operators under the terms of the contract.
- Charges for using transportation networks must be evaluated clearly;
- In cities that are served by a natural gas network, state owned gas distribution system operators are required to connect customers who so request to the existing state-owned distribution networks.

4.2.6 Environmental Protection and Industrial Emissions for HPP

The *Arrêté du 12/02/98 relatif aux prescriptions générales applicables aux installations classées pour la protection de l'environnement soumises à déclaration sous la rubrique n° 4715* provides in Annex I (Sections from 5 to 8) specific requirements for HPP to reduce the environmental impact. The rules concern the water withdrawals, water consumption, releases and prevention to reduce water pollution, atmospheric emissions, waste management and noise and vibration limit emissions. Here after the specific requirements are discussed.

4.2.7 External Hazards and Risks for HPP

Like any industrial facility, hydrogen production plants may be subject to external and internal hazards that can pose risks to their safe operation of the plant

The list of hazards within the design basis are provided in the sections below reported.

4.2.7.1 Internal hazards

1. Generation of missiles and pipe whip.
2. Pressurized equipment failure/structural failure
3. Collisions and load drop.
4. Internal explosion.
5. Internal fire.
6. Emission of hazardous substances Toxic production.
7. Electromagnetic interference.
8. Internal Flooding;
9. Intrusion of humans (Malevolence acts).
10. Single Operator Action Error during Operation.
11. Equipment/Component Misposition after Maintenance.

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12. Loss of structural integrity.
13. Plausible combinations of hazards: Internal fire + Internal explosion, Internal fire + internal flooding.
14. Failures in hydrogen piping systems.
15. Leakage or failure of a system carrying hydrogen
16. Release of <<ground-hugging gases>>
17. Loss of electric power.

4.2.7.2 External hazards

12. Aircraft crash.
13. Earthquake.
14. Lightning and electromagnetic interference.
15. Exceptional mass of snow .
16. Extreme weather or climate conditions involving extreme external temperatures and relative humidity, ice/frost, extreme winds and tornados.
17. Fire.
18. External Explosion.
19. External Flooding or drought.
20. Malevolence acts.
21. Plausible combinations of hazards:
 - i. earthquake + Internal Fire.
 - ii. earthquake + flooding
 - iii. Water table + external flooding;
 - iv. External explosion + External fire;
 - v. Accidental temperature + External Fire.
22. Loss/Malfunctioning of utilities including for example:
 - Loss/Malfunction of External Electrical Power Systems (loss of Site Power)
 - Loss/Malfunction of HVAC Systems
 - Loss/Malfunction of I&C
 - Loss/Malfunction of Fire Protection Systems
 - Loss/malfunction of Hydrogen monitoring systems
 - Loss Malfunction of other systems that serve the HPP

AL: N
ECCN: N

4.2.8 Management of risks of HPP

The identification of risks for HPP and their management is required by ICPE regulations for all activities/facilities in which ICPE substances/activities are manipulated/carried out with greater relevance and details for the ICPE facilities/activities that are included in the authorization scheme “A - Authorization”. In particular with reference to the ICPE facilities/activities that are included in the authorization scheme presented in Section 4.2.4.1 and in accordance to ICPE regulation:

- for the authorization scheme “D- Declaration the Indication of how incidents are managed need to be included in the declaration document;
- for the authorization scheme “R (Registration/Enregistrement «E») need to be provide a report which clearly lays out the site’s compliance with all ministerial decrees concerning minimizing environmental impact;

- for the authorization scheme “A -Authorization, the authorization dossier requires a greater level of detailed information than that required for registration, adding detailed site Environmental Health and Safety measures. In the mainframe of the “Authorization process” it is important to demonstrate the existence of action plans and specific measures for protecting the health and safety of all site personnel.

The risks to be investigated are detailed in 4.2.7. Scope of the safety assessment is to identify potential incident-accident events, causes of postulated events, potential consequences and the levels of defence in depth implemented in the plant in terms of prevention, controls/detection and mitigative measures. For the events that cause potential release of hazardous substances into the environment specific evaluation of the release need to be carried out and quantified. Furthermore this analysis leads to identify the bounding events and to evaluate the impact on operators, public and environment. For each event identified in 4.2.7, the causes, the consequences and the different lines of defense in depth implemented are reported. These lines should include prevention means as well as control/detection and mitigation provisions including zonings. Typically the zonings concern the following:

- **fire zoning:** to protect the element important for the protection and to avoid propagation of fire within the plant (from or to a fire sector), a fire sectorization is implemented. Fire sectors are part of the mitigation means. The areas sensitive to a fire risk are the following:

- Areas/rooms housing a safety target (hazardous substances, stored energy that could potentially cause release of hazardous material in the event of an accident);
- Area/rooms where a fire cannot be excluded because of the combined presence of ignition sources and substantial amounts of combustible materials;
- Rooms where a safety target and a significant fire load are present in adjacent rooms (these areas shall be taken into account if there are openings/penetrations between them).

According to the fire zoning, the walls/slabs, doors, valves and penetrations which contributes to the fire sector shall be rated (R)EI-S, for a time fixed i.e 120 minutes as defied in Arrêté du 12/02/98. Moreover, these items shall consider an overpressure which could be reached in case of a fire event.

- **contamination zoning:** to control the hazardous substances contamination risks, the areas of the plant should be classified according to their contamination levels expected during normal operation and accident situations. An hazardous substance can be treated as radioactive substance from contamination zoning point of view. According to the standard ISO 26802:2010 “Nuclear facilities — Criteria for the design and the operation of containment and ventilation systems for nuclear reactors” the areas are classified as follows:

- C4: areas that are continuously contaminate;
- C3: areas where the contamination level is low or negligible during normal operation and may be high in an accident situation
- C2: areas that is substantially clean during normal operation, only in exceptional circumstances resulting from an incident or accident situation is a medium level or surface or airborne contamination acceptable, so appropriate provision must be made for its control;

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- C1: areas free from normal contamination. Only in exceptional situations a low contamination level can be accepted

In the definition of the ventilation systems a transfer from any contaminated area to a lower contaminated areas shall not be allowed. A negative pressure cascade from the least to the most contaminated area should be ensured.

- **ATEX zoning:** this is applied in the areas where an explosive atmosphere could be present i.e a mixture with air, under atmospheric conditions, of flammable substances in the form of gas, vapour, dust, fibres, or flyings, which, after ignition, permits self-sustaining propagation. The Hazardous Area is an area in which an explosive gas atmosphere is or may be expected to be present, in quantities such as to require special precautions for the construction, installation and use of equipment

The estimation of hazardous zones is carried out in accordance with CEI EN 60079-10-1:2016 in particular the following parameters have been take into account:

- the grade of release;
- the effectiveness of ventilation and degree of dilution;
- the availability of ventilation.

A flammable substance considered is for example hydrogen, which can be generated during the charging process, buffer charging, overloading and during normal operation with lead-acid batteries, which at certain concentrations can form an explosive atmosphere. When it is emitted in the surrounding atmosphere, it can originate an explosive mixture and it may arise when its concentration in the air exceeds 4% vol (LFL). CEI EN 60079-10-1 (2016) defines the methods for classifying explosion risk areas. For any classified area, the corresponding extension will be evaluated in order to clearly specify also the equipment type including the relevant EPL (Equipment Protection Level) that can be installed in these areas.

The areas can be classified in:

- Non - Hazardous Area An area in which an explosive gas atmosphere is not expected to be present in quantities such as to require special precautions for the construction, installation and use of equipment
- Zone 0 An area in which an explosive gas atmosphere is present continuously or for long periods or frequently
- Zone 1 An area in which an explosive gas atmosphere is likely to occur in normal operation occasionally
- Zone 2 Area in which an explosive gas atmosphere is not likely to occur in normal operation but, if it does occur will persist for a short period only. The reference directives are Directive 99/92/CE ATEX Workplace Directive and Directive 2014/34/UE ATEX Equipment Directive

4.2.9 Emergency provisions and response organization for HPP

4.2.10 Operation and organization for HPP

4.3 Conclusions and Findings- France

Sections 4.1 and 4.2 provide a description of licensing policy, licensing process and related documentation to be prepared by the applicant (operator), legal framework, main actors in the

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ECCN: N

licensing process, safety dossier contents, safety approach adopted, emergency provisions, operation and organization respectively for NPPs (Section 4.1) and HPP (Section 4.2) in France. With reference to HPP integrated to NPP the main findings are below provided:

[N1] The integration of HPP in a NPP is not mentioned in TSN Act. Anyway according to Article 29 of TSN ACT, this integration could imply a change in the licensee boundary and a significant change in the installation.

The Nuclear Safety Authority (Autorité de sûreté nucléaire) ASN is the independent authority that provides a legislative framework for basic nuclear installations (INB) integrated with HPP. HPP is considered as Installation Classified for the Protection of the Environment (ICPE), as explained in 4.2.3, Hydrogen and hydrogen production are respectively substance and activities ICPE classified. Inside INB/BNIs (basic nuclear installations including also NPP), the French nuclear regulator ASN (presented in Section 4.1.3.3) manages the ICPE. Outside the INB/BNI, DREAL (presented in Section 4.1.3.4) manages ICPE.

[N2] The integration of HPP in a NPP is not mentioned in French Environment Code. Anyway if the HPP is integrated into a new installation, according to article L 593-7, the creation of the installation is subject to authorization. To obtain this authorization, the operator is requested to demonstrate that the technical or organizational measures adopted or conceived at the design, construction and operation stages, as well as the general principles proposed for decommissioning, are suitable to prevent or limit the risks or drawbacks that the facility presents for the protection of interests mentioned in Article L. 593-1 (public security, health and safety, protection of nature and the environment). The applicant is requested to provide a “dossier” that includes a preliminary version of the safety report, which specifies the risks to which the planned installation may expose the interests mentioned in Article L. 593-1, as well as an analysis of the measures taken to prevent these risks and a description of the measures to limit the probability of accidents and their effects. The contents of a Preliminary Safety Report are presented in Section 4.1.4

[N3] The integration of HPP into an existing basic nuclear facility implies a significant modification of the basic nuclear facility. In accordance with Article L593-15 significant modifications to a basic nuclear installation, its authorised operating procedures, the elements that led to its authorisation or its authorisation for commissioning, or its decommissioning conditions for installations that have been the subject of a decree referred to in Article L. 593-28 are subject, depending on their significance, either to declaration to the Nuclear Safety Authority, or to authorisation by this authority. These modifications may be subject to public consultation in accordance with the procedures laid down in Title II of Book I.

[N4] Although the Order 7th February 2012 does not explicitly mention the HPP integrated within a NPP, the general rules relative to basic nuclear installations are applicable.

The Order applies to all the element important for the protection of the interests mentioned in article L. 593-1 of the environment code (public security, health and safety, protection of nature and the environment), and the activities important for the protection of these interests.

The Order defines Elements important for protection, that is to say structures, equipment, systems (programmed or not, hardware, component or software) present in a basic nuclear installation or placed under the responsibility of the licensee, fulfilling a function necessary for the demonstration that the risks to which the proposed installation may expose the interests referred to in Article L. 593-1 are taken into account and suitable measures are taken to prevent these risks and likely to limit the probability of accidents and their effects, or checking that this function is ensured. Important

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elements for the protection of interests therefore also include components that prevent chemical releases into the environment likely detrimental to the interests. Element important for protection need to be properly defined, tested, fabricated and qualified, in order to comply with the associated functions and to preserve their capacity to fulfil its requirements. Furthermore, a specific demonstration that the safety functions of the Element important for protection of interests are ensured in normal, degraded and accidental conditions is required

[N5] Although the integration of HPP into a NPP is not mentioned in the French Decree 2007-1557, from regulatory point of view the integration of HPP within a perimeter of an existing NBI/INB installation could be configured as significant modification of the NBI/INB and a change of its nature as per article 31 of French Decree 2007-1557 of 2 November 2007. In fact the integration of HPP within a perimeter of INB/NBI implies a modification of the elements essential for protection of the interests mentioned in I of article 28 of the Act of 13 June 2006 (public security, health and safety, protection of nature and environment), which appear in the authorisation decree pursuant to article 16 of the French Decree 2007-1557. The list of equipment, located in with the INB site, necessary for the operations of the INB, that are classified for ICPE is provided as Annex of the Environmental Study, that is submitted to the French Regulator to obtain the Authorization Decree (as explained in Section 4.1.2.4.1). For the application of ICPE regulation please refers to Section 4.2.3. The operator which wishes to make a significant modification to its installation sends an authorisation application to the ministers responsible for nuclear safety. The dossier specifies the impact of the modification on the various aspects of the current authorisation. The application is examined and is the subject of a decision in accordance with the procedures defined in chapter II of title III. If the integration of HPP and NPP implies a modification of the perimeter of INB/BNI, the operator shall submit an application to the ministers responsible for nuclear safety. The list of dangerous substances/activities that are classified under ICPE are provided in Book V of the French Environmental Code (Appendix to Article R-511-9).

According to ICPE regulation, in particular as provided in Book V of the French Environmental Code (Appendix to Article R 511-9), the substances and the activities are classified in the four main categories provided in Table 4. Table 5 provides the list of substances/activities belonging to each category of interests for a HPPs provided that hydrogen is one of the substances classified: in particular Hydrogen is mentioned among the Hazardous substances and mixtures (Seveso 3) with ICPE Heading 4xxx and among the activities that imply the production of inorganic chemicals (such as hydrogen in industrial quantities by chemical or biological transformation) with the ICPE heading 3420. Table 6 provides the authorization scheme for HPP integrated within a NPP, the thresholds and the Display radius expressed in kilometres provided for in Article L. 512-11 of the Environmental Code. The authorization, known as an environmental authorization or Environmental Permit, is issued under the conditions provided for in the single chapter of Title VIII of Book I.

[N6] In case of integration of HPP in a new installation NPP, to create/ build a basic nuclear installation, according to article 8 of Decree 2007-1557 of 2 november 2007, the documents/data specified in Section 4.1.2.4.1 need to be provided. The documentation to prepare includes the impact assessment and the preliminary safety case, the content of which is specified in article 10 and assessed in Section 4.1.4

[N7] The operator of the HPP integrated with a NPP in France shall be required to carry out regular safety assessments to identify potential hazards and risks and to ensure that appropriate measures are in place to control these risks.

The preliminary safety report is the key safety document that aims to demonstrate that the safety functions associated to the element important for the protection of interests are ensured in normal,

incidental and accidental conditions. A specific safety assessment is required to identify potential incident-accident events, causes of postulated events, potential consequences and the levels of defence in depth implemented in the plant (prevention, controls/detection and mitigation).

This principle needs to be implemented in the safety demonstration of the HPP integrated with NPP. This principle consists in the implementation of successive and independent lines of defense against the risks identified including the cliff-edge effect. These lines include prevention means as well as detection and mitigation provisions including zonings.

With reference to HPP integrated into a NPP, the preliminary safety report should include a description of facilities, a description of safety functions applicable and preliminary list of element important for the protection of interests, the analysis of operating situations. This analysis aims to identify potential incident-accident events, causes of postulated events, potential consequences and the levels of defence in depth implemented in the integrated plant in terms of prevention, controls/detection and mitigative measures. For the events that cause potential release of hazardous (i.e hydrogen)/radioactive substances into the environment specific evaluation of the release need to be carried out and quantified. Furthermore this analysis leads to identify the bounding events and to evaluate the impact on operators, public and environment. The lines of defense in depth implemented include prevention means as well as control/detection and mitigation provisions including zonings. Typically the zonings concern the following fire zoning, contamination zoning, ATEX zoning, The preliminary safety reports should provide safety and seismic classification of the systems, structures and components and identification of detailed defined safety requirement

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[H1] The integration of HPP with a NPP implies the introduction of an IED (Industrial Emissions Directives) activity as hydrogen production and an Hazardous substance and mixture (Directive 2012/18/UE Seveso 3) as hydrogen; these represent, respectively, an activity/substance classified according ICPE regulation with nomenclature 3420 and 4715. Table 6 provides the authorization scheme for HPP integrated within a NPP, the thresholds and the Display radius expressed in kilometres provided for in Article L. 512-11 of the Environmental Code (applicable only for Scheme A).

The authorization, known as an environmental authorization or environmental permit, is issued under the conditions provided for in the single chapter of Title VIII of Book I.

[H3] For the integration of HPP into a NPP all the hazards above mentioned need to be taken into account; furthermore, as provided in [46], the HPP introduces, as specific risk to the nuclear plant, the release of <<ground-hugging gases>>. According to [46], oxygen has been established as the most important <<ground-hugging gases>> infact it is a significant by-product from all hydrogen production process based on electrolysis and it may be released continuously as a “waste” if there is no local market. Oxygen introduce risks related to its combustion aspects, plume behavior, and allowable concentration, and is consistent with the chemical safety aspects and known risks of oxygen plants. Accidental hydrogen releases from HPP is a risk considered in [46], of minor importance in terms of reactor safety because of the high buoyancy of hydrogen and its tendency towards dilution.

5 Analysis for Netherlands

5.1 Hydrogen Production Plant

5.1.1 General description of licensing policy

In the Netherlands the licensing framework relevant for an H2 production facility is complicated and spread over many different laws and authorities. The laws are structured in such a way that there are

a few main laws, that each encompass a number of smaller laws. In this section, the focus is placed on the main laws, as a detailed analysis of the smaller laws is not efficient at this stage of the project.

There is no hydrogen specific regulation or policy, and a link between hydrogen and energy production is also not present. Instead, hydrogen production is classified as the production of inorganic gas, as a part of the chemical industry.

A set of EU directives regarding environment, industrial emissions, and industrial accidents are implemented through the application of framework laws. These framework laws were created to simplify and streamline the licensing process, by referring to the many small laws that were and often still are in place. [47]

The difficulty in this licensing framework lies in the many different variations that are possible. For each application, a different set of requirements and extra applications for additional licenses can be needed. These variations can be caused by different configurations or plant characteristics, but also by a unique set of communal, regional, provincial, or national requirements.

The main legislation relevant for HPP licensing is:

- i. WABO: General Provisions Act (Wet Algemene Bepalingen Omgevingsrecht) [47]
- ii. BRZO: Major Accidents Risks Decree (Besluit Risico's Zware Ongevallen), which is the implementation of the Seveso Directive 2012/18/EU [48], [49]
- iii. BEVI: External Safety of Establishments Decree (Besluit Externe Veiligheid Inrichtingen) [50]

The first act, WABO, encompasses at least 8 other laws, and stipulates which requirements must be met for any activity, installation, building, with regards to their effect on the surroundings. Some specific topics are environment, nature, construction, and spatial planning.

The second piece of legislation, the BRZO decree, is mainly focused on regulating industrial activities, with the aim of prevention of severe accidents.

The third piece of legislation, the BEVI decree, establishes the requirements regarding acceptable risk from the establishment towards the population.

The requirements stemming from the BRZO and BEVI can be incorporated into the license that is used to prove compliance with the WABO. In this way, one license is used to cover multiple laws. [51]

5.1.2 Relevant Authorities

Three levels of authorities can be distinguished in the Netherlands, differentiated by their region of influence, i.e. national, regional, and local. On the national level are authorities such as the government, ministries and departments. The regional level contains mainly provinces and regional services, and the local level consists of city councils.

The relevant authorities are listed below:

1. *National:* Ministries: of Domestic Affairs (Binnenlandse Zaken); of Economic Affairs (Economische Zaken); of Agriculture, Nature, and Food Quality (Landbouw, Natuur, en Voedselkwaliteit); of Infrastructure and Water Management (Infrastructuur en Waterstaat)
2. *National:* **Department of Waterways and Public Works** (Rijkswaterstaat)
3. *Regional:* **Water authority** (Waterschap)

4. *Regional: Deputy States (Gedeputeerde Staten)*
5. *Regional: **Provinces** (Provincies)*
6. *Regional: **Regional Services** (Omgevingsdiensten)*
7. *Local: **City Council** (Gemeenteraad)*

One of the most relevant authorities concerning the WABO and BRZO licenses, is the Regional Service (Omgevingsdienst). Of the 29 Regional Services in the country, of which 6 are specialized in and responsible for the area of BRZO and WABO. They cooperate in an initiative called “BRZO+” and have aligned interpretations of norms and guidelines. [52] They are responsible for:

- Issuing WABO licenses
- Supervision regarding WABO and specified tasks for BRZO and RIE category 4 companies
- Supervision regarding BRZO for BRZO and RIE category 4 companies
- Assessment of safety reports

In the Netherlands, special attention is given to the control of groundwater, waterways, and the defense against high tides and flooding. These responsibilities are directed to the Department of Waterways and Public Works on a national level, and directed to the 21 Water Authorities on a regional level. The Department of Waterways and Public Works is an agency, meaning it is an independently operating body within the responsibility of a ministry, in this case the Ministry of Infrastructure and Water Management. The Water Authorities are democratically elected public bodies.

The provinces decide what is allowed in their nature areas, based on national and international regulations. They also issue licenses and exemptions for activities in close proximity to nature protection areas.

5.1.2.1 Legislation

The legislative framework relevant for HPP licensing contains several acts, decrees, and guidances that are based on EU legislation. The main pieces of legislation are listed below, together with the relevant EU legislation. For further analysis of the EU legislation, the reader is directed to the appropriate separate chapter on EU legislation in the deliverable of this task.

National legislation

1. WABO (General Provisions Act) [47]
2. WRO (Spatial Planning Act) [53]
3. Wet Natuurbescherming (Nature Conservation Act) [54]
4. Waterwet (Water Act) [55]
5. BRZO (Major Accidents Risks Decree) [48]
6. BEVI (External Safety of Establishments Decree) [50]

Related EU Legislation

1. **Directive 2011/92/EU** of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (EIA) [56]

2. **Directive 2001/42/EC** on the assessment of the effects of certain plans and programs on the environment [57]
3. **Directive 2010/75/EU** on industrial emissions (integrated pollution prevention and control) (IED) [58]
4. **Directive 2012/18/EU** of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances (SEVESO) [49]

WABO stands for ‘Wet Algemene Bepalingen Omgevingsrecht’, which translates to the General Provisions Act. The WABO was created to simplify the process of applying for a license to start an activity which has an effect on its surroundings. Before the WABO was activated, up to 25 different licenses could be required, which now all fall under one WABO license. The WABO is set to be replaced by the ‘Omgevingswet’, Environment and Planning Act, in 2024. Requirements from other laws and decrees such as the BRZO, BEVI, and WRO are enforced through the WABO license.

The WRO (Wet Ruimtelijke Ordening) translates to the Spatial Planning Act. In short it regulates the land use plan, how activities and buildings should fit into the spatial planning policy of both local and national authorities. Its goal is to coherently approach the shared use of space by different activities such as housing, work, recreation, mobility, water and nature.

The BRZO is the Dutch implementation of the Seveso Directive (2012/18/EU), and sets requirements for activities that can have a large consequence on the surroundings, in general these are chemical facilities. The requirements for BRZO, such as for example the need for a Major Accident Prevention Policy and safety reports, are taken care of under the WABO license.

If an establishment is subject to the BRZO, it is automatically subject to the BEVI, the decree on external safety of establishments, which stipulates the acceptable risk of the establishment to the public. Within the BEVI, requirements for risk calculation under the Quantitative Risk Assessment are set.

A hydrogen production facility is, as stated in the WABO, also subject to Integrated Pollution Prevention and Control (IPPC), as regulated through the Industrial Emissions Directive (IED) 2010/75/EU, which aims to reduce harmful industrial emissions through the use of Best Available Techniques (BAT). Within the IED, hydrogen is considered a Category 4 chemical, which makes the activities concerning hydrogen subject to a strict set of requirements. The IED requirements are implemented through the WABO license.

The Water Act (Waterwet) is similarly to the WABO, a framework law redirecting to many other laws. Unlike the above mentioned laws, the license for the Water Act is not integrated into the WABO, but the relevant authorities do work in a coordinated manner and issue the separate licenses in a coordinated manner. The Water Act and its subsidiary laws set requirements ranging from the use of groundwater to the acceptable contamination of surface water and the protection of waterworks (e.g. dikes, dams, etc.).

5.1.2.2 Licensing Process

Various licenses are necessary for an HPP installation, such as a license for environmental protection (based on an environmental impact assessment), or sometimes a license for the water law, if the activities have a significant impact on (local) waterworks, waterways, or groundwater. In all cases, a license that regulates the effects on the surroundings is needed (WABO). Since this license is the most

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complicated and encompasses a few other important licenses, the licensing process for this license is taken as guide for the entire licensing process. The impact of additional licenses on the process will be less pronounced than that of the WABO license.

For the application of the WABO license, the following steps can be discerned. Figure 8 shows for each of the steps whether the applicant or the authority (Regional Service) has to take action [51].

Applicant	Authority
1. Self preparation	2. preparation
3. Pre discussion	4. Pre discussion
	5. Concept application
6. Delivery of final application	
	7. Check final application for completeness
8. Process any amendments or additional requests of application	
	9. Check amendments for completeness
	10. concept license
11. judgement of concept license	
	12. concept license made public
	13. definitive license made public

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Figure 8 Application process for a WABO license. The competent authority is the Regional Service.

At step 06, the legal term of 6 months starts, in which the Regional Service has time to assess the license application and issue the draft license (step 12). Following this is a term of 6 weeks, in which the public can view the draft license, and submit any standpoints. The authority is required to take these standpoints into account, and provide them with a justified response, in the final license. Not shown in this list are the steps for appeal, which the applicant can take when they don't agree with the final decision.

The roles and relations between the different authorities during the application of a WABO license is shown in Figure 9. The entire process is coordinated by one authority, the Regional Service. The applicant communicates with the Regional Service, which coordinates any further communications to the other authorities, inspectors, advisors and stakeholders. This constitutes a significant simplification of the license application process.

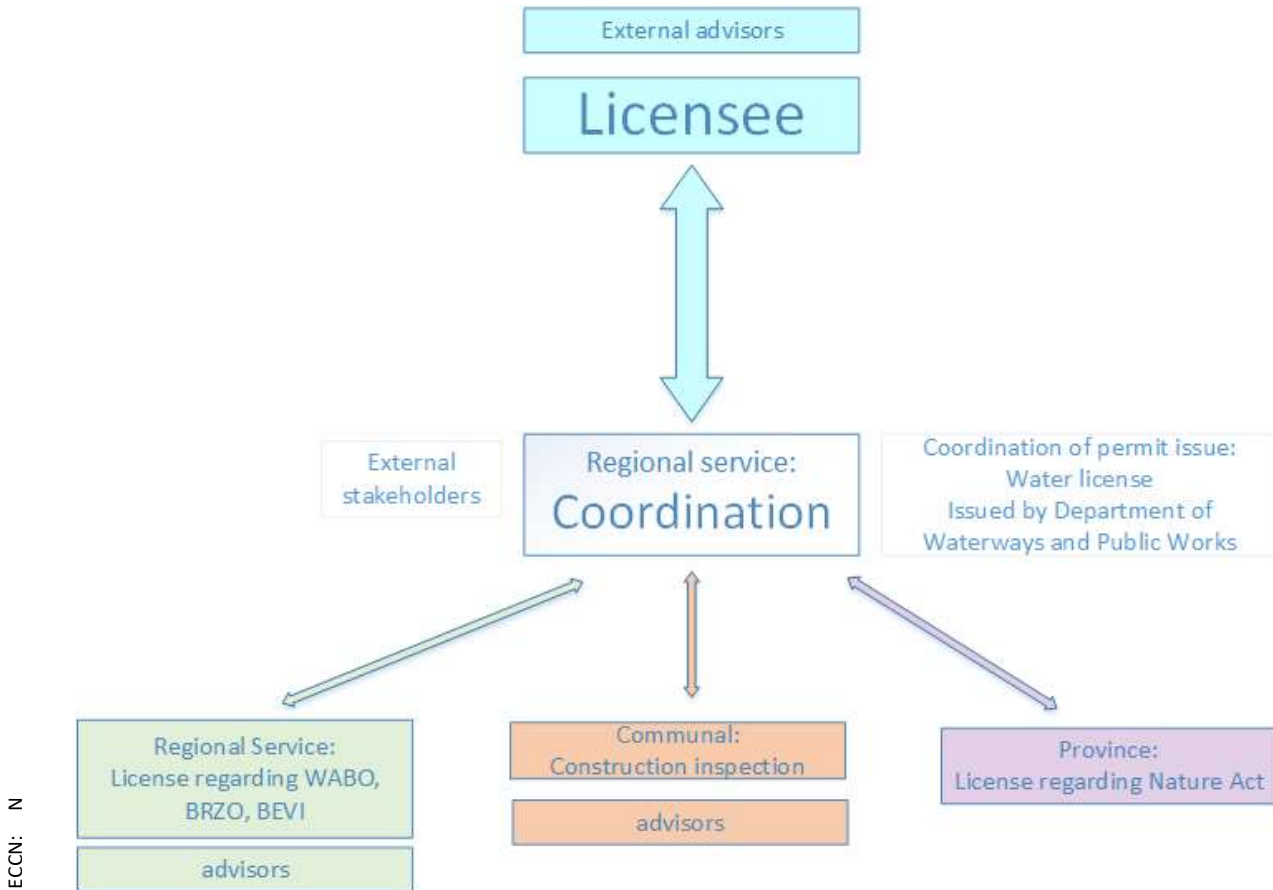


Figure 9 Roles and authorities during WABO license application.

5.1.3 Safety Concept for HPP

There is no authority in the field of hydrogen production, so legislation related to safety (risks, emissions, emergency plans etc.) of a chemical activity must be observed. This results in requirements referring to national regulations, EU directives and mandatory application of general principles/current standards. For example, standards with regard to building constructions (e.g. coming from the Dutch Building Decree), electrical systems (NEN standards), systems under pressure (CE-marking based on the PED 2014/68/EU), storage of chemicals/gasses (PGS Guidelines referring to standards like NEN, EN, ISO), etc.

Safety in National Legislation: BRZO and BEVI

The European Seveso III Directive (2012/18/EU) has been implemented in the Netherlands in the Major Accident Risks Decree: the **BRZO**. The BRZO is effective as of 2015. The Major Accident Risks Regulation (RRZO) is in force from 2016.

The objective of the External Safety of Establishments Decree, **BEVI**, is to protect people in the vicinity of a company with hazardous substances. In the case of an environmental permit or a spatial decision concerning such a company, the competent authority must take into account safety distances for the protection of individuals (local risk) and groups of people (group risk). Determination and application of the safety standards are further elaborated in the accompanying Regulation on External Safety Establishments (REVI) [59]. For so-called 'categorical establishments', the REVI provides tables with

fixed safety distances which dictate the minimum distances between the establishment and a vulnerable object.

BRZO specific requirements

Quantitative requirements

The BRZO integrates laws and regulations in the field of occupational safety, external safety and disaster relief. The BRZO sets requirements for the riskiest companies in the Netherlands, such as preparing every five years for company safety a quantitative risk assessment (QRA). The calculation rule for the preparation of a QRA for a BRZO establishment is described in Module C of the *Manual BEVI Risk Assessments* (<https://www.rivm.nl/documenten/reference-manual-bevi-risk-assessments-version-32>)

Calculation program

Calculations on BRZO establishments are performed with the calculation package SAFETI–NL (current: version 8+) (<https://www.rivm.nl/omgevingsveiligheid/rekeninstrumenten/rekenpakketten>). For this purpose, a sample study is available. Based on the results of the calculations SAFETI–NL it can be determined whether an industry meets the risk standards for external safety, as stipulated in the External Safety of Establishments Decree (BEVI: <https://wetten.overheid.nl/BWBR0016767/2016-01-01>) [50].

Performance requirements

BRZO requires joint inspections and notifications. The BRZO–inspection team always consists of inspectors from different authorities (municipalities/provinces, Social Affairs Inspectorate, Safety Regions). Inspection topics includes all safety topics (fire, emergency, toxic emissions, working conditions etc.).

BRZO requirement derived from (Seveso) DIRECTIVE 2012/18/EU (art. 8-13)

The obligations with respect to safety from the BRZO decree for the HPP licensee are the same as defined in Seveso Directive. The requirements distinguishes in establishments at/above a lower threshold value (Lower-tier, storage capacity of 5 ton) and at/above a higher threshold value (Higher-tier, storage capacity of 50 ton). For activities below the lower threshold values the Seveso directive does not apply.

Important aspects to consider are “Domino effects”. These are related to the proximity of other facilities with specific hazards. With respect to this project a nuclear power plant should be considered. The operators must exchange information and cooperate in the area of risk management, emergency response and public information.

In the case of an upper-tier establishment a safety report is required, demonstrating that:

- A Major-Accident Prevention Policy has been established by a Safety Management System
- Identification of Hazards has been performed
- Analysis and Assessment of Risks has been performed and adequate Prevention/Limitation Measures are implemented
- adequate safety and reliability have been taken into account in the design, construction, operation and maintenance of any installation, storage facility, equipment and infrastructure

connected with its operation which are linked to major-accident hazards inside the establishment;

- Internal Emergency Plans has been elaborated and information for elaboration of external emergency plans provided
- providing sufficient information to the competent authority to enable decisions to be made regarding the siting of new activities or developments around existing establishments.

Standards Hydrogen Generation

The following standard is applied for hydrogen generators, containing safety aspects:

ISO 22734:2019 *Hydrogen generators using water electrolysis — Industrial, commercial, and residential applications*

This document defines the construction, safety, and performance requirements of modular or factory-matched hydrogen gas generation appliances, herein referred to as hydrogen generators, using electrochemical reactions to electrolyze water to produce hydrogen.

- This document is applicable to hydrogen generators that use the following types of ion transport medium:
 - group of aqueous bases;
 - group of aqueous acids;
 - solid polymeric materials with acidic function group additions, such as acid proton exchange membrane (PEM);
 - solid polymeric materials with basic function group additions, such as anion exchange membrane (AEM).

This document is applicable to hydrogen generators intended for industrial and commercial uses, and indoor and outdoor residential use in sheltered areas, such as car-ports, garages, utility rooms and similar areas of a residence.

5.1.4 Environmental protection and industrial emissions

In the Netherlands, the Industrial Emissions Directive (2010/75/EU) has been implemented since 2013 in the General Provisions Act (*WABO*) [47], the Environmental Legislation Decree (*Bor*) [60], the Activities Decree (*Activiteitenbesluit*) [61] and in the Environmental Management Act (*Wm*) [62] and in the Water Act (*Waterwet*) [55]. The Netherlands must, among other things, report the number of IPPC installations and permits to the European Commission.

The Industrial Emission Directive (IED, Directive 2010/75/EU) [58] aims to achieve a high level of protection of human health and the environment taken as a whole by reducing harmful industrial emissions across the EU, in particular through better application of Best Available Techniques (BAT). The permit should contain conditions set in accordance with the principles and provisions of the IED. The permits must take into account the whole environmental performance of the plant, covering e.g. emissions to air, water and land, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents, and restoration of the site upon closure. The permit conditions including emission limit values must be based on the Best Available Techniques (BAT) on EU level. This process results in BAT Reference Documents (BREFs); the BAT conclusions contained are adopted by the

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Commission as Implementing Decisions. The IED requires that these BAT conclusions are the reference for setting permit conditions. IED relation with permit should be covered.

Heat discharge

When assessing heat discharges, a balance is made between the characteristics of the discharge and the effects on the surface water to which the discharge is carried out. Heat discharges smaller than 50 MW are regulated by the Activities Decree [61] (<https://wetten.overheid.nl/BWBR0022762/2022-09-21/>, *Activiteitenbesluit Article 3.6*). Discharges of cooling water with a higher heat load are subjected to a permit.

Spraying discharges of cooling water from closed cooling systems fall outside this section of the Activities Decree.

5.1.5 External Hazards and Risks

Companies where large quantities of hazardous substances are present above a certain threshold value fall under the scope of the BRZO/Seveso III. In the Netherlands more than 400 companies fall under BRZO regulations, ranging from complex chemical industry to relatively simple storage companies for certain types of hazardous substances.

In the case of intended constructions, the municipality must check whether this affects the External Safety in that area. This is done by testing the land use plans to the BEVI. It must also be assessed whether the zoning plan can allow planned developments. The BEVI stipulates that all BRZO companies are subject to BEVI [50].

The BEVI stipulates that the risks and effects of a company in which hazardous substances are present must comply with safety standards and guideline values. The intention is to keep or create sufficient distance between the danger objects and civilians/vulnerable objects. Key parameters in this context are the Local Risk (PR) and the Group Risk (GR):

- Local Risk (PR): the chance that someone will die at a certain location outside the company site due to a calamity involving hazardous substances.
 - Article 6 (BEVI): the limit value for projected or non-projected vulnerable objects is 10^{-6} per year.
- Group Risk (GR): the chance that several people die outside the company premises due to a calamity involving hazardous substances.
 - Article 12 (BEVI): the group risk of the establishment to which the decision relates and also the contribution of the change of the establishment to the total group risk of the establishment, compared with the probability of an accident with 10 or more fatalities not exceeding 10^{-5} per year, with the probability of an accident with 100 or more fatalities not exceeding 10^{-7} per year and the probability of an accident involving 1000 or more fatalities not exceeding 10^{-9} per year.

Risk assessment

From the BRZO the following is required [48]:

- A Quantitative Risk Assessment (QRA)
- A Manufacturing Risk Assessment (MRA)
- A Safety Report (*Veiligheidsrapport*)

The BRZO sets requirements for the riskiest companies in the Netherlands (more than 400), such as preparing a quantitative risk assessment (QRA) every five years. Calculations on BRZO establishments are to be performed according to BEVI prescriptions (e.g. use of the calculation tool SAFETI-NL from DNVGL, described in Module C of the Manual BEVI Risk Assessments).

Relevant guideline

- PGS 15 Storage of Hazardous Goods (Opslag van verpakte gevaarlijke stoffen) [63]

A PGS (*Publicatiereeks Gevaarlijke Stoffen*) guideline is a document about activities with hazardous substances. The PGS guideline lists the most important risks of these activities for the health and safety of employees, the safety of the environment and fire safety.

5.1.6 Emergency Provisions and response organization

Regulations

The BRZO follows Directive 2012/18/EU [48], [49], concerning emergency arrangements. For upper-tier establishments article 12 concerning Emergency Plans is in force:

- Ensuring: internal emergency plan and external emergency plans
- Objectives to: minimize effects, limit damage to human health the environment and property; implement necessary measures; communicate necessary information; provide for restoration and clean-up of the environment following a major accident.

Internal Emergency Plans

In general, the internal emergency response organization of an upper-tier establishment consists of:

1. Policy team
2. Emergency responders
3. Specific and Technical Services
4. Security

Main tasks of the policy team are for instance:

- General coordination (contact with mayor, fire chief and press)
- Interpretation of the situation, assesses what measures must be taken and which higher authorities may need to be notified of the calamity.
- Decides whether the establishment must be evacuated
- If required by the municipal emergency services, takes a seat on the Municipal Crisis Staff.

External emergency plans: safety regions in the Netherlands [64] [65]

The Netherlands is divided into 25 safety regions. Each region is committed to the safety of the residents and visitors to that area, for example, the safety region ensures that there is a fire brigade. The safety region also makes agreements about how to cope with calamities and crises. Good cooperation between emergency services, governments, companies and citizens is important in this respect.

Tasks

The main tasks of a safety region are:

- Prevent and fight fires (the fire brigade is part of the safety region)
- Preparing for risks, calamity and crises.

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- Coordination, management and combating of calamities and crises

Responsibilities in case of fires, calamities and crises

The mayor is responsible for a proper approach in the event of a (threat of) fire, calamity or crisis in his municipality. When the (threat of a) fire, calamity or crisis occur in several municipalities at the same time, than the chairman of the safety region is responsible for the approach in his region.

Activation of regional crisis structure

The classification and severity of the accident determines whether or not the regional response organization (via the safety region) should be activated and, if so, to what extent. For this, Coordinated Regional Incident Response Procedures (Dutch abbreviation: GRIP) are defined, ranging from GRIP1 (least severe accidents) to GRIP5 (most severe accidents). (In the event of radiation_accidents, coordination must take place immediately for a possible upscaling to GRIP2).

Preparedness

The Safety Regions have Emergency Plans (recently updated), attack plans, education in radiation protection and phenomena (when applicable to the region), perform inspections, and periodically practice/follow training programs.

5.1.7 Operation and Organization

Regulations concerning operation and organization in general for lower/upper-tier establishments are not specifically considered in legislation. In the applicable Dutch legislation and related EU Directives like 2010/75/EU and 2012/18/EU, high level requirements are given with concern to safe, reliable and responsible operation e.g. meeting requirements on risks and emissions, prevention measures, emergency arrangements and working conditions. For this, several aspects on operation and organization are required in practice by authorities and subsequent standards (NEN, ISO, IEC, ATEX etc.). Periodic inspection of compliance with the regulations of lower/upper-tier establishments are carried out by authorities of various government departments.

The establishment should for instance provide:

- Identification of the necessary skills
- Description of the functions and responsibilities
- Procedures and instructions to ensure a safe design and operation
- Training and exercise programs
- Use of an adequate management system
- Etc.

5.2 Nuclear Power Plant

5.2.1 General description of the licensing policy

The legal framework in the Netherlands with respect to nuclear installations can be presented as a hierarchical structure and is presented in Figure 10 [66].

The Nuclear Energy Act (*Kernenergiewet* <https://wetten.overheid.nl/BWBR0002402/2022-02-16/0>) [67] is the most prominent law governing nuclear activities. It is a framework law, which sets out the

basic rules on the application of nuclear technology and materials, makes provision for radiation protection, designates the competent authorities and outlines their responsibilities. All applications of ionizing radiation and protection against it are exclusively regulated by the Nuclear Energy Act.

Subordinate to this act are a number of decrees containing additional regulations related to the use of nuclear technology and materials. These decrees and the ministerial regulations (see below) are continuously updated in the light of ongoing developments, partly owing to the mandatory implementation of amended EU directives on nuclear safety (Directive 2009/71/Euratom, as amended by Directive 2014/87/Euratom) and radiation protection (Basic Safety Standards: Directive 2013/59/Euratom).

Ministerial regulations are at a lower level than decrees. These regulations can be issued by the minister responsible for conducting the regulatory process under the Nuclear Energy Act (Minister of Infrastructure and Water Management).

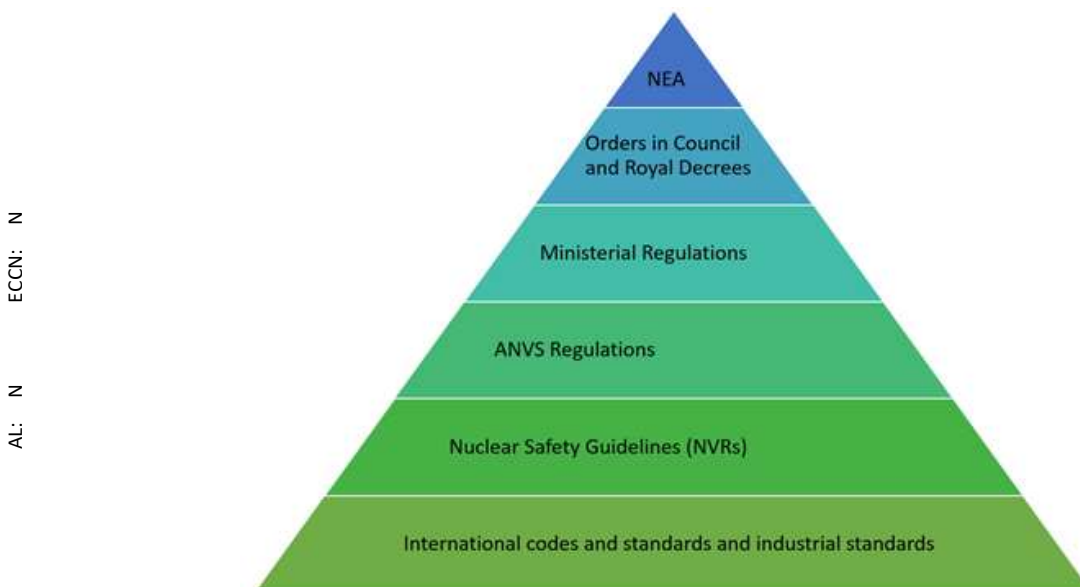


Figure 10 Hierarchy in the Dutch legal framework

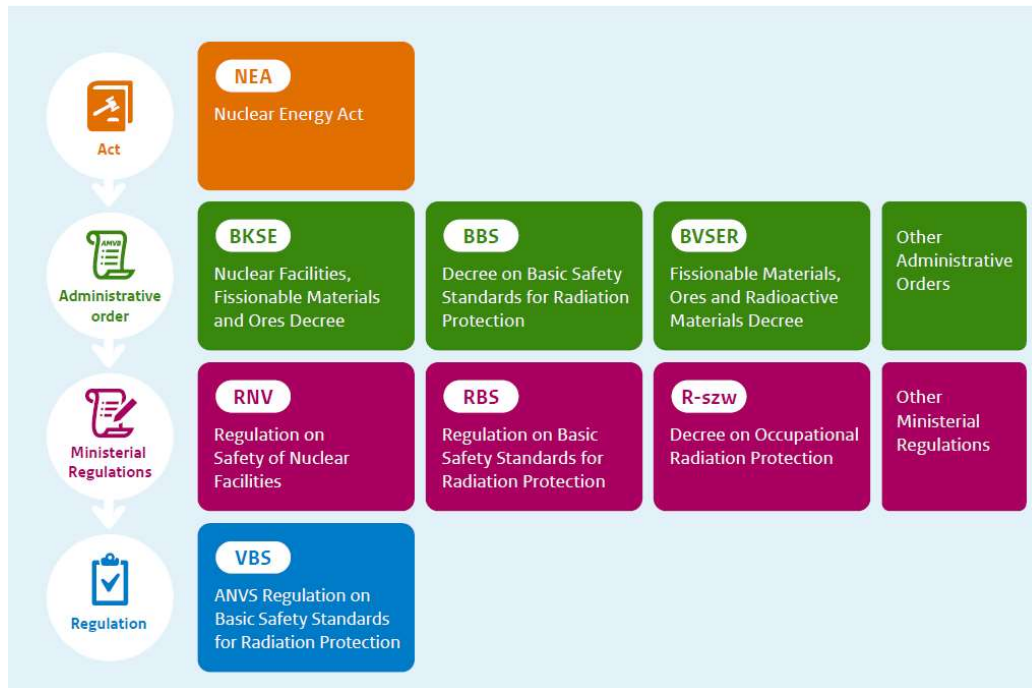


Figure 11 Examples of effects of different regulations [68]

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Program and Licensing

The Netherlands has a small but diverse nuclear program. Because of this diversity and to allow maximum flexibility, generic and specific requirements from the IAEA and WENRA are listed in the license, tailored to the characteristics of the installations, rather than in general ministerial regulations. The licenses cite international codes and standards, such as American Society of Mechanical Engineers (ASME) Standards, Kerntechnischer Ausschuss (KTA) safety standards and standards from other reputable sources.

The ANVS (the Netherlands nuclear regulatory body) has drawn up the Safety Guidelines on the Safe Design and Operation of Nuclear Reactors [69] (Safety Guidelines, for short) in response to two important initiatives: the proposed construction of a new medical research reactor in Petten (the PALLAS project) and the planned modernization of the existing research reactor in Delft (investment in HOR at TU Delft — the OYSTER project). At the moment the building of two Nuclear Power Plants is investigated; potential locations are currently assessed. The initiatives can be licensed only if they meet the latest safety standards. The Safety Guidelines apply to the design and operation of light water cooled nuclear reactors and set out requirements for both power reactors and research reactors. The requirements for research reactors may be applied on a graded approach if they demonstrably have a smaller potential risk for the environment.

The specific requirements defined in the Safety Guidelines are aligned with the latest insights, particularly those disseminated by the IAEA and WENRA, and may, where applicable and necessary, serve as a basis for formulating the conditions attached to licenses for new reactors (see also Figure 12). Although the Safety Guidelines do not have the status of (ministerial) regulations and do not therefore define any legal requirements, license applications will be assessed on the basis of the safety requirements described in the Safety Guidelines. The Safety Guidelines provide insight into the best technology currently available for designing the safest possible (new) reactors and operating such

reactors as safely as possible. The aim is to update the Dutch Safety Guidelines once every 5 years, or more often if there is reason to do so.

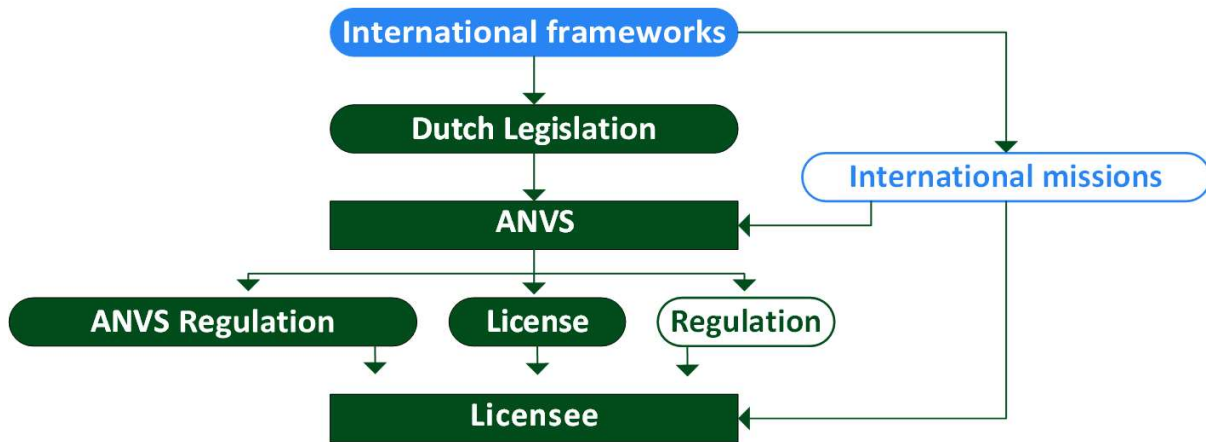


Figure 12 Schematic overview of the relationship between international frameworks and Dutch legislation [68]

Where existing reactors are concerned, the Safety Guidelines provide insight into the latest nuclear safety developments and insights to facilitate continuous improvement. Evaluation of a nuclear reactor’s safety in the light of the best technology currently available may warrant action to improve nuclear safety, insofar as such action may reasonably be expected.

The ANVS is the competent authority for nuclear facilities for all environmental aspects, so also conventional activities are part of the nuclear license of the facility. So environmental related activities within the establishment shall meet environmental rules and regulations, licensed by the ANVS.

5.2.2 Safety Concept for NPP

The (Dutch) Safety Guidelines [69] consist of a general part containing nuclear safety philosophy and radiation protection, and a requirement part (Dutch Safety Requirements for Nuclear Reactors. Acronym: **DSR**).

Technical Safety Concept

In the Dutch Safety Requirements part, the Technical Safety Concept is described in section 2. Section 2 states:

In order to meet the radiological safety objectives , the radioactive materials present in the nuclear power plant shall be confined by multiple technical barriers and/or retention functions, and their radiation shall be sufficiently shielded. The effectiveness of the barriers and retention functions shall be ensured by the fulfilment of fundamental safety functions . A defense in depth safety concept shall be implemented that ensures the compliance of the fundamental safety functions and the protection of the barriers and retention functions on several consecutive levels of defense as well as in case of internal and external hazards. The levels of defense in depth shall be independent as far as is practicable. The safety objectives for new power reactors recommended by the Western European Nuclear Regulators Association (WENRA) are implemented in the technical safety concept, which is defined in the subchapters.

Radiological objectives



Legislation

Article 18 of the Nuclear Facilities, Fissionable Materials and Ores Decree (Dutch acronym: **Bkse** https://wetten.overheid.nl/BWBR0002667/2018-02-06#HoofdstukIII_Paragraaf3) [70] defines a number of grounds on which a license application, as referred to in Section 15b (among other things installations generating nuclear power) of the Nuclear Energy Act (*Kernenergiewet*), must be or may be refused. The basis for refusal referred to in Article 18, clause 2a, of the Bkse relates to the maximum doses for postulated initiating events. Such events are accidents that the facility is designed to withstand. In line with the risk policy, a maximum allowable dose is formulated for each probability frequency for such postulated and radiologically relevant initiating events, namely releases during normal operation, anticipated operational occurrences and design basis accidents.

Requirements new reactors

The Safety Guidelines [69] contain a number of more stringent requirements compared to the Bkse. For example, the Safety Guidelines sets more stringent requirements regarding radiological objectives, reflecting the increased capabilities associated with technological progress and the recommendations made by the WENRA. New reactors must now also be designed to withstand postulated multiple-failure events and postulated core-melt accidents, which were previously regarded as beyond the scope of the design basis. In Figure 13 a simplified representation of the design basis provided for the Bkse and the Safety Guidelines is presented.

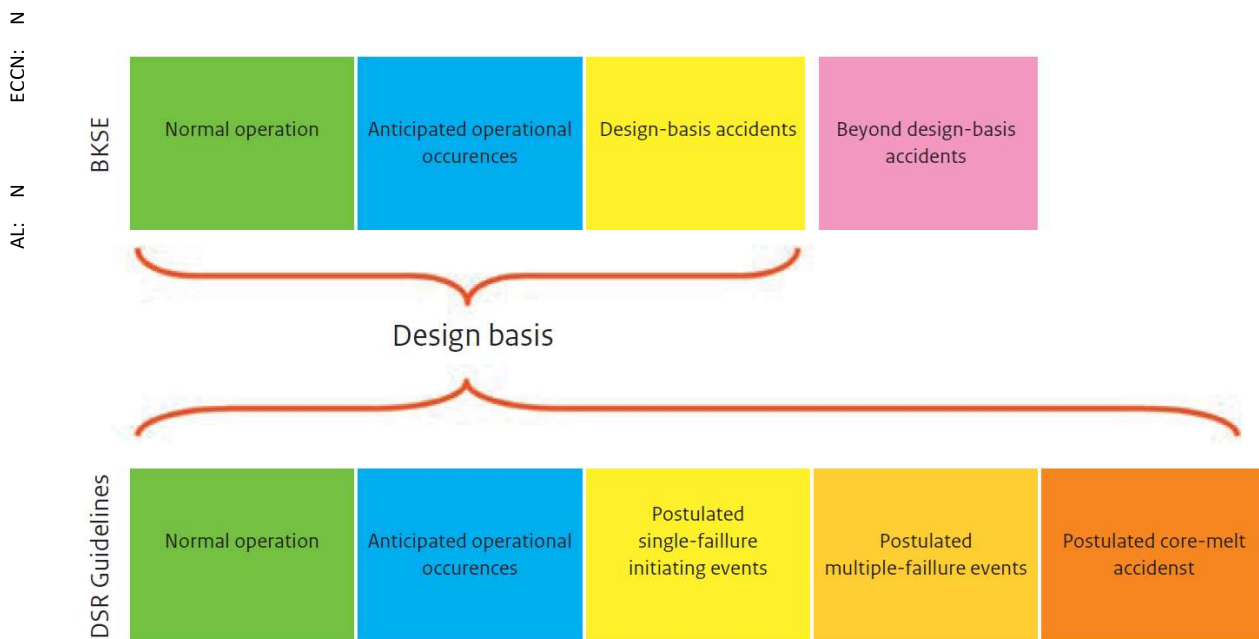


Figure 13 Simplified representation of the design basis provided for in the Bkse and the DSR

5.2.3 Environmental protection and industrial emissions

For industrial emissions, heat discharge and environmental protection the same legislation is applied as described in 5.1.4. Important legislation concerns the

- General Provisions Act (*WABO*)

- Environmental Legislation Decree (*Bor*)
- Activities Decree (*Activiteitenbesluit*)
- Environmental Management Act (*Wm*)
- Water Act (*Waterwet*)

Radiation protection

The Basic Safety Standards for Radiation Protection Decree (*Besluit basisveiligheidsnormen stralingsbescherming*, acronym: **Bbs**, <https://wetten.overheid.nl/BWBR0040179/2021-07-01>) [71] is an Order in Council, which further elaborates the Nuclear Energy Act. The decree protects various groups that have to deal with ionizing radiation: employees, patients, the public and the environment.

The Bbs is based on European regulations in the field of radiation protection. Recommendations of the International Committee on Radiological Protection (ICRP) have been implemented in European legislation. As a result, the regulations comply with the latest scientific insights. Employees who work with ionizing radiation, the population and patients undergoing treatment with ionizing radiation are thus even better protected. On 6 February 2018, the provisions of Directive 2013/59/EURATOM, the Basic Safety Standards, were incorporated into the Dutch system of radiation protection (as a result, the Radiation Protection Decree (Bs) lapsed).

The rules from the Bbs ensure that the population, the environment, employees and patients are protected now and in the future against the consequences of ionizing radiation. The regulations from the Bbs have been elaborated in three ministerial regulations and an ANVS regulation. Relevant regulations are:

- Regulation on Basic Safety Standards for Radiation Protection (<https://wetten.overheid.nl/BWBR0040509/2022-08-24>) [72]
- Radiation Protection Occupational Exposure Regulation 2018 (<https://wetten.overheid.nl/BWBR0040573/2021-02-06>) [73]

5.2.4 External Hazards and Risks

External Hazards

In the DSR part of the Safety Guidelines [69] the following is stated in section 2.5:

Concept of protection against internal and external hazards

2.5 (1) All items required for the safe shutdown of the nuclear reactor, for maintaining it in a shutdown state, for residual heat removal or the prevention of a release of radioactive materials shall be designed such and constantly kept in such a condition that they can fulfil their safety related tasks even in case of any internal hazard or relevant site specific external hazards. A site specific hazard analysis shall be performed to develop a hazard curve for each external hazard. Specific requirements regarding compliance with radiological safety objectives are given in Annex 2.

2.5 (3) If due to the site characteristics no appropriate protection measures against the relevant external hazards can be developed (e. g. in case of a capable fault underneath the site), the site shall be deemed unsuitable or no longer suitable.

Risks

A specific article (Art.18) concerning risk is stated in the Bkse Decree [70]. The decree prescribes the allowed radiological effective dose for nuclear facilities (as stated in Art. 15b in the Nuclear Energy Act) in relation to the frequency of occurrence, divided for persons up to and above 16 years old. The decree distinguishes two types of risks: the individual risk and the group risk. Where the individual risk is concerned, the risk analysis shall show that the probability of a person permanently located off-site who makes no use of protection dying as a result of an accident (any accident, not only a beyond design-basis accident, as referred to in Article 18, clause 3, of the Bkse) is less than 10^{-6} per year. Where the group risk is concerned, the risk analysis shall show that the probability of a group of ten or more people outside the facility dying as a direct result of an accident is less than 10^{-5} per year (or that the probability of n times as many direct fatalities is n^2 times smaller).

5.2.5 Emergency Provisions and response organization

In the Netherlands, emergency provisions and the organization for emergency response are described in a National Plan for Nuclear and Radiological Emergencies (NPNRE). Specific requirements for provisions that need to be made by NPPs, are set in the DSR.

National Plan for Nuclear and Radiological Emergencies (NPNRE) [74]

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 The NPNRE (Dutch: ‘Landelijk Crisisplan Straling’) describes the organization for crisis management in case of radiation accidents, the division of responsibility, accident scenarios and the response processes, as well as the necessary operationalization (protection measures, zoning, intervention levels, etc.). This also includes international cooperation with neighboring countries, the EU and the International Atomic Energy Agency (IAEA). The NPNRE is partially based on international regulations and guidelines such as IAEA GSR 7, EURATOM directives 2016/52, 2013/59, 87/600, and IAEA conventions on Early Notifications of a Nuclear Accident, and for Assistance in Case of a Nuclear Accident or Radiological Emergency.

Crisis organization

The generic system of crisis management forms the basis for crisis management in the Netherlands. Specifically in the case of radiation accidents, when scaling up, a connection is made with the national knowledge and advice network for radiation accidents: the Crisis Expert Team radiation and nuclear (CETsn). For illustration, the figure below provides an overview of the radiation and generic crisis structure (Figure 14).

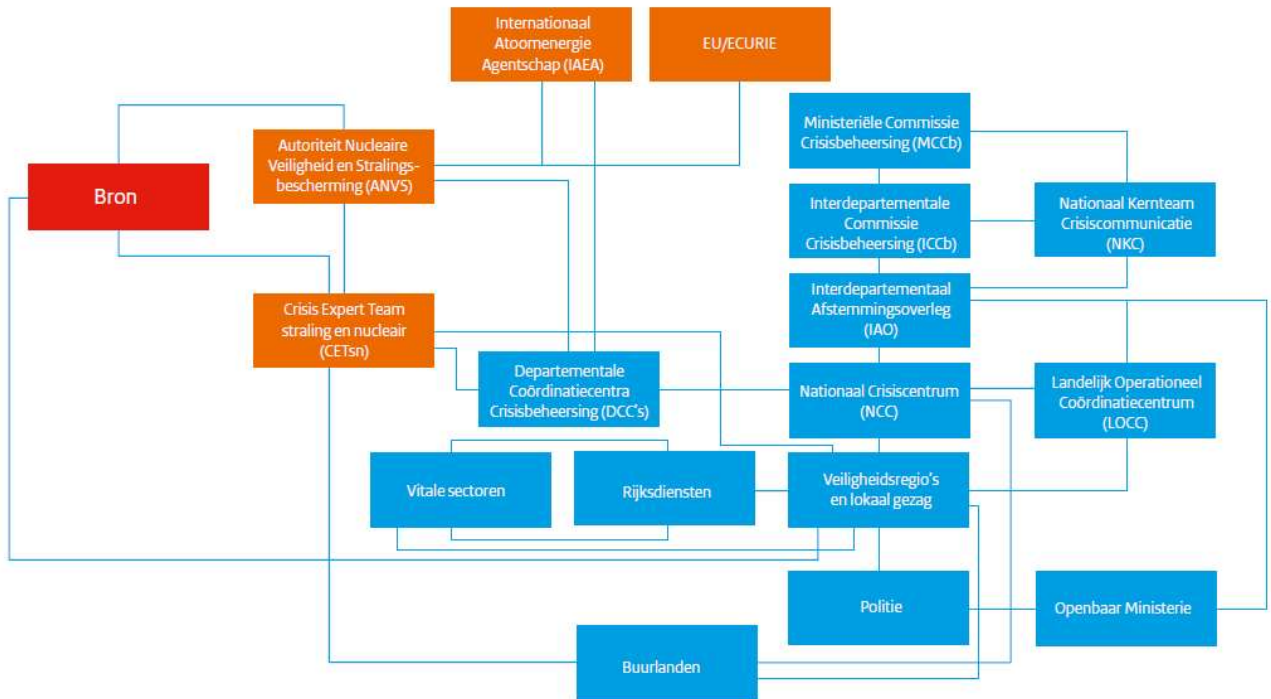


Figure 14 Radiation and generic crisis structure. The blue color indicates the organizations that are part of the generic structure (e.g Safety Regions, Ministerial Committees, Police, Coordination Centre Crisismanagement), the orange color indicates the organizations that specifically comes into force in case of radiation accidents (e.g. ANVS, CETsn, IAEA), the source ('Bron') is indicated by the red color. The lines between the organizations indicate that these organizations are connected [74].

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Requirements from the DSR

The National Plan for Nuclear and Radiological Emergencies [74]) and the Regional Emergency Response Plans (following the Safety Regions Act) specify the action to be taken in the event of an accident and the associated preparation zones. NPP design requirements for emergency situations are incorporated in the DSR. Hence, an applicant shall demonstrate that, in the event of any postulated core-melt accident, the requirements will be met. In the DSR the following is stated with respect to severe accident (with core melt) situations:

Protective action	Evacuation zone (< 3 km)	Sheltering zone (< 5 km)	Beyond sheltering zone
Permanent evacuation	No	No	No
Evacuation	May be needed	No	No
Sheltering	May be needed	May be needed	No
Iodine prophylaxis ¹⁰	May be needed	May be needed	No

The zones serve as design requirements in combination with the Dutch intervention levels. In that context, the following intervention levels apply:

- for sheltering, the intervention level is an effective dose of $E \geq 10$ mSv;
- for evacuation, the intervention level is an effective dose of $E \geq 100$ mSv;

- for the distribution of iodine prophylaxis, the intervention level for children is a thyroid dose of $H_{thy}(<18 \text{ yr}) \geq 50 \text{ mSv}$ and the intervention level for adults is a thyroid dose of $H_{thy} (\geq 18) \text{ yr} \geq 100 \text{ mSv}$.

The DSR [69] also provides technical requirements related to organizing the emergency response on site:

Requirements for control rooms and emergency response facilities

3.8 (3a) An on-site technical support center, separate from both the plant control room and the supplementary control room, shall be provided and suitably equipped from which technical support can be provided to the control room operational personnel during accident conditions.

3.8 (3b) An emergency center shall be provided and suitably equipped from which on-site emergency response as well as the interface to external response forces can be managed.

3.8 (7) The control room, supplementary control room, technical support center and emergency center shall remain operable, accessible and habitable for a protracted period of time in situations generated by accidents and conditions due to or resulting from hazards considered in the design of the plant.

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5.2.6 Operation and Organization

In the Dutch legislation a regulation indicated Nuclear Safety of Nuclear Installations (Dutch: 'Regeling nucleaire veiligheid kerninstallaties', [https://wetten.overheid.nl/BWBR0039625/2018-02-06/_\[75\]](https://wetten.overheid.nl/BWBR0039625/2018-02-06/_[75])) covers operational and organizational requirements of the licensee. The regulation takes the following topics into account:

- **Paragraph 2: Responsibilities and Obligations of licensees**
 - Responsibilities for nuclear safety
 - Financial and personnel means
 - Provision of information to authorities and population
- **Paragraph 3: Specific obligations licensee related to nuclear safety objectives**
 - Nuclear safety objectives for nuclear installations
 - Defense in depth
 - Safety culture
 - Management System minimum requirements
 - Training and education
 - Continuous improvements and safety evaluations
 - Measures to improve nuclear safety
 - Reporting improvements and policy evaluations
- **Paragraph 4: Provisions in case of accidents**
 - Procedures and measures for management of accidents
 - Obligation of a company emergency plan, further explained in art. 14.3a-d
 - the company emergency plan alignment with the national crisis agreements and safety region.

- **Paragraph 6: Obligations for governing bodies**
 - Effective nuclear safety culture
 - Achievement of the nuclear safety objective
 - Performance of the Management System related to nuclear safety
 - ✓ Awareness, critical attitude, levels of personnel
 - ✓ Measures for reporting safety issues
 - ✓ Detailed and comprehensive description of the organization culture including functions, tasks, responsibilities, competence and processes, quality assurance

Specific Requirements DSR

In the DSR some high level requirements are stated covering nuclear safety in the operation and organization of the NPP. The safety demonstration is based on the Safety Analysis Report (SAR) and the underlying documentation used for it. The Management System (also a chapter in de SAR) describes in what way the required safety level will be maintained during operation or accident conditions.

For operation, the required safety level is incorporated in instructions and procedures.

Abstracts of the requirements from the DSR are given below:

5 Requirements for the safety demonstration

5 (1) The licensee/applicant shall be in the position to provide documentary evidence on plant safety covering all the stages during the lifetime of the plant. The safety demonstrations shall be documented in the Safety Analysis Report.

6 Requirements for the operating rules

6 (1) Written instructions shall exist for normal operation, anticipated operational occurrences and accident conditions (further specified in the requirements)

Annex 2: Requirements for provisions and protection against hazards

2 Requirements for Preventive Measures

2 (6) If administrative measures and related operator actions are part of preventive measures, their effectiveness and reliability shall be demonstrated by methods such as failure mode and effect analysis or hazard analysis. In particular, systematic failures shall be considered.

2 (7) Validity of the boundary conditions for the efficiency and reliability of preventive measures has to be ensured over the whole operational life of the plant.

5.3 Conclusions and Findings

Findings



H1. There is no specific HPP regulation in the Netherlands. Hydrogen production is considered as chemical industry, inorganic gas production. There is no differentiation for the method of hydrogen production, only for the *amount* of hydrogen stored. Requirements, standards and (threshold) values are based on EU legislation (e.g. Seveso Directive).

H2. The difficulty in the licensing framework lies in the many different variations, caused by regional differences (e.g. water authorities, safety region), that are possible. For each application, a different set of requirements and extra applications for additional licenses can be needed. These variations can be caused by different configurations or plant characteristics, but also by a unique set of communal, regional, provincial, or national requirements.

H3. The main legislation relevant for HPP licensing is:

- WABO: General Provisions Act
- BRZO: Major Accidents Risks Decree
- BEVI: External Safety of Establishments Decree

The requirements stemming from the BRZO and BEVI can be incorporated into the license that is used to prove compliance with the WABO. In this way, one license is used to cover multiple laws. The entire process is coordinated by the Regional Service authority.

H4. The BRZO integrates laws and regulations (also Directive 2012/18/EU) in the field of occupational safety, external safety and disaster relief. Important aspects to consider are “Domino effects”. These are related to the proximity of other facilities (e.g. NPP) with specific hazards.

The BEVI stipulates that the risks and effects of a company in which hazardous substances are present must comply with safety standards and guideline values. The intention is to keep or create sufficient distance between the danger objects and civilians/vulnerable objects. Key parameters in this context are the Local Risk (PR) and the Group Risk (GR). Determination and application of the safety standards are further elaborated in the accompanying Regulation on External Safety Establishments (REVI). For so-called 'categorical establishments', the REVI provides tables with fixed safety distances which dictate the minimum distances between the establishment and a vulnerable object.

H5. For the situation in which the heat sink (surface water) of both facilities can be shared: a balance is made between the characteristics of the discharge and the effects on the surface water to which the discharge is carried out. Heat discharges smaller than 50 MW are regulated by the Activities Decree. Discharges of cooling water with a higher heat load are subjected to a permit.

N1. The ANVS has drawn up the Safety Guidelines on the Safe Design and Operation of Nuclear Reactors. The specific requirements (called Dutch Safety Requirements or DSR) defined in the Safety Guidelines are aligned with the latest insights, particularly those disseminated by the IAEA and WENRA, and may, where applicable and necessary, serve as a basis for formulating the conditions attached to licenses for new reactors.

The ANVS is the competent authority for nuclear facilities for all environmental aspects, so also conventional activities are part of the nuclear license of the facility. Therefore, when integrating an HPP in a licensed NPP establishment, the permit application is to be submitted to the ANVS.

N2: The nuclear license for an NPP can be refused based on Article 18 of the Bkse. This article contains the maximum allowable radiological effective doses for individuals, specified per frequency of

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occurrence, and maximum allowable risk of dying for an individual and for groups. These risks can change after implementation of an HPP.

N3: The National Plan for Nuclear and Radiological Emergencies (NPNRE) describes the national crisis management for radiation accidents. It refers to national regulations and guidelines, and is based on international regulations and guidelines. Regional authorities (like Safety Regions) have an important role in this. New scenarios concerning HPP will have to be implemented in the NPNRE and to be aligned with the Safety Regions.

Conclusions

In the Netherlands, the production of hydrogen is regulated as part of the chemical industry, with no specific regulation related to the method used for hydrogen production. An HPP shall comply with regulations largely based on EU directives, such as the Seveso directive. The complete set of regulatory requirements comprises European, national, regional, and local requirements, leading to unique requirements of each location. The regional authorities have a central role in the coordination of these various requirements.

The main topics for which compliance is needed, regard external safety, major accident prevention and mitigation, environmental impact, and spatial planning.

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Nuclear facilities are regulated by the framework set in the Nuclear Energy Act, which refers to a set of decrees, acts and requirements that are largely based on international guidance and adapted to the Dutch case, and are enforced by one central authority. Topics specified in these requirements include nuclear safety, emissions, radiological protection, accident prevention, emergency response provisions, and other organizational requirements. Compliance is also required in non nuclear specific topics such as spatial planning and environmental impact, for which the regional authorities again take a central role.

The ANVS is the competent authority for nuclear facilities for all environmental aspects, so also conventional activities are part of the nuclear license of the facility.

A combined HPP-NPP facility will have to comply with both aforementioned nuclear and hydrogen related requirements and legislation. The central authorities enforcing the regulations will be the regional services and the nuclear authority, and a bi-directional exchange of influences between the nuclear and hydrogen related requirements is expected. Regarding spatial planning, environmental impact, and organizational requirements, a partial overlap in regulations could occur, meaning similar or equal requirements could be set for both NPP's and HPP's.

The ANVS will have a central role in this integration process.

6 Analysis for Romania

6.1 Hydrogen Production Plant in Romania

According to the Integrated National Plan in the field of Energy and Climate Change 2021-2030 (“PNIESC”) [76], the Romanian Government considering the implementation of a pilot and demonstration projects to promote the use of hydrogen in the production of electricity and in the industrial sectors.

In order to promote decarbonization and the adoption of these new technologies, there will need to be a consolidation of the legal framework, intensifying dedication to research and innovation (in both state-owned and private companies), increasing and diversifying funding sources and developing educational resources, as well as supporting projects that promote the increased use of hydrogen.

Romania is also developing a hydrogen strategy, which is envisaged by the recently approved National Recovery and Resilience Plan [77]. The strategy focuses on the development of new distribution networks capable of supporting a gas blend comprising of initially 10% gas and hydrogen. The National Recovery and Resilience Plan includes provisions regarding:

- the development of renewable gas distribution infrastructure (using natural gas in combination with green hydrogen as a transitional measure);
- green hydrogen production capacity; and/ or
- an electricity storage, hydrogen-ready distribution network. This is to be completed and function in the Oltenia region.

In August 2022 the European Commission has approved, under EU State aid rules, a €149 million Romanian scheme made available through the Recovery and Resilience Facility (‘RRF’) to support the production of renewable hydrogen. The scheme is aimed at supporting the construction of new installations for the production of renewable hydrogen, to achieve by 31 December 2025 renewable hydrogen production capacities of at least 100 MW in electrolysis installations [78].

6.1.1 General description of HPP Licensing policy

6.1.1.1 Legislation

The Romanian legislation on hydrogen production began to be developed in 2020, when Electricity and Natural Gas Law no. 123/2012 [79] (the “Electricity and Natural Gas Law”) was frequently amended by several pieces of legislation introducing various provisions, such as:

- The Ministry of Energy is entitled to issue authorizations for the set-up of new hydrogen production capacities on the basis of certain procedures approved by order of the minister – no related procedures have been enacted so far.
- The National Energy and Regulatory Authority (“ANRE”) is entitled to issue licenses for commercial exploitation of hydrogen production installations and authorizations related to the design, execution and use of such facilities.
- Hydrogen producers are subsumed under the regulations for natural gas producers. This sub summation is probably a legislative drafting error; most obligations applicable to natural gas producers are simply incompatible with the production of hydrogen.

According to PNIESC, in order to achieve energy security, Romania needs to “diversify its resources, including the development of new capacities of renewable energy and integration with other markets in the region, as well promoting the use of hydrogen”.

The Romanian Government has recently adopted a Memorandum initiated by the Ministry of European Funds and supported by the Ministry of Education and Research. The Memorandum proposes funding in the next programming period (2021-2027) for Romania’s first hub dedicated to hydrogen, for research and development in respect to the use of hydrogen in transportation, district heating and nuclear energy generation, as the “fuel of the future”.

An amendment was made to the Energy Law on 24 July 2020 in order to include hydrogen production provisions (“Law 155”, [80]).

In accordance with Law 155 and as said above, the general regulatory framework on hydrogen will be established by the energy regulator, ANRE. ANRE will elaborate on the technical and commercial regulations regarding the operation of a hydrogen terminal and the methodology of related tariffs within six months from receiving an application to authorise the construction of the terminal. Tariffs for services provided by the hydrogen terminal operator, regarding the operation of the terminal (e.g. hydrogen storage facilities), are established by the economic operator concerned. These will be approved by ANRE and published on the operator's own web page. According [81] the Ordinance 143/2021 defines the core hydrogen related concepts as follows:

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- ‘hydrogen terminal’ is defined as all installations necessary for the import, discharge and regasification of hydrogen for subsequent delivery to the system, but which do not include any part of the installations / equipment used for the storage of liquid or gaseous hydrogen;
 - ‘hydrogen terminal operator’ is defined as the natural or legal person who carries out hydrogen production or its import, unloading and regasification, responsible for the hydrogen terminal operation;
 - ‘commercial operation of the hydrogen terminal’ is defined as the commercial activity of selling hydrogen to customers; and
 - ‘access to the hydrogen terminal’ is defined as the right of an economic operator in the natural gas sector or of a final customer to use the hydrogen terminal

Law 155 introduced also the requirement for a license to be held for the commercial generation of hydrogen. Secondary legislation is soon expected which will provide further regulatory provisions in respect of licensing and the operation of hydrogen production.

According to Law 155, ANRE will need to establish the conditions and standards for the injection of hydrogen into existing natural gas networks. This will facilitate hydrogen blending into the gas grid and will need to be in line with the proposals awaited in the national hydrogen strategy.

The draft of Romania’s National Energy and Climate Plan includes various references to hydrogen. There have also been a number of initiatives set out by various stakeholders advocating for a transition to a hydrogen economy from a carbon-dependent one.

At the end of 2020, ANRE published in the Official Gazette several orders outlining a legal framework for hydrogen projects: Order 200/2020 on the approval of the Framework Conditions for validity associated with the establishment authorisation for new hydrogen production installations; Order 201/2020 on the approval of the Framework Conditions for validity associated with the license for commercial operation of new hydrogen production facilities; and the 2020 Validity condition associated with the establishment authorisation for new hydrogen production facilities.

6.1.1.2 Relevant Authorities

In general, the key regulatory authorities in the electricity market include the following [82] :

- Ministry of Economy, Energy and the Business Environment. Its responsibilities include:
 - managing the public assets in the energy sector;
 - drafting the national energy policy and strategy, and the implementation of the government policy in the energy sector;
 - identifying and defining the objectives of the energy sector and the best ways of achieving such objectives;
 - initiating legislative projects in the energy sector; and
 - monitoring compliance with EU obligations and requirements.
- Romanian Energy Regulatory Authority (ANRE). The Romanian energy regulator is responsible for adopting regulations in the electricity and gas sectors, as well as the energy efficiency sector. It has broad regulatory powers, mainly in relation to:
 - establishing the contracting framework in the energy sector, setting up prices and tariffs for the natural monopoly segments of the markets;
 - monitoring the electricity market and compliance with the existing regulations; and
 - authorising and licensing companies in the energy sector.
- National Environmental Protection Agency. A public central administration authority, subordinated to the Ministry of Environment, with competences in the following areas:
 - strategic environmental planning and environmental factors monitoring;
 - permitting of activities which have an impact on the environment;
 - implementation of the environmental legislation and policies;
 - reporting to the European Environment Agency;
 - co-ordinating the implementation of environmental strategies and policies; and
 - permitting activities having an impact on the environment and providing the compliance with the legal provisions.

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In particular, the Romanian Energy Regulatory Authority (ANRE) is responsible for the drafting of the regulatory framework regarding technologies such as hydrogen.

A number of regulators also have responsibilities depending on the activity in question, as provided in Table 8.

Table 8 Regulators and responsibilities

<i>Local Authority / Town and Country Planning Authority</i>	<ul style="list-style-type: none"> • Regulates the use of land • Undertakes Environmental Impact Assessment • Usually has the role of the hazardous substance authority in relation to storage
<i>National Agency for Mineral Resources</i>	<ul style="list-style-type: none"> • Manages the national pipeline system of oil and natural gas transportation
<i>Transgaz</i>	<ul style="list-style-type: none"> • Technical operator of the national gas transmission system and is responsible for its operation. It monitors quality, safety, efficiency and environmental conditions.

6.1.1.3 Licensing Process

As provided in [83], the existing regulatory and legal-administrative processes (LAPs) aim to:

- identify the actual legislation and practices;
- compare production processes, identify similitudes, differences and best practices;
- address recommendations for improvement of current legislation and policies at European and national level.

Currently, the main means of the hydrogen production in Romania is steam methane reforming and by-product in chlor-alkali plants and is mostly used at the place of production.

The hydrogen production facility must be located in an area with industrial activities, according to urbanism plans. These specific requirements is realised on the bases of certifications and authorisations issued by:

- for “fire safety and emergency situations”- Inspectorate for Emergency Situations ISU (Inspectoratul pentru Situații de Urgență);
- for “pressurised vessels”- ISCIR State Inspection for Control of Boilers, Pressure Vessels and Hoisting (Inspekția de Stat pentru Controlul Cazanelor, Recipientelor sub Presiune și Instalațiilor de Ridicat – ISCIR);
- and for “explosion prevention inspection” - Technical Inspection Body - INSEMEX COV. The urbanism plan and necessity for an urbanism certificate should be analysed before the project planning.

6.1.2 Safety concept for HPP

Since specific legislation related to safety of Hydrogen production plant still does not exists in Romania, the legislation related to safety of a chemical industry would be applicable so far.

The safety concept for hydrogen production plants in Romania would likely include the following general elements, as they can be inherited from regulatory framework listed in Section 6.1.1.1 (especially from Governing Law 95/2003 and Law no. 64/2008):

- **Safety culture:** As with nuclear power plants, safety culture is a critical component of the safety concept for hydrogen production plants. A safety culture program needs to be developed and implemented to ensure that all staff and contractors understand their responsibilities for safety and security.
- **Safety assessment:** Safety assessments need to be conducted regularly to identify potential hazards and risks and to ensure that appropriate measures are in place to control these risks.
- **Design and construction:** Hydrogen production plants need to be designed and constructed in accordance with international safety standards and guidelines. The design needs to incorporate safety features and systems that ensure that the plant can be safely shut down in the event of an accident.
- **Emergency preparedness:** The operator of the hydrogen production plant needs to have an emergency preparedness program that includes procedures for responding to accidents or incidents. The emergency plan needs to be regularly reviewed and updated.
- **Fire safety:** Hydrogen is highly flammable and presents unique challenges for fire safety. Therefore, specific safety measures need to be implemented to minimize the risk of fires and explosions.
- **Environmental protection:** Hydrogen production plants need to comply with environmental regulations, including measures to control emissions and waste from the plant.

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More in details, as reported in [84], it is expected that an Hazard Analysis by (HAZOP) and/or Checklist would be required to be implemented as general safety guidelines when addressing the risks of HPP (in order to be also in compliance with the Seveso regulations).

It should be based on:

- the selection of an appropriate methodology for systematic identification of unit/ equipment specific hazards, producing a detailed identification of hazards;
- the definition of the prevention measures which ensure that an accident caused by process deviations is avoided as far as possible;
- definition of single scenarios identified during Checklist or HAZOP analysis that shall be passed further to quantitative risk analysis to decide on the adequacy of safeguards;
- depending on the severity of the worst credible consequence, definition of a certain number and/or a certain quality (characterized by the probability of failure on demand) of barriers required to end up with a tolerable/acceptable risk for the single scenario;
- description of Consequence Analysis of Accidental Scenarios, referring to the detailed analysis of the consequences resulting from fire/explosion scenarios of dangerous materials (including Hydrogen)

6.1.3 Environmental Protection and Industrial Emissions for HPP

Environmental protection and industrial emissions are important considerations for any hydrogen production plant in Romania, and the following regulations and guidelines apply:

- Law no. 278/2013 on industrial emissions [85]: This law implements the European Union's Industrial Emissions Directive and establishes rules for preventing and controlling emissions of pollutants into the air, water, and soil from industrial activities. Hydrogen power plants in Romania need to comply with the emission limit values specified in this law. This law aims to prevent pollution from industrial activities to water, air and soil. However, it has a special section on geological storage of CO₂ that stipulates all combustion plant operators with electrical output of 300MW and above to have suitable storage sites, transport facilities, have technical capacity to capture and compress CO₂.
- Environmental permit: Hydrogen production plants in Romania need to obtain an environmental permit from the Ministry of Environment and Climate Change. The permit outlines the environmental conditions that the plant must comply with.
- Environmental monitoring: Hydrogen production plants in Romania need to conduct environmental monitoring to assess the impact of plant operations on the environment. This would include monitoring of air, water, and soil quality.
- Health and Safety: Hydrogen production plants are subject to the same health and safety regulations as other industrial facilities in Romania, including regulations on worker safety and emergency preparedness.
- European Union regulations: Romania is a member of the European Union, and therefore, any hydrogen production plants in the country needs to comply with EU regulations on industrial emissions and environmental protection.

More in details, the key aspects of Law no. 278/2013 are:

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- **Best Available Techniques:** The law requires hydrogen production plants to implement Best Available Techniques (BAT) to minimize emissions and prevent pollution. BAT represents the most effective and advanced techniques and practices available for a particular industrial sector.
- **Integrated Permitting:** The law establishes an integrated permitting system for industrial activities, including hydrogen production plants. The permit process takes into account the environmental performance and sets emission limit values specific to each installation, considering the applicable BAT and associated emission levels.
- **Emission Limit Values :** they set specific emission limits for various pollutants released by industrial activities, including hydrogen production plants. They are determined based on BAT and must comply with the requirements outlined in Annex II of the Industrial Emissions Directive.
- **Monitoring and Reporting:** Hydrogen production plants are required to monitor and report their emissions regularly. The law specifies the monitoring methods, frequency, and reporting requirements for different pollutants. This includes continuous monitoring, periodic measurements, and reporting of emissions to the competent environmental authorities.
- **Compliance and Enforcement:** The law establishes procedures for compliance assessment and enforcement. This involves inspections, audits, and penalties for non-compliance with emission limit values or other requirements outlined in the permit.
- It's important to note that the specific emission limit values for hydrogen production plants under Romanian Law no. 278/2013 may vary depending on the specific pollutants, production capacities, and other factors.

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6.1.4 External Hazards and Risks for HPP

Like any industrial facility, hydrogen production plants are subject to external hazards that can pose risks to their safe operation. Some potential external hazards and risks for hydrogen production plants in Romania could include:

- **Seismic activity:** Romania is located in a region with moderate to high seismic activity [86], which could potentially damage hydrogen power plant equipment and cause safety hazards.
- **Extreme weather events:** Romania is susceptible to extreme weather events such as heavy snowfall, high winds, and storms. These events could potentially damage hydrogen production plant equipment and cause safety hazards.
- **Fire and explosions:** Hydrogen is a highly flammable gas, and as such, hydrogen production plants could be at risk of fires and explosions if there is a leak or release of hydrogen gas.
- **Human error:** Human error is a potential hazard in any industry, including hydrogen power. Operators of hydrogen power plants must be highly trained and vigilant to ensure that safety protocols are followed at all times.
- **Terrorism:** As with any critical infrastructure, the threat of terrorism is a concern for hydrogen power plants in Romania. A terrorist attack on a hydrogen power plant could result in significant safety hazards and damage to the surrounding environment.

At European Union level, rules and regulations for the control of major accident hazards involving dangerous substances are driven by the Seveso Directive. Romania, as an EU member state, is required to transpose the Seveso Directive into its national legislation. The primary legislation in Romania for implementing the Seveso Directive is the Government Emergency Ordinance no. 99/2000 on the control of major accident hazards involving dangerous substances (also known as the "Seveso Law"). It aims to prevent and mitigate the effects of accidents and protect human health and the

environment. In Romania, the Seveso Directive is implemented through national legislation and regulatory frameworks. Here is an overview of how the Seveso Directive is implemented in Romania:

- **Classification of Establishments:** The National Environmental Protection Agency (ANPM) is responsible for classifying establishments into lower-tier and upper-tier based on their potential risk and impact. Lower-tier establishments have lower thresholds for hazardous substances, while upper-tier establishments handle larger quantities of such substances.
- **Safety Reports:** Upper-tier establishments in Romania are required to prepare safety reports, as per the Seveso Directive's requirements. These reports provide detailed information about the establishment's activities, hazardous substances, accident scenarios, risk management measures, emergency plans, and preventive measures. The safety reports are submitted to the ANPM for evaluation and approval.
- **Competent Authority and Inspection:** The ANPM serves as the competent authority responsible for implementing and enforcing the Seveso Directive in Romania. It carries out inspections, audits, and assessments of establishments to verify compliance with the Seveso Law. The ANPM ensures that establishments have appropriate safety measures, emergency plans, risk assessments, and notification procedures in place.
- **Public Information and Consultation:** In Romania, the ANPM ensures that information related to establishments covered by the Seveso Directive is made available to the public. This includes providing access to safety reports, emergency plans, and other relevant information through public consultation and awareness initiatives.
- **Coordination and Cooperation:** The implementation of the Seveso Directive in Romania involves coordination and cooperation between various stakeholders, including the ANPM, local authorities, emergency response organizations, industry operators, and the public. These stakeholders work together to ensure effective prevention, preparedness, and response to major accident hazards.

6.1.5 Emergency provisions and response organization for HPP

It is important to consider emergency provisions and response organization in the planning stages to ensure safe operation of these facilities.

In general, as it can be inherited from regulatory framework listed in Section 6.1.1.1 (especially from Governing Law 95/2003 and Law no. 64/2008) emergency provisions and response organization for hydrogen production plants would include:

- **Emergency Response Plan:** An emergency response plan is a written document that outlines the procedures for responding to an emergency at a hydrogen power plant. This plan should cover potential hazards and risks and outline the roles and responsibilities of each member of the response team.
- **Emergency Response Team:** The emergency response team is responsible for implementing the emergency response plan in the event of an emergency at a hydrogen power plant. The team should be highly trained and include members with expertise in emergency management, hazardous materials, and other relevant areas.
- **Communication and Warning Systems:** Communication and warning systems are critical to quickly notifying the public and authorities of any emergency situation. A warning system should be in place to alert the public of an emergency, and communication channels should be established to ensure effective coordination among response team members.

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- **Protective Equipment:** Protective equipment is necessary to keep the emergency response team safe while responding to an emergency at a hydrogen power plant. This equipment could include personal protective equipment, such as respirators and protective clothing, as well as monitoring equipment to detect hydrogen gas leaks.
- **Evacuation Plans:** Evacuation plans should be developed and periodically tested to ensure that the public can be quickly and safely evacuated in the event of an emergency.

In the event of an accident at a hydrogen production plant, response organizations at the national, regional, and local levels may be involved, as briefly explained here below:

- **National Level:**
 - **Inspectorate for Emergency Situations (Inspectoratul General pentru Situații de Urgență - IGSU):** The IGSU is responsible for coordinating and managing emergency situations at the national level in Romania. It oversees and directs the response efforts of various emergency services and agencies.
 - **Romanian Energy Regulatory Authority (Autoritatea Națională de Reglementare în Domeniul Energiei - ANRE):** ANRE is responsible for regulating and overseeing the energy sector in Romania. In case of an accident at a hydrogen production plant, ANRE may be involved in providing technical expertise, guidance, and coordination.
- **Regional Level:**
 - **County Inspectorates for Emergency Situations (Inspectoratele Județene pentru Situații de Urgență - IJSU):** Each county in Romania has its own IJSU, which is responsible for managing emergency situations at the regional level. These organizations coordinate and oversee the response efforts of local emergency services and agencies within their respective counties.
- **Local Level:**
 - **Local Emergency Management Inspectorates (Inspectoratele Locale pentru Situații de Urgență - ILSU):** ILSUs operate at the municipal or city level and are responsible for managing emergency situations within their jurisdictions. They coordinate and support the response activities of local emergency services, such as fire departments and medical services.
 - **Fire Departments:** Local fire departments play a crucial role in responding to emergencies, including accidents at industrial facilities. They are often the first responders and provide firefighting, rescue, and hazardous materials response capabilities.

These response organizations work together in a coordinated manner to handle emergency situations, including accidents at hydrogen production plants. They follow established emergency response protocols, which may include incident management, evacuation procedures, containment measures, and mitigation strategies. The specific roles and responsibilities of these organizations may vary depending on the nature and severity of the incident.

6.1.6 Operation and organization for HPP

The Operator of an HPP in Romania has first of all the obligation to demonstrate compliance by submitting a safety report. This documentation serves not only as a demonstration that all necessary measures are in place but also as a basis for the supporting activities as mentioned before: emergency response and land-use planning. In order to be compliant with the legal framework depicted in Section 6.1.1.1, it is suggested that any Operator of HPP in Romania shall:

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- establish the most appropriate organizational structure:
 - sizing correctly resources within the structure, defining the key roles and allocating clearly responsibilities;
 - making the work team capable of carrying out its task thanks to a strong attitude to "problem solving" and to the early identification of risks and opportunities;
 - managing efficiently workload and constraint;
 - defining coordination rules between resources, putting those in charge of the various management roles, in the ideal conditions to face and overcome the physiological managerial and short-term difficulties;
 - establishing close collaboration and teamwork.
 - planning in the best way the path of the qualification and training of personnel;
 - using a planned decision system that makes use of tools and / or methods capable of attributing corporate data, a strong ability to transmit information;
- adopt a robust process management;
- the standardization of physical and information flows;
- strong performance control (measurement, incentive, feedback);
- the use of clear communication structure and reporting systems;
- set up continuous improvement processes.

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6.2 Nuclear Power Plant in Romania

6.2.1 Introduction

The existing nuclear installations in Romania, all licensed by the Commission for Nuclear Activities Control (CNCAN, see its description in Section 6.2.2.1), the national authority with responsibility for regulation, licensing and control of nuclear activities, are the following:

- Cernavoda Nuclear Power Plant (NPP) and its associated spent fuel storage and radioactive waste management facilities;
- The TRIGA Research Reactor and its associated spent fuel storage and radioactive waste management facilities;
- The Nuclear Fuel Manufacturing Plant and its associated radioactive waste management facilities;
- The decommissioned VVR-S Research Reactor in Magurele, near Bucharest, and its associated radioactive waste management facilities.

As provided in [82] Romania has one nuclear power plant, Cernavoda NPP, with two units in operation, pressurized heavy water reactors (PHWRs) of CANDU 6 design (CANadian Deuterium Uranium), each with a design gross output of 706.5 MWe. Unit 1 and Unit 2 started commercial operation on the 2nd of December 1996 and on the 1st of November 2007, respectively. The plant was initially intended to have 5 units. The construction of the other three units on the site was stopped at different stages, and these units are currently under preservation. All units are pressurized heavy water reactors (PHWR), CANDU 6 type. Cernavoda NPP Units 1 and 2 cover approximately 18% of Romania's total energy

production. The Government has plans to further increase nuclear generating capacity through the resuming of construction and commissioning of Units 3 and 4 of the Cernavoda NPP. The decision to complete Units 3 and 4 was taken in June 2007. Pre-licensing reviews have been successfully completed, but no application for a construction license has been submitted yet, according to [87]. The construction of Unit 5 has been cancelled by a decision of the General Shareholder Assembly of the SNN, the owner and operator of Cernavoda NPP. The existing structures of Unit 5 will be used for different activities connected to the operation of Units 1 and 2 and, in the future, of Units 3 and 4. Each unit is provided with a dedicated Spent Fuel Bay (SFB) for the spent fuel temporary storage. The SFB is designed to accommodate the fuel discharged during 8 years after its removal from the reactor core. After 6-7 years of cooling in the SFB, the spent fuel bundles are transferred to the on-site, naturally air-cooled Intermediate Dry Spent Fuel Storage Facility (IDSFS) for the spent fuel long term storage.

The PHWR design is known for its reliability and safety features, including a passive cooling system that doesn't require any external power source.

The following sections provide an overview of the NPP licensing process, the main actors involved, the safety concepts, the steps to follow to demonstrate that the fundamental safety functions are ensured in operational states, in and following accidents.

6.2.2 General description of NPP licensing policy

In Romania, the relevant guides, regulations, codes, and standards for Nuclear Power Plants (NPPs) are established by the Romanian regulatory body, the [National Commission for Nuclear Activities Control \(CNCAN\)](#). Section 6.2.2.1 provides a description of the main actors in the development of nuclear power programme in Romania (Ref. [82], [88], [89], [87]). In section 6.2.2.2 and 6.2.2.1 is provided, respectively, an overview of the legislative and regulatory framework for the licensing process (Ref. [90], [91], [92] and [93]), and an overview of the regulatory framework for management system in force in Romania (Ref. [92]). The licensing process of a Romanian nuclear power plant is introduced in Section 6.2.3. The qualification of the applicant and the involvement of the applicant, Technical Support Organization (TSO) and Regulatory Body is presented in Sections 6.2.3.1, 6.2.3.2, 6.2.3.3 and 6.2.3.4.

6.2.2.1 Actors involved in the nuclear Regulatory Framework

The actors involved in the nuclear power programme are depicted in the figure below. The Prime Minister, through the General Secretariat of the Government, coordinates the activities of the National Commission for Nuclear Activities Control (CNCAN) that represents the national authority with responsibility for regulation, licensing and control of nuclear activities. This authority is in charge of the development of strategy and the policies involving the nuclear and radiological safety, the non-proliferation of nuclear weapons, the security of nuclear plants and materials, the safe management and transport of radioactive materials, waste and spent fuel.

The Ministry of the Environment is responsible for the environment protection; this ministry has responsibilities in the environmental licensing and control of nuclear installations, including facilities for the management of spent fuel and radioactive waste.

Policies and strategies related to the nuclear energy sector are developed by the Ministry of Energy. This ministry is responsible for the policies regarding the nuclear fuel, the research, the technology

and engineering for nuclear projects and the production of energy from nuclear power plants based on CANDU technology.

The ministry of Energy exercises its functions through its subsidiaries

- the *nuclearelectrica* national company (SNN) that is the owner of the Cernavoda nuclear power plant (through its subsidiary Cernavoda Nuclear Power Plant -CNE Cernavoda) and the fuel manufacturing plant at Pitesti (through its subsidiary Nuclear Fuel Plant-FCN);
- the National Uranium Company (CNU) that has responsibilities for uranium mining and milling activities, including geological research and exploitation activities for uranium ores, and the ores themselves;
- the State Owned Company for Technologies for Nuclear Energy (RATEN), that is the strategic entity that is responsible for the research activities in the nuclear energy matter, and in developing and technical supporting the National Nuclear Energy Programme. RATEN coordinates the activities of its subsidiaries: the Institute for Nuclear Research (RATEN ICN) and the Centre for Nuclear Projects Engineering (RATEN CITON). These organizations provide technical support for the safe operation of the Cernavoda NPP, for new builds and for the other nuclear installations and projects under the national nuclear power programme. Furthermore, RATEN is involved in technology development for the new type of GEN IV reactors and in the research activities for GEN IV reactors.

The Ministry of Internal Affairs through the General Inspectorate for Emergency Situations is responsible in the preparedness and response in case of nuclear accident.

The Ministry of the Economy is the authority responsible for approving the National Nuclear Programme and ensuring it is implemented through its subsidiaries:

- The Nuclear Agency for Radioactive Waste is responsible for safe disposal of the spent nuclear fuel and the radioactive waste, including those resulted from the decommissioning of nuclear and radiological facilities.
- The National Authority for control and approval of Boilers, Pressure Vessels and Heating Equipment (ISCIR), has responsibilities in licensing and control of the pressure systems and equipment, including those used in nuclear and radiological installations. This authority cooperates and consults CNCAN.

The Ministry of Research and Innovation develops policies in the areas of scientific research, technological development and innovation. In carrying out activities and duties in the mainframe of the nuclear power programme, uses expertise and experience of the subsidiaries:

- Horia Hulubei Institute for R&D in Physics and Nuclear Engineering (IFIN-HH), this institute is involved in the research and development activities in Nuclear Physics and Nuclear Engineering;
- National Institute of Research and Development for Cryogenic and Isotopic Technologies (ICSI) that supports the nuclear fusion national program; this institute is also involved in studies and research in the cryogenic field, materials, hydrogen and fuel cells and renewable energy.

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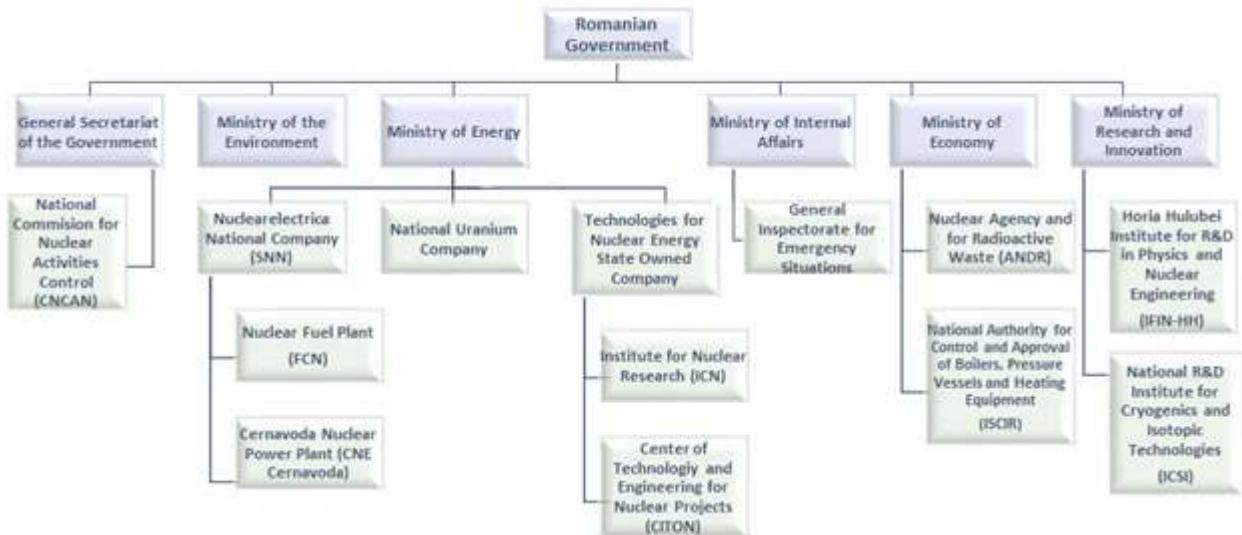


Figure 15 Main actors involved in the Romanian nuclear programme Ref. IAEA Country Nuclear Power Profiles [82]

6.2.2.2 Overview of legislative and regulatory Framework

The legal framework for the licensing process in Romania is based around the [Law no. 111/1996](#) on the safe deployment, regulation, licensing and control of nuclear activities, republished in the Official Gazette 552/27.06.2006 [94]. This law defines roles, duties and responsibilities of organizations involved in the licensing process. The Article 7 of the Law no.111/1996 establishes CNCAN as responsible for the regulation, licensing and control of the nuclear installations, nuclear materials and related activities. CNCAN is also in charge for inspections of nuclear facilities to check the compliance with the nuclear safety requirements established in the CNCAN regulations.

These regulations provide detailed requirements and support for the licensing and control activities.

The licensing requirements and the licensing process are set in the CNCAN Regulation on the licensing of nuclear installation (NSN-22). The CNCAN regulatory requirements, criteria and conditions for the licensing of a nuclear installation are derived from: Romanian regulations, regulatory guides, IAEA Safety Standards and Guides, Safety Reports, Safety practice Documents and TECDOCs, ICRP recommendations, applicable codes and standards (CSA, ANSI, ASME, IEEE, etc.), safety related documents prepared by the licensee and accepted or approved by CNCAN (Safety Analysis Reports, Safety Design Guides, technical basis documents, etc.). The documents containing requirements used by CNCAN in the licensing process are shown in Table 9. Specific Requirements for operating and management personnel applicable to nuclear installations, research reactors and nuclear power plants are reported in NSN.14 rev.1 and in NSN 23.

After Fukushima Daiichi accident, CNCAN has developed the following new regulations and regulatory guides to implement the lesson learnt: a regulation on the response to transients, accidents and emergency situations at nuclear power plants (NSN-07), a regulation on nuclear safety requirements on the protection of nuclear installations against external events of natural origin (NSN-06), a regulation on the operational limits and conditions (OLCs) for nuclear installations (NSN-05) and a regulation on the nuclear safety policy and on the independent nuclear safety oversight (NSN-20). It is pointed out that in the regulation NSN-21 and the guide GSN-03 are set up new quantitative nuclear safety objectives.

The relevant regulations and guidance published by CNCAN are listed in Table 9.

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Table 9 Relevant regulations and guidance published by CNCAN

Relevant regulations and guidance published by CNCAN	
NSN-05 - Nuclear safety requirements on the operational limits and conditions for nuclear installations (2015) [95]	
NSN-06 - Nuclear Safety Requirements for the protection of nuclear installations against external events of natural origin (2015) [96]	
NSN-07 (rev.1) - Nuclear Safety Requirements on the response to transients, accident management and on-site emergency preparedness and response for NPPs (2020) [97]	
NSN-14 (rev.1) - Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations; (2014) [98]	
NSN-20 - Regulation on the nuclear safety policy and independent nuclear safety oversight for nuclear installations (2015) [99]	
NSN-21 – (rev.1) Fundamental nuclear safety requirements for nuclear installations (2020) [100]	
NSN-22 - Regulation on the licensing of nuclear installations (2019) [101]	
GSN-03 - Guide on fulfilling the overall nuclear safety objective set in the fundamental nuclear safety requirements for nuclear installations (2018) [102]	
GSN-04 - Guide on the format and content of the final safety analysis report for nuclear power plants (2015) [103]	
Regulation on the management of emergency situations specific to nuclear or radiological risk (2018) [104]	
Regulation on the prevention, preparedness and response in case of emergency situations for the emergency preparedness categories I, II and III (2018) [105]	
Regulation on the prevention, preparedness and response in case of emergency situations for the emergency preparedness categories IV and VI (2018) [106]	

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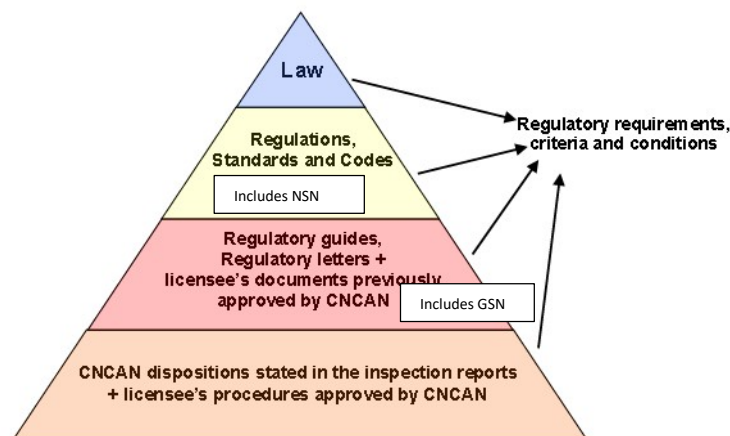


Figure 16 Hierarchical Organization of Documents containing requirements used by CNCAN in the licensing process Ref [90]

6.2.3 Licensing Process

The licensing process of a nuclear plant is carried out according to Articles 17 and 19 of the Law no.111/1996. According to Article 8 of the Law no 111/1996, the authorization phases of a nuclear facility shall be the following:

- a) design;
- b) placement;
- c) siting;

- d) construction and/or assembly;
- e) commissioning;
- f) trial run;
- g) operation;
- h) repair and/or maintenance;
- i) modification;
- j) conservation;
- k) decommissioning.

An authorization is required for each step of the process.

CNCAN will require from the holder of the license or the applicant the documents specified in the regulations and license conditions to demonstrate the license condition compliance arrangements and proper management of the safety. An example of documentation issued by the applicant in the licensing process is shown in Figure 17.

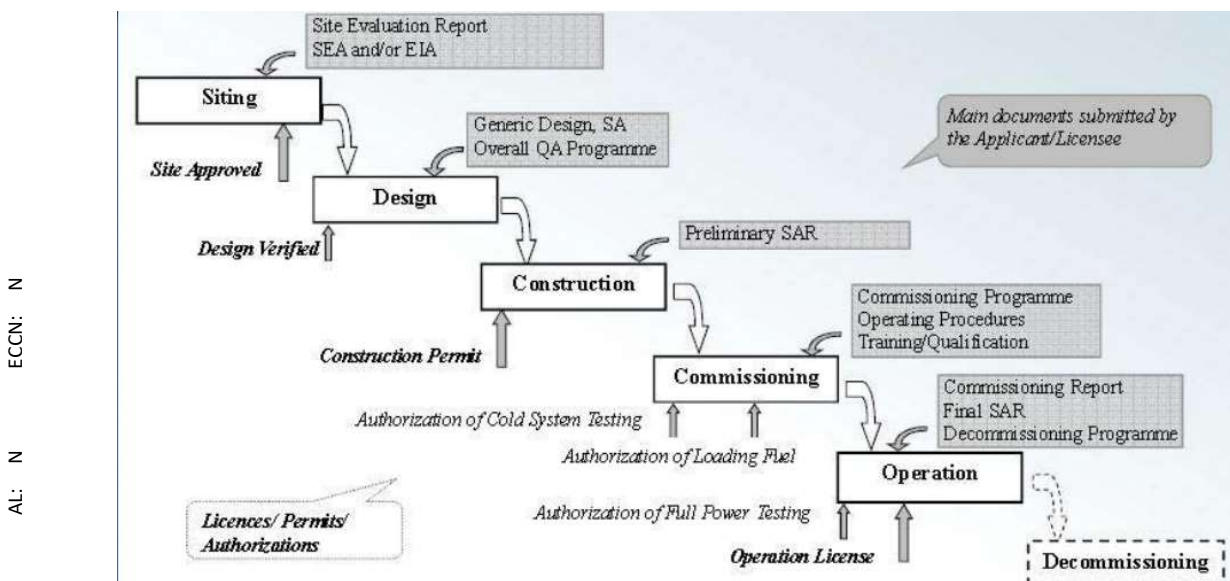


Figure 17 Licensing Steps and relevant licensing documents Ref [91]

6.2.3.1 Qualification of the applicant

Article 18 of the Law no 111/1996 establishes the requirements of the applicant to obtain the license; these are detailed in the specific regulations issued under the provisions of Article 5 of the Law no 111/1996.

In compliance with the Law no 111/1996 a license for the quality management system (QMS) needs to be released by CNCAN as pre-condition for the release of the design, siting, construction, commission, operation and decommissioning license. The licensing of the Quality management System is mandatory not only for the operators but also for the suppliers of products, services and systems classified as important for nuclear safety.

The role of “applicant for the design authorization” may be assumed by:

- a legally established design consortium with one QMS license or
- all organization performing project design activities including supporting activities (e.g., codes development or V&V, analysis, experimentation) having a separate QMS license (if the consortium is not a legal entity).

Each organization involved in the design activities shall have to be licensed by CNCAN for design activities (NMC 05). In addition, if a company coordinates the whole set of activities, acting as design manager, the company has to apply also to project management for design activities (NMC 02). In general, for commercial power plants, the license applicant for the design certification is the owner of the design, which corresponds to the plant vendor, thereby being the entity holding the intellectual property rights and covering the costs of the design certification process, because of the economic advantage deriving from selling the plant. The applicant of the design certification may be different than the applicant for construction.

The nature of the applicant can evolve in the different licensing steps (e.g., engaging with other entities that will take the role of license holder).

6.2.3.2 Role of Regulatory Body

The main responsibilities of the regulatory body are the following:

- Development and updating of regulations and guides;
- Regulatory Review and assessment of the licensing documentation;
- Regulatory Inspections;
- Release of authorizations in the licensing procedures;
- Emergency preparedness and response;
- Communication and Consultation activities with interested parties.

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In carrying out its duties, the regulatory body may make use of technical and scientific expertise of a Technical Support Organization (TSO) as explained in the following Section. The Romanian national nuclear regulatory body is CNCAN according to the Law no.111/1996.

6.2.3.3 Role of Technical Support Organization (TSO)

The Technical Support Organization (TSO) provides technical and scientific expertise in nuclear and radiation safety matters to the regulatory body, as necessary for the regulatory functions. The TSO supports the regulatory body also in security and safeguards aspects. The description of the technical and scientific supporting activities of the TSO to a regulatory body is reported in IAEA-TEC-DOC-1835. The document describes also the services provided to the regulatory body and the processes needed to maintain the required level of the expertise. The TSO can be an internal organizational unit of the regulatory body or external to the regulatory body. The general interaction of the TSO with the regulatory body and other actors involved in support of regulatory functions is shown in Figure 18.

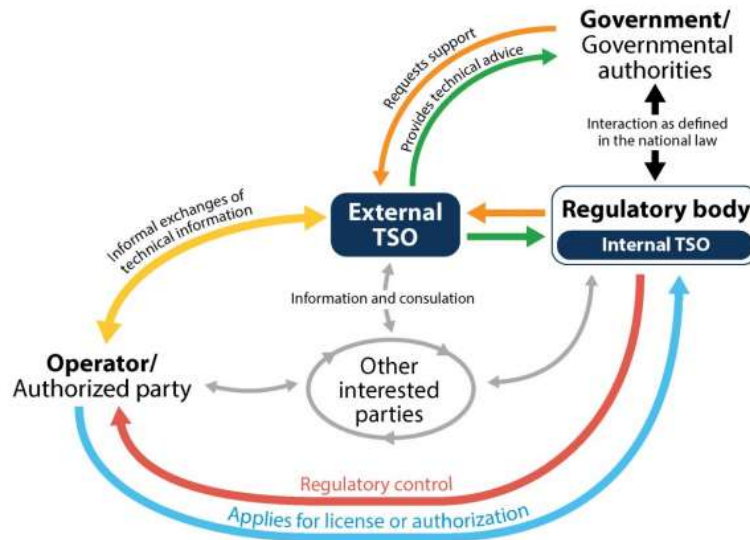


Figure 18 Illustration of general interactions of the TSO with the regulatory body and other interested parties in support of regulatory functions [107]

The TSO is involved in supporting activities to the regulatory body and in expertise gaining, maintaining and developing, as indicated in [107]. From the several activities carried out by a TSO, there are also research and development activities, needed to develop knowledge and expertise, and the review of safety assessment. For example, the TSO is involved in activities such as thermohydraulic safety analysis, performance and reliability analysis, analysis of accidents. The TSO also provides technical support to develop or update national regulations and may support inspection activities carried out by regulators. TSO's activities are supervised by the regulatory body.

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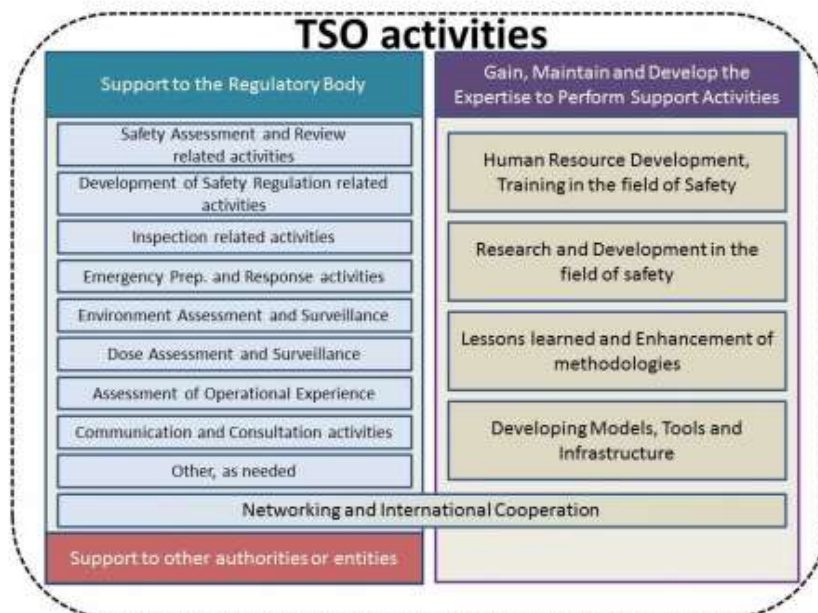


Figure 19 TSO activities [107].

6.2.3.4 Involvement of Applicant, Regulatory body and TSO during the licensing procedure

During the licensing process, the involvement of applicant, regulatory body and TSO can be resumed as shown in Figure 20.

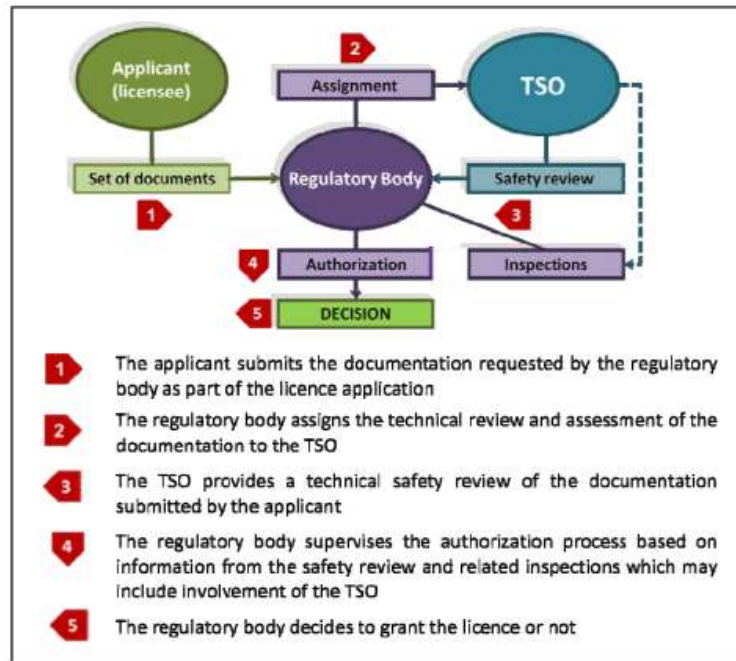


Figure 20 Involvement of applicant, regulatory body and TSO in the licensing procedure [107].

6.2.4 Safety Concept for NPP

The regulatory authority responsible for nuclear safety in Romania is the National Commission for Nuclear Activities Control (CNCAN) as provided in 6.2.3.2. Documents demonstrating that the safety is ensured in normal, off-normal and accident conditions for NPP need to be prepared in all licensing steps (with different levels of detail) as provided in the sections here after provided.

6.2.4.1 Safety functions

To ensure safety, the following fundamental safety functions shall be ensured in operational states, in and following a design basis accident and, to the extent practicable, on the occurrence of those selected accident conditions that are beyond the design basis accidents:

- Control of the reactivity (reactor power);
- Removal of heat from the core (cooling the fuel);
- Confinement of radioactive materials (within the appropriate barriers) and control of operational discharges, as well as limitation of accidental releases.

Once a release of radioactive material is foreseen, either as a routine part of normal operation or as the consequence of an accident sequence, this release shall be controlled for the normal operation case and limited or delayed, as much as possible, for the accident condition case.

Incidents or accidents may therefore be initiated whenever a failure, malfunction or faulty operation of a system or component endangers the fulfilment of one of these fundamental safety functions.

A systematic approach shall be followed to identify the structures, systems and components that are necessary to fulfil these safety functions at the various times of a nuclear power plant operation following a PIE.

6.2.4.2 Design certification

As first step of the licensing process, the applicant will submit a Licensing Basis Document to CNCAN. This document will be based on Romanian regulations and other international regulations, industrial codes and standards. For design phase the main regulatory requirements are indicated in NSN-02 and NS03.

An updating of FSR/FSAR will be provided to include the results of the trial operation and an updating on the report of design modification. The assessment of unplanned events is included. The operating license is reviewed periodically.

6.2.5 Environmental Protection and Industrial Emissions for NPP

The following regulations and guidelines apply to nuclear power plants in Romania regarding environmental protection and industrial emissions:

- N
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- [Law no. 278/2013](#) on industrial emissions: This law establishes rules for preventing and controlling emissions of pollutants into the air, water, and soil from industrial activities. Nuclear power plants in Romania must comply with the emission limit values specified in this law.
 - [Government Decision no. 860/2002](#) on the approval of the Norms for the Limitation of Environmental Radioactive Releases from Nuclear Facilities: This decision establishes the regulatory framework for limiting environmental radioactive releases from nuclear facilities in Romania.
 - [Government Decision no. 938/2005](#) on the approval of the Norms for the Limitation of the Consequences of Accidents in Nuclear Power Plants: This decision establishes the regulatory framework for limiting the consequences of accidents in nuclear power plants in Romania.
 - Environmental permit: Nuclear power plants in Romania must obtain an environmental permit from the Ministry of Environment and Climate Change. The permit outlines the environmental conditions that the plant must comply with.
 - Environmental monitoring: Nuclear power plants in Romania must conduct environmental monitoring to assess the impact of plant operations on the environment. This includes monitoring of air, water, and soil quality, as well as radiation levels in the environment.
 - [International Atomic Energy Agency \(IAEA\) guidelines](#): Romania is a signatory to several international agreements and guidelines established by the IAEA. These guidelines provide additional guidance for nuclear power plant operators regarding environmental protection and industrial emissions.

In summary, nuclear power plants in Romania must comply with the country's regulatory framework for environmental protection and industrial emissions, as well as international guidelines established by the IAEA. Environmental monitoring and reporting are critical components of compliance with these regulations, and nuclear power plant operators must work to minimize the impact of their operations on the environment.

6.2.6 Hazards and Risks for NPP

6.2.6.1 Internal Hazards

The design shall take into consideration internal events such as:

- Compartment over-pressurization, pipe whipping or jet impingement forces due to leaks or breaks of pipes;
- Internal flooding;
- Internal missiles;
- Load drop;
- Internal explosion;
- Fire;
- Specific loads and environmental conditions (temperature, pressure, humidity, radiation) imposed on structures or components

It shall be demonstrated that these events do not prevent safety-related functions of safety classified equipment, supports for this equipment, and associated building structures.

6.2.6.2 External Hazards

The external hazards are those natural or man-made hazards that originate externally to the installation. Unlike internal hazards, external hazards may simultaneously affect the whole facility, including the redundant safety systems and non-safety systems. In addition, the potential for failures to human intervention may occur. For HPP integrated within a NPP, if these plants share common equipment or services, the proper interface arrangements need to be analyzed as well as potential domino effects.

The generic list of external hazards to be considered is reported in [108]. It includes natural and man-made hazards like, for example, the following:

- Natural external events:
 - Extreme weather conditions (temperature, wind, snow, rain);
 - Earthquakes;
 - External flooding;
 - Cyclones (hurricanes, tornadoes and tropical typhoons);
 - Ice formation;
 - Lightning;
 - Drought.
- Human induced events:
 - Aircraft crashes;
 - Explosions (deflagrations and detonations) with or without fire, with or without secondary missiles;
 - Release of hazardous gases (asphyxiant, toxic) from off-site and on-site storage;
 - Release of radioactive material from off-site sources;
 - Release of corrosive gases and liquids from off-site and on-site storage;
 - Fire generated from off-site sources;
 - Electromagnetic interference from off the site and on the site;

Any combination of the above as a result of a common initiating event (such as an explosion with fire and release of hazardous gases and smoke).

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6.2.7 Emergency provisions and response organization for NPP

In Romania, the emergency provisions and response organization for nuclear power plants are established by the [National Emergency Management System \(NEMS\)](#) and the [National Commission for Nuclear Activities Control \(CNCAN\)](#). The NEMS is responsible for coordinating the national emergency response system, while the CNCAN regulates the nuclear industry, including nuclear power plants.

The emergency provisions and response organization for nuclear power plants in Romania include:

- **Emergency Planning Zones:** These are areas surrounding the nuclear power plant where emergency response measures and plans are developed and implemented. In Romania, the Emergency Planning Zones extend to a radius of 20 kilometers around the power plant.
- **Emergency Response Centers:** These are centers that are established to coordinate the emergency response in the event of an accident at a nuclear power plant. In Romania, the Emergency Response Centers are located at the power plant and the NEMS headquarters in Bucharest.
- **Emergency Response Teams:** These are specialized teams that are trained to respond to nuclear emergencies. In Romania, the Emergency Response Teams are composed of personnel from the nuclear power plant, the CNCAN, and other emergency response agencies.
- **Early Warning Systems:** Romania has established an early warning system that can detect and alert authorities to a nuclear emergency in a timely manner.
- **Emergency Exercises and Drills:** Regular emergency exercises and drills are conducted to test the emergency provisions and response organization and to ensure that personnel are prepared to respond to a nuclear emergency.

As provided in [109], in accordance with the Law, CNCAN is empowered to issue regulations for the detailed specification of the general requirements on intervention in case of nuclear accidents. In this respect, the current specific requirements are provided in the following regulations, issued in alignment with the latest applicable international standards and European directives and reflecting the lessons learned from the Fukushima accident:

- Basic Requirements on Radiological Safety (2018);
- Regulation on the management of emergency situations specific to nuclear or radiological risk (2018);
- Regulation on the prevention, preparedness and response in case of emergency situations for the emergency preparedness categories I, II and III (2018);
- Regulation on the prevention, preparedness and response in case of emergency situations for the emergency preparedness categories IV and VI (2018);
- Fundamental Nuclear Safety Requirements (NSN-21 rev.1, 2020);
- Nuclear Safety Requirements on Preparedness for Response to Transients, Accidents and Emergencies at Nuclear Power Plants (NSN-07 rev.1, 2020).

All the requirements of the Directive concerning on-site emergency procedures and arrangements, including severe accident management guidelines or equivalent arrangements, for responding effectively to accidents in order to prevent or mitigate their consequences have been included and detailed in the nuclear safety regulations (NSN-21 rev.1 and NSN07 rev.1) and in the emergency preparedness and response regulations and licensees' compliance with these requirements is verified by CNCAN on regular basis through specific inspections, assessments and observation of emergency exercises.

6.2.8 Operation and organization for NPP

Nuclear power plants in Romania are operated by the state-owned company, [Nuclearelectrica](#).

As provided in [87], the National Company "Nuclearelectrica" SA (Societatea Nationala Nuclearelectrica SA, referred as SNN) is the owner and operator of Cernavoda NPP. The company includes two subsidiaries, one for nuclear power production (Cernavoda NPP) and one for nuclear fuel production (Nuclear Fuel Plant - FCN Pitesti), respectively. SNN is a government owned company, subordinated to the Ministry of Economy, Energy and Business Environment.

Nuclearelectrica has a comprehensive safety program in place, including regular inspections and maintenance, emergency response plans, and training for all personnel.

Roles of license holder, regulatory body and TSO in the licensing steps (that include also the operation phases) are discussed in Section 6.2.3.

6.3 Conclusions and Findings- Romania

Sections 6.1 and 6.2 provide a description of licensing policy, licensing process and related documentation to be prepared by the applicant (operator), legal framework, main actors in the licensing process, safety dossier contents, safety approach adopted, emergency provisions, operation and organization respectively for NPPs (6.2) and HPP (Section 6.1) in Romania. With reference to HPP integrated to NPP the main findings are below provided:

[N1] The integration of HPP in a NPP is not mentioned in the current Romanian legislation framework.

[N2] Currently in Romania hydrogen is produced by steam methane reforming and by-product in chlor-alkali plants and is mostly used at the place of production [110].

[N3] The Romanian Ministry of Energy is going to issue a national hydrogen strategy (expected date by 2023); this plan includes measures to develop the hydrogen supply chain in Romania, particularly for electrolyzer manufacturing. According to this strategy, clean hydrogen from renewable electricity shall be supported, involving public and private stakeholders, to outline a strategic roadmap with targets and potential funding sources [110].

[N4] The actors in the regulatory framework involved for the integration of HPP in a NPP are not mentioned in the current Romanian legislation framework as the concerned regulatory framework has not yet been established. It is expected that for the integration of HPP-NPP the actors involved could be those involved in the nuclear programme, shown in Figure 15, together with the following authorities:

- Romanian Energy Regulatory Authority (ANRE) that is involved in the development, licensing and operation of new installations for hydrogen generation;
- Local Authority / Town and Country Planning Authority that is involved in issuing regulation for the use of land, in Environmental Impact Assessment and is also the competent hazardous substance authority in relation to storage.

[N5] The relevant regulations and guidance published by CNCAN that could support the licensing of the integrated plant NPP-HPP are the following:

- NSN-22 - Regulation on the licensing of nuclear installations (2019) [101].
- NSN-14 (rev.1) - Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations; (2014) [98].
- GSN-03 - Guide on fulfilling the overall nuclear safety objective set in the fundamental nuclear safety requirements for nuclear installations (2018) [102].

- GSN-04 - Guide on the format and content of the final safety analysis report for nuclear power plants (2015) [103].

[N6] The integration of HPP in a NPP is not mentioned in Law no.111/1996. Anyway if the HPP is integrated into a new installation, according to Article 8 of the Law no 111/1996, the design, placement, siting, construction and commissioning of the installation is subject to authorization. To obtain this authorization, the operator is requested to demonstrate that the safety of the facility or proposed activity is ensured in normal, incidental and accidental conditions and to give evidence of compliance with regulatory requirements. Any new technical solutions adopted need to be proven or qualified by experience or testing or both and is capable of achieving the required level of safety.

[N7] The integration of HPP into an existing NPP implies a modification of the basis licensing document. The licensee is obliged to notify the Regulatory Body of any modifications impacts the safety of the facility. In particular the integration of HPP into a NPP implies the need to update the information/documents provided in support of the application and those used by the Regulatory Body in the review and assessment process, which together form the basis for issuing the license:

- A sufficiently detailed description of the installation, its location and its activities, including a description of the site boundaries.
- The maximum allowable inventories of radiation sources and hazardous substances covered by authorizations.
- Any limits on operation and use (such as dose and discharge limits).
- Arrangements for emergency preparedness.
- List of the structures, systems and components important to safety (safety related).
- Updating of the Final Safety Analyses Report (FSAR) before to start operation of the integrated plant HPP-NPP.
- Fire protection plans.
- Operating manuals and procedures/instructions.
- Training and qualification plans for operation personnel.
- Commissioning program and commissioning reports.
- Emergency plan and procedures.

[N8] The HPP integrated within a NPP is to be considered as part of the nuclear installation. A detailed nuclear safety analysis should be required of all nuclear and conventional (industrial) systems in order to ensure that the nuclear safety functions are ensured and all the potential impacts due to potential missiles, security issues, flooding events, or any other incident/accident that may influence a component involved in the safety function are assessed: the nuclear safety functions shall be ensured in operational states, in and following a design basis accident and, to the extent practicable, on the occurrence of beyond the design basis accidents

[N9] The integration of HPP within a NPP implies a modification of the basis licence documents. In case of significant modification to safety the following information/documents are requested to the licensee:

- Review the design basis for all safety related systems.
- Review of the safety analysis (chapter 15 of the PSAR) is requested to confirm that sufficient analyses are performed to identify all design requirements for safety related systems arising from consideration of internal plant events including also leakage or failure of a system carrying hydrogen and release of <<ground-hugging gases>>.
- Review of the acceptability of design basis external events (earthquakes, floods, high winds, toxic gases, projectiles, etc.).
- Review of the impact of modifications on safety analysis, reliability analysis, and on the compliance with the regulatory requirements.

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The updated safety assessment report shall provide the following information:

- Description of the facility and its operation.
- Presentation of modification to NPP introduced by HPP and evaluation of their impact on the safety.
- Safety Assessment of the plant systems to confirm that they assure an acceptable safety margin during normal operation, transients and accidents and the existence of the proper technical and administrative measures to cope with all events, including beyond-design basis events.
- Description of the technical limits and conditions.
- Description of the emergency plan to be implemented up to operation of the integrated plant HPP-NPP.

[N10] The licensing process and the operation of HPP integrated within NPP should consider the regulation on licensing of nuclear installations (NSN-22) which establishes that operating licenses for nuclear installations are granted for the periods estimated by the applicant, taking into account the design basis, the ageing mechanisms, the operational experience available and the possibility for refurbishment. The main document submitted to CNCAN by the licensee for justifying long term/extended operation is the updated final safety analysis report. This report contains the safety demonstration for the plant, taking into account the physical state of the installation, the impact of ageing, the safety upgrades performed and the current safety requirements and standards.

H1 In general, there is the need to better consolidate of the legal framework, intensifying dedication to research and innovation (in both state-owned and private companies), increasing and diversifying funding sources and developing educational resources, as well as supporting projects that promote the increased use of hydrogen.

H2 For hydrogen production facilities in Romania, relevant guides, regulations, codes, and standards may be established by the Romanian Ministry of Energy. It is important to note that the specific codes, standards, and regulations applicable to a given hydrogen production facility in Romania depend on the location and operating conditions.

H3 Hydrogen production plants in Romania need to comply with the country's regulatory framework for environmental protection and industrial emissions, as well as with EU regulations. Environmental monitoring and reporting would be critical components of compliance with these regulations, and hydrogen power plant operators would need to work to minimize the impact of their operations on the environment.

In summary, in Romania:

- The regulation related to the Nuclear Power Plants follows the rules set by the National Commission for Nuclear Activities Control (CNCAN), having decades of operating experience in the Country.
- The regulation related to the Hydrogen Production Plant is less experienced and follows by law the rules set by the Romanian Energy Regulatory Authority (ANRE) generally applicable to the electricity and gas sectors.

In principle, the coupling of a NPP and HPP in Romania would imply to fulfill the complete list of requirements and rules set by both these regulatory entities, conducting a comprehensive feasibility study to evaluate the technical, economic, and environmental viability.

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7 Analysis for Spain

The energy system in Spain is regulated by the Ministry for the Ecological Transition (MITECO) and by the National Commission on Markets and Competition (CNMC). MITECO holds regulatory powers, whereas CNMC is in charge of supervision, control and information gathering in order to promote the proper functioning of the system.

The energy policy in Spain has tended to progressively liberalize the markets with the main target of decreasing energy prices, ensuring the energy supply and quality, improving energy efficiency, reducing consumption, and protecting the environment. This liberalization of the system began with Law No. 54 of 27 November 1997 on the electricity sector, and with Law No. 34 of 7 October 1998 on the hydrocarbon sector. In 2013, a new Law on the Electric Sector (Law No. 24 of 26 December 2013) replaced the previous law, after a deep reform of the system aimed to ensure the economic and financial sustainability of the system.

Spain is relatively dependent on foreign energy resources. Therefore, renewable energy and nuclear energy have become of key importance in the challenge of reducing Spain's dependence on foreign resources, in order to foster the guarantee of supply, which is one of the main goals of its energy policy.

Regarding nuclear energy, Spain has currently seven power reactors in operation in five sites: Almaraz I and II, Ascó I and II, Cofrentes, Trillo and Vandellós II. In 2021, nuclear energy was the second source of electricity in Spain with a share of 20,8 percent. The first source was wind energy with 23 percent of the total electricity generation. Nuclear power, with half a century of operation in Spain, has been producing more than 20 percent of all the electricity consumed in Spain for more than ten years in a row.

Regarding Hydrogen Production, there is a regulatory framework that is still very limited and in continuous development in Spain. The application of other pre-existing rules therefore takes precedence. However, the influence of some European directives suggests that it will soon have a specific legislative framework.

Currently, hydrogen production is considered a classified industrial quality activity within the chemical industry to produce inorganic gas. Therefore, the currently applicable environmental and industrial regulations do not consider that there is a link between hydrogen production and energy generation or storage.

7.1 Hydrogen Production Plant

7.1.1 General description of HPP Licensing policy

In Spain there is no specific legislation for hydrogen production plant (HPP) and it is considered as chemical/industrial facility as any other inorganic gas production facility, Furthermore, there is not differentiation for the method of production of hydrogen (PEM, alkaline, reforming...), the daily amount produced, the storage capacity or the purpose of the gas. This consideration restricts this type of infrastructure to be constructed on industrial soil. Traditionally, the production of hydrogen in large quantities has taken place through industrial processes such as steam methane reforming (SMR), and the limitation of these activities to industrial zones is understandable.

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In Spain legislation has three main levels: national legislation, regional legislation, and local legislation. The three levels apply and need to provide authorizations to the implementation of a hydrogen production facility, regardless of the method of production of hydrogen.

The licensing process is regulated mainly by:

- a) [Royal Decree 1/2016 \[111\]](#) that incorporates European Union Directive 2010/75/EU on integrated pollution prevention and control.
- b) [Law 21/2013 \[112\]](#) on Environmental Assessment that transposes Directives 2011/92/EU and 2001/42/CE.
- c) [Royal Decree 1196/2003 \[113\]](#) and [Royal Decree 840/2015 \[114\]](#) on Control of major accident hazards that transpose Directive 2012/18/EU (Seveso Directive) [1].

This is national legislation that has an equivalent law for each region in Spain (Autonomous community). In addition, each local administration (city council) has its own legislation for obtaining licenses for the construction of facilities, or for starting a new economic activity.

Figure 21 summarizes the licensing process for a HPP, that, with the current legislation, is the same that for any chemical plant.

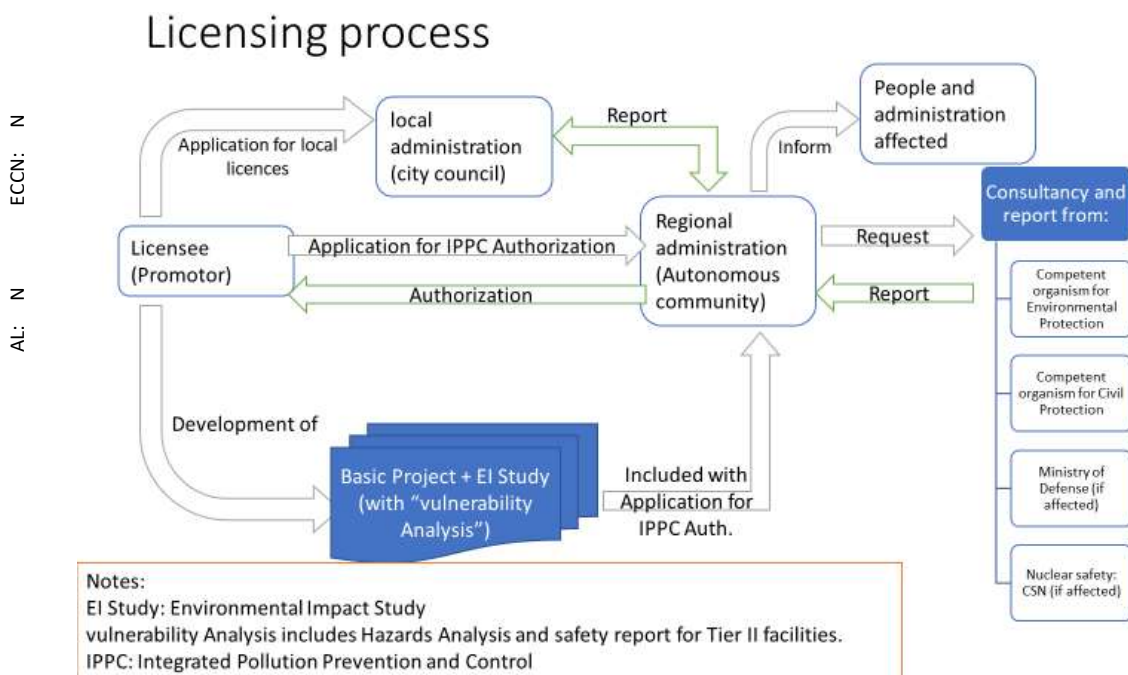


Figure 21: Overview of licensing process for HPP in Spain

Main steps of the licensing process are:

1. Development of project with information related to: activities, facilities, processes, kind of production, environmental study, raw materials, substances and energy generated, kind and quantities of emissions, measures for the prevention and management of waste and control systems for emission and discharges.
2. Development of construction project and application for licenses to the local administration (city council).
3. Urbanistic report from city council (according [Urban Land and Rehabilitation Law RDL 7/2015 \[115\]](#))

4. Application for Integrated Pollution Prevention and Control (IPPC) authorization from competent authority (Regional Level) when H₂ production is at industrial scale as required in [Royal Decree 1/2016](#) [111]. This is based in the technical project developed. Regarding the production process it should be justified that the Best Available Techniques (BAT) are used according to BAT reference documents. In Spain, the minister for Ecological transition (MITECO) is responsible of provide this BAT reference documents to the industry and regional environmental authorities. They can be found in this page: [BAT reference documents | Eippcb \(europa.eu\)](#). The environmental study (as required in [Law 21/2013](#) [112]) should be included in the application for IPPC authorization. [Law 21/2013](#) [112] was modify by Law 9/2018 [116] in order to introduce modifications of Directive 2014/52/EU to 2011/92/EU. One of the modifications requires to include in the environmental assessment an specific point related to “vulnerability Analysis” of the project to major accident hazards. So, for obtaining the authorization is required to satisfy Seveso Directive.
5. Regional administration should inform to people and other administration affected by the project.
6. Regional administration should request the required reports to the competent organisms in each case to provide the authorization, including the environmental impact assessment.
7. Obtainment of business activity license and authorization from city council.
8. Resolution from the regional administration to the IPPC authorization application. If the authorization is provided the contents of the authorization include the conditions to satisfy, such as emissions limits, and controls and measures to be implemented.

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7.1.2 Safety concept for HPP

Regarding safety three aspects can be considered:

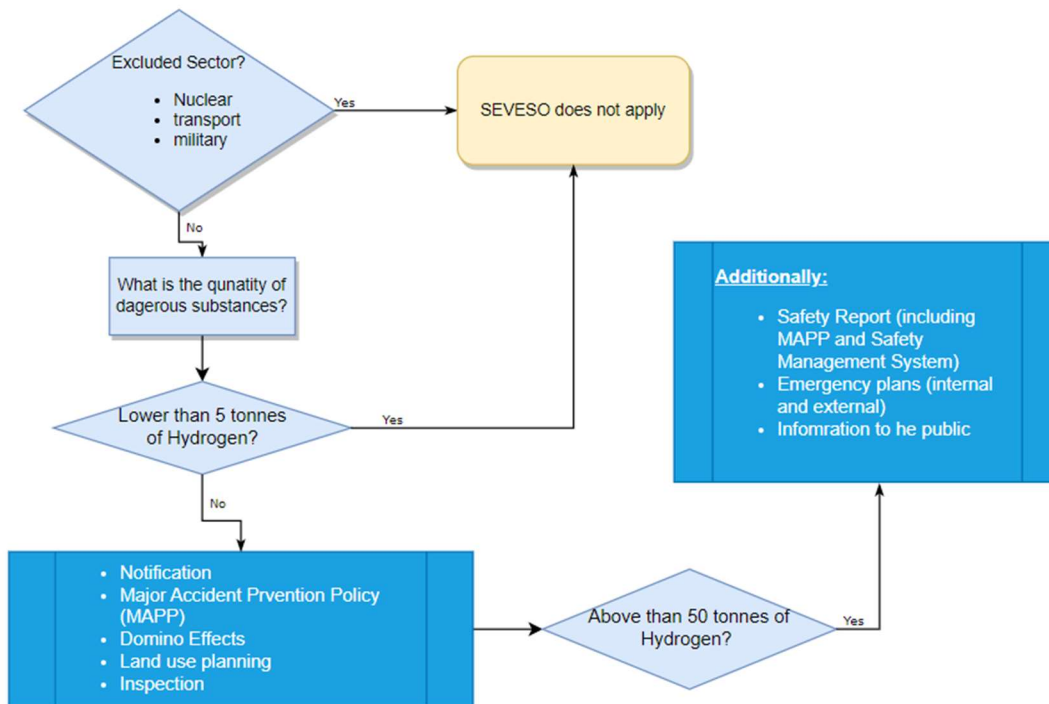
1. Control of major accident hazards
2. Occupational Health and Safety
3. Product safety

7.1.2.1 Control of major accident hazards

The control of major accident hazards is regulated by [Royal Decree 840/2015](#) [114] that transposes partially Directive 2012/18/EU (Seveso Directive) [1].

In the “vulnerability Analysis” included in the environmental study should be collected and analyzed all the information required by this Royal Decree [114] (equivalent to Seveso Directive) related to the amount of dangerous substances present. Depending on the amount of dangerous substances present, establishments are categorized in lower and upper tier, the latter are subject to more stringent requirements.

The obligations for the HPP licensee are the same that defined in Seveso Directive [1] (see chapter 2.1.4) and figure .



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Figure 22: Flowchart for the application of Seveso Directive for Hydrogen facilities

One important aspect to consider is the called “Domino effects” related to the proximity of other facility with specific hazards. In this case the nuclear power plant should be considered. The operators must exchange information and cooperate in risk management, emergency response and public information.

The safety report must demonstrate that:

- A Major Accident Prevention Policy has been established through a Safety Management System.
- Identification of Hazards has been performed.
- Analysis and Assessment of Risk has been performed and adequate Prevention/Limitation Measures are implemented.
- The design, construction, operation and maintenance of any installation, storage area, equipment and infrastructure linked to its operation, which are related to the risk of a major accident in the establishment, are sufficiently safe and reliable.
- Internal Emergency Plans has been elaborated and information for elaboration of external emergency plans provided.
- Information for Land-use Planning has been provided.

7.1.2.2 Occupational Health and Safety

Law 31/1995 on the Prevention of Occupational Risks [117] determines the basic body of guarantees and precise responsibilities to establish an adequate level of protection of workers' health against the risks arising from working conditions. This Law transposes 89/391/EEC Occupational Health and Safety Framework Directive.

According to Article 6, specific regulatory rules should set the minimum measures to be taken for the proper protection of workers. These include those aimed at ensuring the protection of workers against the risks arising from explosive atmospheres in the workplace. This risk is the most relevant for an HPP. It is also the main risk of a HPP that is not included in the risks of a nuclear power plant.

The specific regulatory rule for the protection of the health and safety of workers exposed to the risks from explosive atmospheres in the workplace is [Royal Decree 681/2003 \[118\]](#) that transposes directive 1999/92/EC.

For other risks related to industrial facilities there are specific regulatory rules that also transposes specific European directives and are considered in a nuclear power plant.

Equivalent Spanish regulation to OHS European Directives



Figure 23: Equivalent Spanish regulation to Occupational Health and Safety (OHS) European Directives

7.1.2.3 Product safety

Regarding product safety regulation the European directives and approach explained in chapter 2.1.2.2 is transposed to Spanish regulation in the form of Royal Decrees. Nex table shows some of the transposed directives.

Table 10: Spanish equivalence of Product Safety European Directives

European Directive	Spanish Royal Decree
2001/95/EC General product safety	Royal Decree 1801/2003 on general Product Safety
2014/34/EU ATEX Product	Royal Decree 144/2016 ATEX products
2014/68/EU Pressure Equipment	Royal Decree 709/2015 Pressure equipment
2006/42/EC Machines	Royal Decree 1644/2008 Machines

7.1.2.3.1 Product specific standards

Standard UNE-ISO 22734-1:2008 [119] defines the construction, safety and performance requirements of packaged or factory matched hydrogen gas generation appliances, using electrochemical reactions to electrolyze water to produce hydrogen and oxygen gas. This standard is intended to be used for certification purposes. This standard is now replaced by ISO 22734:2019 [120] and reference other documents as source of requirements.

Section 4 of the standard contains the requirements regarding operating conditions, risk management, mechanical equipment, electrical equipment, wiring and ventilation, control systems, and ion transport medium. Specific aspect regarding safety is considered for control systems as the safety control circuit, control function in the event of failure, the use of programmable electronic equipment, interconnected installations, safety components, alarms, and the case of remote-control systems.

In section 5 of the standard, test methods are provided for the qualification of the equipment.

7.1.3 Environmental Protection and Industrial Emissions

In Spain environmental protection and industrial emissions is regulated at national level by:

- [Royal Decree 1/2016](#) [111] that incorporates European Union Directive [2010/75/EU](#) [2] on integrated pollution prevention and control, and
- [Law 21/2013](#) [112] on Environmental Assessment that transposes Directive [2011/92/EU](#) [3] and 2001/42/CE.

For this reason, the general principles of the obligations for operators of plants and the requirements for the environmental impact assessment are the same that those defined in European directives and explained in chapter 2.1.3.

7.1.3.1 Chemical emissions

Chemical emissions are regulated at national level by the environmental protection and industrial emissions legislation indicated in section 7.1.3

In addition, Spain has transposed EU rule REACH (1907/2006 and 453/2010) to Spanish regulation in [Royal Decree 1802/2008](#) [121] and [Royal Decree 430/2022](#) [122], so principles explained in chapter 2.1.3 regarding registration, evaluation, authorization and restriction of chemical substances are also applicable to Spain.

7.1.3.2 Heat discharge

Heat discharge is considered pollution and consequently is regulated at national level by the environmental protection and industrial emissions legislation indicated in section 7.1.3

7.1.4 External Hazards and Risks

[Royal decree 1196/2003](#) [113] and [Royal Decree 840/2015](#) [114] on Control of major accident hazards require to the plant operator of facilities which store more than 5 tonnes of Hydrogen to implement a Major Accident Prevention Policy through a Safety Management System. The minimal content is defined in [Royal decree 1196/2003](#) [113] and consist of:

- a) Organization and staff.
- b) Identification and evaluation of major-accident risks.
- c) Control of the operation.
- d) Adaptation of modifications.
- e) Planning for emergency situations.
- f) Monitoring of the objectives set.

g) Audit and review.

Point b) also includes the identification and evaluation of external hazards and risks.

7.1.4.1 External Events and accident scenarios

The following requirements applies to facilities which store more than 5 tonnes of Hydrogen.

The Safety Management System required by [Royal decree 1196/2003 \[113\]](#), requires developing a methodology for the systematic identification and evaluation of internal and external risks. External risk considered should include natural risks (adverse weather conditions, floods, earthquakes), transport operations, etc.

“Domino effect” should also be considered in relation to the proximity of other facility with specific hazards. In this case the nuclear power plant should be considered. The operators must exchange information and cooperate in risk management, emergency response and public information.

In addition to prevention measures it is required to develop and internal emergency plan and for Tier II facilities (more than 50 tonnes of Hydrogen) external emergency plan

7.1.4.2 Accepted risk and evaluation methods.

According to 3.3 of [Royal decree 1196/2003 \[113\]](#), the internal emergency plan must contemplate the identification of accidents that justify its activation, based on a risk analysis.

In the case of Tier I facilities, the minimal content of the risk analysis is indicated in 3.3.1 of [Royal decree 1196/2003 \[113\]](#). In this case, risk analysis should indicate a general description of the facility with evacuation routes, location of external means, and areas where dangerous substances may be present. A brief description and justification of the principles and methodology used for risk assessment and determination of possible accidents likely to activate the self-protection plan will be included, indicating their possible consequences.

in the case of Tier II facilities risk analysis should be included in the safety report and the minimal content is indicated in 4.4 of [Royal decree 1196/2003 \[113\]](#):

- **Identification of major accident hazards:** including hazards from operations, external events, domino effect, security and other origins related with design, maintenance, etc. Those accidental hypotheses that, due to their very remote probability of occurrence, are considered very unlikely to materialize, may be discarded. This should be justify with fault tree analysis.
- **Calculation of consequences. Risk zones according to threshold values:** The calculation methodologies will be based on scientific and internationally accepted models.
- **Vulnerability Calculation:** An analysis of the vulnerability that these values represent for people, the environment and property will be carried out, using probabilistic methodologies.
- **Quantitative risk analysis (ACR):** the competent authority may require, for specific cases, an ACR, with the following content:
 - Identification of initiating events
 - Determination of the causes and frequencies of these initiating events.
 - Determination of the evolution of the initiating events until the final accidents. Quantification of the frequencies of the final accidental events.
 - Determination of the lethal consequences of final accidents, using adequate models.
 - Risk determination

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- Comparison of risk with acceptability criteria. The competent authority (Regional authority) in each case will set these criteria that will be, in any case, comparable to internationally adopted standards.
- **List of major accidents identified:** With event trees for each of them.
- **Prevention, control and mitigation measures.** It should include information on the technical parameters and technological safeguards to avoid and mitigate their consequences, as well as the procedures provided for in the internal emergency plan for said event.

7.1.5 Emergency provisions and response organization

[Royal decree 1196/2003 \[113\]](#) and [Royal Decree 840/2015 \[114\]](#) on Control of major accident hazards require to the plant operator of facilities which store more than 5 tonnes of Hydrogen to implement a Major Accident Prevention Policy through a Safety Management System. One of the elements required is related to planning for emergency situations. It includes the procedures related to its development and implementation, evaluation, and review.

These procedures determine the necessary skills and aptitudes of the personnel and the resources necessary to carry them out, taking extreme care regarding the risk identification process and the necessary measures to communicate the plans to all those who could be affected by an emergency. In general, those measures that ensure the integration of the emergency plan in the organizational structure of the establishment are included, which affects the processes and the overall content of the security management system.

7.1.6 Operation and organization

Operation and organization are considered in other important elements included in the Safety Management System required by [Royal decree 1196/2003 \[113\]](#):

- Organization and staff.
- Control of the operation.

Organization and Staff element should provide:

- Description of the functions and responsibilities of the organizational structure and detail of the operating procedures that affect the safety of its facilities and production processes.
- Definition of the training needs of personnel associated with the prevention and risk management of serious accidents at all organizational levels, as well as the organization of training activities and personnel participation.
- Identification, by the operator, of the necessary skills and abilities of his staff, ensuring continuous training for workers and subcontractors on procedures, instructions and work methods.
- Description of the organizational chart, development of the chain of command and responsibility.
- Definition of the functions, responsibility, accountability, authority, and interrelationship of all staff who carry out work that affects safety.
- Definition of procedures to ensure the participation of employees, contractors or others who may be present at the facilities, both in determining the safety policy and for its implementation.

Control of the operation:

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- Includes the development of the necessary procedures and instructions to ensure a safe design and operation of the facilities, processes, and equipment. Determination of the necessary work practices for all important safety activities, in all operating stages.
- In determining the procedures, instructions and work methods, cooperation between the people who must carry them out is contemplated, expressing them in a way that is easily understandable by them and ensuring that they are put into practice.
- The written procedures will be available to the entire staff and all the people involved, periodically evaluating them to guarantee their operability.

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7.2 Nuclear Power Plant

7.2.1 General description of NPP licensing policy

The following figure shows the current institutional framework of nuclear energy in Spain.

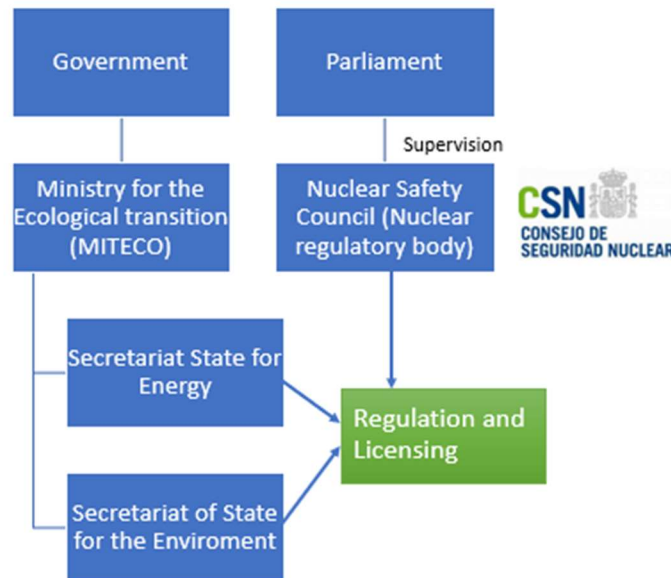


Figure 24 Current institutional framework of nuclear energy in Spain

The main entities and organizations with powers and responsibilities regarding nuclear power are the Nuclear Safety Council (CSN) and the Government through Ministry for the Ecological Transition (MITECO).

The CSN is the sole nuclear safety and radiation protection authority in Spain. The CSN is independent from the central Government and has its own legal personality and its own assets. It is accountable to the Parliament. The CSN ensures that nuclear and radioactive facilities are operated safely and establishes the preventive and corrective measures to apply in all radiological emergencies, no matter their source.

MITECO is organized in two Secretariats of State: The Secretariat of State for Energy and the Secretariat of State for the Environment. Regarding nuclear energy, MITECO holds regulatory and licensing powers, and its responsibilities include undertaking regulatory initiatives, adapting Spanish regulations to legislation of the European Union, planning the energy infrastructure, and granting nuclear facilities licensing and authorization.

Next figure shows the nuclear licensing framework that is established in [Royal Decree 1836 /1999 \[123\]](#).

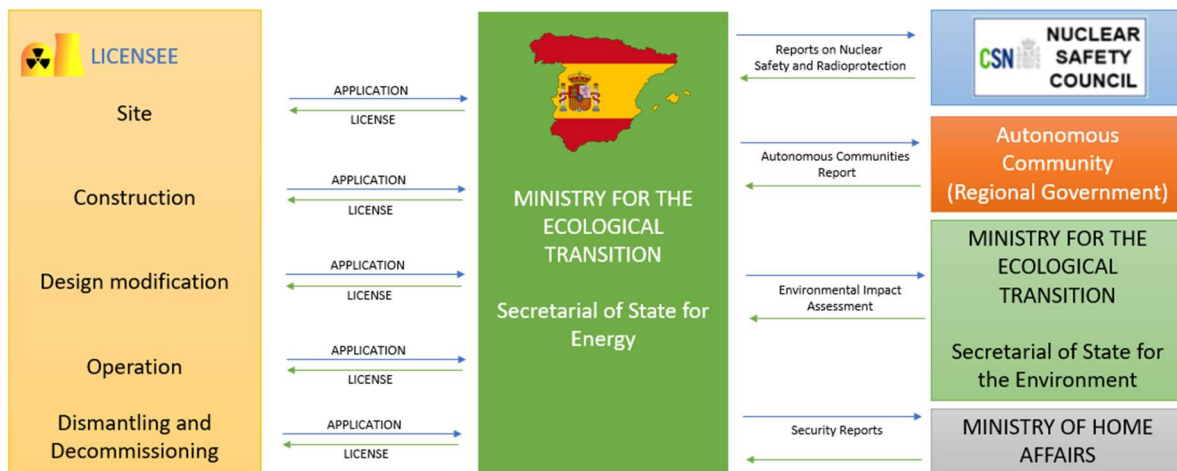


Figure 25 Nuclear licensing framework

According to this regulation, MITECO is responsible for granting the authorizations needed for the siting, construction, operation, modification, transport, dismantling and decommissioning of facilities. Such authorizations require a mandatory report on nuclear safety and radiation protection matters, issued by the CSN. This report is binding in the case of refusal and regarding the conditions it sets for granting the authorization.

To obtain these authorizations, the documents determined in the current regulations must be submitted to the licensing authorities and the suitable tests, analyses and validations must be performed. Nuclear installations require authorizations granted by other administrative bodies, belonging to local administrations, according to the rules of these bodies, although these cannot be denied or conditioned for safety related reasons. Before granting the preliminary or the dismantling license, a 30-day period is established for public hearings. During this period, anyone can present allegations. This public information process is developed jointly with the information process required for an environmental impact assessment, which must be approved by MITECO, through the Secretariat of State for the Environment.

The licenses required for physical protection of nuclear installations are regulated by [Royal Decree 1308/2011 \[124\]](#). These licenses require reports from the CSN and the Ministry of Home Affairs.

The operation authorization issued by MITECO set limits and conditions that the facilities' licensees must comply and list the Official Operating Documents (OOD's) that are mandatory. Changes to these documents (changes in the way that the facility is operated) requires the issuing of a report by the CSN.

7.2.1.1 Licensing for a design modification

The case of install a new HPP sharing resources from an existing NPP will be treated as a design modification. According to article 25 of [Royal Decree 1836 /1999 \[123\]](#), modifications to nuclear installations require analysis by the licensee to verify compliance with safety and radiological protection criteria. Safety Guide [GS 01-11 \[125\]](#) from CSN (regulatory body) provides an accepted method to perform this analysis. If modifications affect exploitation authorization criteria, the owner must obtain approval from MITECO before implementing changes. In any case, MITECO may require

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authorization for major design modifications. Article 26 outlines the necessary documentation for modification approval requests:

- a technical description of the modification,
- the safety analysis performed,
- identification of affected documents (like the operating technical specifications) and
- identification of necessary pre-restart tests

Article 27 details the documentation required for authorization of execution of the modification:

- a general description of the modification,
- applicable normative for the design, construction, assembly and test of the modification,
- basic design,
- quality assurance plan,
- analysis of compatibility and safety,
- equipment replacement plan, and budget for significant modifications.

7.2.1.2 Spanish nuclear legislation and normative

In 1964, the [law 25/1964 on nuclear energy \[126\]](#) was promulgated, forming the basis of the regulation of nuclear energy from which the rest of the laws and royal decrees has been developed. On a more detailed level, the CSN (created in 1980 as an independent nuclear safety regulatory body) approves instructions and published technical guides. In 1985 Spain signed European treaties included EURATOM wich directives has been adopted. The figure below represents the hierarchical structure of codes and standards that applies to nuclear power plants in Spain.

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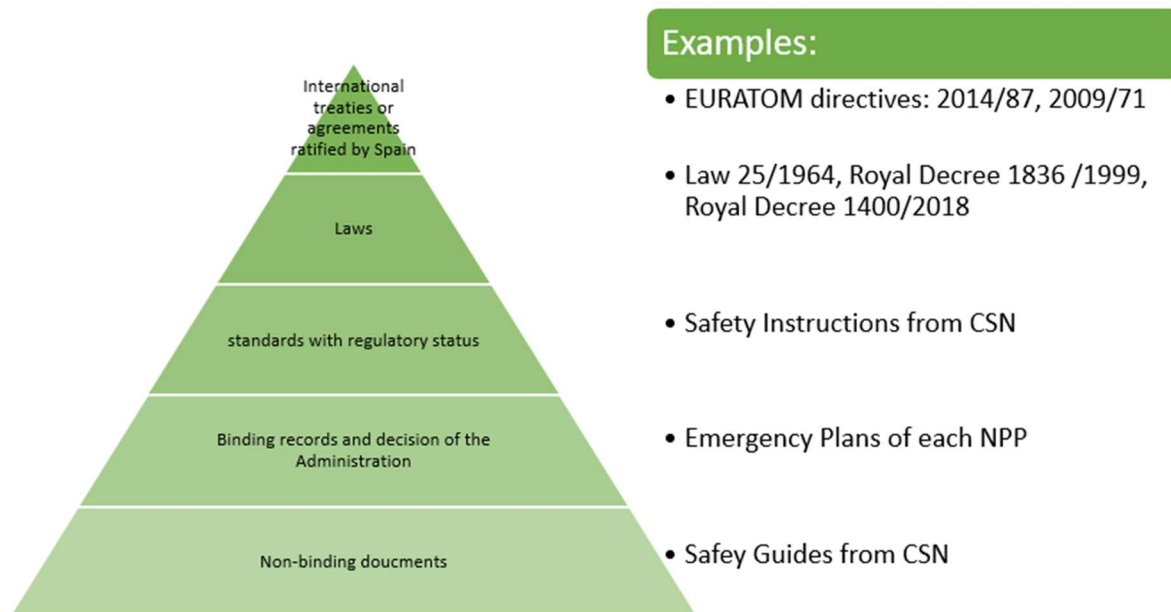


Figure 26: Hierarchical structure of codes and standards for Nuclear Power Plants.

7.2.2 Safety Concept

The present regulation on nuclear safety in nuclear facilities is approved in [Royal Decree 1400/2018 \[127\]](#) which incorporates the Directive 2014/87/EURATOM amending Directive 2009/71/EURATOM.

[Royal Decree 1400/2018](#) [127] includes not only what is required by Euratom Directives, but in addition, the basic requirements for nuclear safety applicable to nuclear facilities during their life cycle.

Regarding safety concept, it is based in the application of principle of **defense in depth** (article 11), incorporating multiple levels of protection to achieve the safety objective.

It is required a **safety assessment** (article 12) on the facility (siting, design, and operation) to confirm that an adequate level of nuclear safety has been achieved. The safety assessment must be documented in a **Safety Study** that shall explicitly identify the codes, standards and design bases that apply to all structures, systems and components that appear from the analysis to be important to safety and that need to be clearly identified and defined. The Safety Study must be kept up to date, so it reflects the analyses and modifications made to the facility and the site conditions.

Article 31 establishes requirements to modifications to the facility. The owner must ensure that no modification of the facility, individually or in conjunction with others, whether permanent or temporary, impairs the ability to operate the facility safely, ensuring compliance with the fundamental safety functions and the objective of facility safety.

In addition, [Royal Decree 1836 /1999](#) [123], chapter V, establishes requirements to modifications in the design, or in operating conditions, of the nuclear facility. In general, to obtain the authorization from the CSN and MITECO it is required a Safety Analysis of the modification. Safety Guide [GS 01-11](#) [125] provides an accepted methods to demonstrate compliance with these requirements.

7.2.3 Environmental Protection and Industrial Emissions

[Law 21/2013](#) [112] on Environmental Assessment that transposes Directive 2011/92/EU and 2001/42/CE is the application to nuclear power plants (group 3 in Annex I of the law) and Hydrogen production facilities (Group 5 in Annex I of the law).

This law requires to perform an Environmental Impact Study that shall provide information regarding the Identification, description, analysis and, where appropriate, quantification of the possible significant direct or indirect, secondary, cumulative and synergistic effects of the project on the following factors: population, human health, flora, fauna, biodiversity, geodiversity, soil, subsoil, air, water, marine environment, climate, climate change, landscape, the material assets, the cultural heritage, and the interaction between all the aforementioned factors, during the phases of execution, exploitation and, where appropriate, during the demolition or abandonment of the project.

7.2.3.1 Radiological emissions

Article 6 of [Royal Decree 1400/2018](#) [127] establishes the safety objective for nuclear facilities. This article states that the purpose of all the life cycle of a nuclear facility must aim to avoid, either by physical impossibility or being extremely unlikely with a high level of confidence:

1. early radioactive releases that require emergency measures outside the site without sufficient time for their application;
2. major radioactive emissions that require protection measures for the population that must not be limited in duration or area.

[Royal Decree 1029/2022](#) [128] on protection against the dangers arising from exposure to ionizing radiation transposes partially directive 2013/59/EU. It provides rules for protection of human health and environment from exposure to ionizing radiation.

Article 63 of [Royal Decree 1029/2022 \[128\]](#) states that the levels of activity for the emission of radioactive effluents into the environment must be such that the activity concentrations of radionuclides that they contain, and the doses that are susceptible of being received by the population, that may potentially be affected, are the lowest possible, taking economic and social factors into account. These levels must always be lesser than the specified limits for members of the public, that is 1 mSv per official year according to article 15.

CSN's safety instruction IS-26 [129] requires the development of a program for controlling effluents. Annual reports are sent periodically to Congress and Senate, European Commission, and IAEA.

CSN's Safety Guide GS-01.04 revision 1 [130] provides an accepted method to implement that program for controlling radioactive effluents from nuclear power plants.

Data on the discharge of liquid and gaseous effluent from nuclear facilities are stored in the CNS's ELGA database that is updated monthly with the information sent by the owners.

7.2.3.2 Chemical emissions

Law 21/2013 [112] of environmental evaluation applies. See chapter 7.2.3.

In addition, CSN's safety instruction IS-26 [129] establishes in chapter 4 that all potential sites for a nuclear installation must be properly evaluated. During the evaluation, the nuclear installation's possible **thermal or chemical impacts** on the site must be considered, as well as the potential interaction between those emissions and liquid or gaseous radioactive effluents. The licensee must evaluate the changes in site-related aspects during the life of the installation in order to ensure that the safety conditions stay unchanged.

7.2.3.3 Heat Discharge

See previous chapter 7.2.3.2

7.2.3.4 Other factors

Law 21/2013 [112] of environmental evaluation applies. See chapter 7.2.3.

7.2.4 External hazards and Risks

Article 18 of [Royal Decree 1400/2018 \[127\]](#) requires to the license holder to identify the postulated initiating events to be considered in the design to satisfy with safety objective of the nuclear facility.

7.2.4.1 External events and accident scenario's

Article 19 of [Royal Decree 1400/2018 \[127\]](#) requires to the license holder to:

- Verify that the installation is designed to support postulated external events in the site, so as to ensure compliance with the main safety functions.
- Analyze the design of the installation to ensure compliance with the safety objective established in Article 6 of Royal Decree 1400/2018 [127] in extreme external natural events and unintended man-made events.

7.2.4.2 Accepted risks and evaluation methods

According to article 12 of [Royal Decree 1400/2018 \[127\]](#), License holder shall complement safety assessment mentioned in 7.2.1 with a systematic approach to facility risk analysis. to verify that all possible scenarios that may result in risks, including all possible initiating events or deviations from the process, internal and external events, multiple failures, common cause failures and human errors,

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have been adequately considered in the design and operation of the facility, according with its expected frequency and estimated severity, also checking that there are adequate preventive or mitigating measures to deal with such situations.

These risk analyses must be updated appropriately to reflect the actual situation of the installation and its sitting.

[Safety Instruction IS-25](#) [131] from CSN (Spanish nuclear regulator) provide criteria and requirements for development of PSA (Probabilistic Safety Analysis, also called Probabilistic Risk Analysis) and its applications to nuclear power plants. The PSA analyzes the risks to determine the frequency of occurrence of the possible sequences of events that can lead to accidents with serious consequences in the installation under analysis or in its exterior. PSA discusses aspects of facility design, procedures, and operating practices that may cause and determine nuclear accidents. PSA should consider all internal and external events and must be kept updated by the licensee holder.

Licensee holder shall, as a result of the implementation of its PSA, have clearly identified the aspects that contribute most to the risk of its installation and will have made the modifications of design, procedures or aspects that are appropriate to reduce the risk where it is still reasonable.

7.2.4.3 Safe distance

An acceptable method for establishing the distances beyond which no adverse effect would occur is defined in [Regulatory Guide 1.91 rev.2](#) (RG 1.91) "EVALUATIONS OF EXPLOSIONS POSTULATED TO OCCUR AT NEARBY FACILITIES AND ON TRANSPORTATION ROUTES NEAR NUCLEAR POWER PLANTS" [132] from NRC. This guide can be used in Spain as Spanish nuclear regulator (NRC) accepts guidance from the countries where the plants has been designed.

RG 1.91 [132] describes the calculation of minimum safe distance based on estimates of Trinitrotoluene (TNT)-equivalent mass of potentially explosive materials. The minimum safe distance from an explosion that results in peak overpressure equal to 1.0 psi (6.9 kPa) can be calculated as:

$$R_{min} = Z * W^{1/3}$$

Where:

R_{min} = distance from explosive where overpressuere will equal 6.9 KPa (meters)

W= mass of TNT (kg)

Z= scaled distance equal to 18 (m/kg^{1/3})

The mass of TNT has long been used in stablishing safe operation distances for explosives.

Also [IAEA Safety Guide No. NS-G-3.1](#), "External Human Induced Events in Site Evaluation for Nuclear Power Plants" [133], 2002, identifies, describes, and evaluates the hazards of explosions at or near nuclear power plants. According to this guide (page 37) some countries adopt a safe distance for explosions in the range of 5-10 km.

7.2.5 Emergency provisions and response organization

Article 29 of [Royal Decree 1400/2018](#) [127] requires to the license holder to:

1. Have an internal emergency plan (PEI) as established in the Regulation on nuclear and radioactive facilities, ([Royal Decree 1836/1999](#) [123]).
2. Ensure the availability of adequate resources on site for the management of emergency conditions, as well as mechanisms to receive external assistance.

3. Establish the necessary channels and procedures to collaborate with the competent authorities in the implementation of external emergency plans, in the information to the population and in the response foreseen in these to protect the population in case of accident, in the terms provided for in Law 17/2015 [134], in [Royal Decree 1546/2004 \[135\]](#), approving the Basic Nuclear Emergency Plan (PLABEN), or in other applicable regulations.

PLABEN structures the response to nuclear emergencies into two levels of planning:

- Internal Emergency Plans (PEI) whose responsibility falls on the licensee holder of the NPP.
- External Emergency Plans (PEN) in which the responsibility for their application falls on the General State Administration with the assistance of the other public administrations, as appropriate and the necessary collaboration that must be provided by the licensee of nuclear power plants.

Each nuclear power plant has a specific PEI that details the actions, measures and responsibilities of preparation and response to the accident, to mitigate its consequences, protect the personnel of the installation and immediately notify the competent authorities, including the initial evaluation of the potential consequences of the emergency. In addition, the PEI establish the actions planned by the licensee holder to provide their help in protection interventions outside the installation, as established by the Basic Nuclear Emergency Plan (PLABEN).

7.2.5.1 Emergency planning zones

Three different emergency planning zones are defined around the NPP:

- Zone 0, under license holder control. Protection measures in this zone are defined in PEI.
- Zone I is a zone where urgent protection measures are required. This zone has a radius of 10 km, and it is subdivided in 3 subzones: subzone IA (radius up to 3 km), subzone IB (radius between 3 and 5 km) and subzones 1C (radius between 5 and 10 km).
- Zone II is a zone where long-term measures are required. This zone has a radius between 10 to 30 km.

7.2.5.2 Emergency resources

In a nuclear emergency are involve:

- The nuclear facility: Its responsibility is to restore the facility to safe state, minimize radioactive materials emissions and provide to the director of the External Emergency Plan (PEN) and the regulator (CSN) the information needed to response the emergency. In these tasks are involved facility staff, technical support staff, and engineering companies.
- The government delegate in the NPP region is the External Emergency Plan director and has the support of five groups in the Operative Coordination Centre (CECOP) as represented in the figure.
- The nuclear regulatory body (CSN) with the Emergency room (SALEM) as control and coordination center of its emergency actuations.

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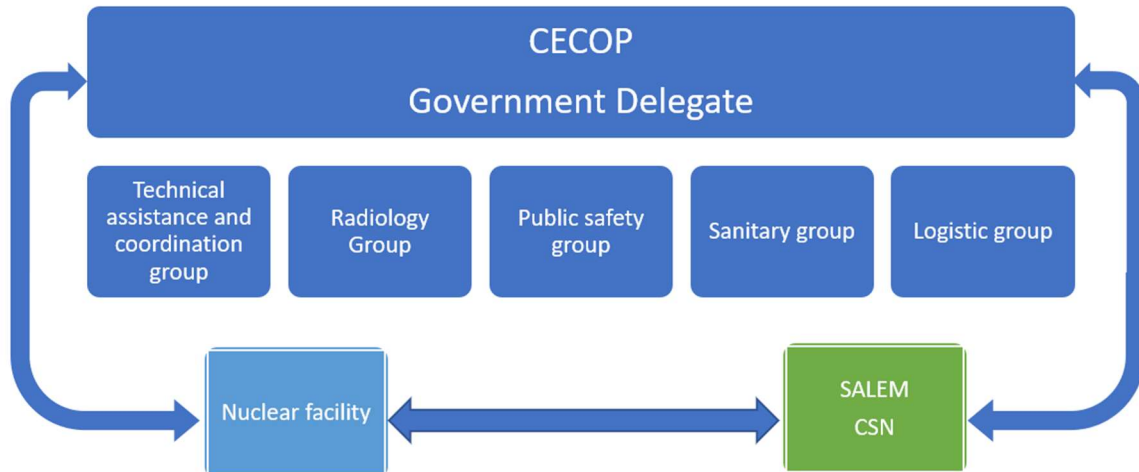


Figure 27 Organization of External Emergency Plan

7.2.6 Operation and organization

The licensee of a nuclear facility authorization is responsible for the facility’s safety in all stages of its life, especially during operation. This responsibility cannot be delegated.

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The operating permits granted to the nuclear power plants set limits and conditions covering the various aspects of operation and include the Official Operating Documents (OOD’s), according to which each authorization is granted, and the conditions necessary for reviewing them. These notably include the Operating Technical Specifications (OTS’s) for each facility which set the operating conditions and the monitoring requirements to which the facility is subjected to ensure the good condition of the systems. When these conditions are not met, the documents themselves describe the actions to be taken and, when necessary, the shutdown of the plant. Any change in these documents must be approved beforehand, with a favorable report from the Spanish Nuclear Safety Regulator (CSN).

7.2.6.1 Organization and management system

Article 7 of [Royal Decree 1400/2018 \[127\]](#) requires to the license holder to:

1. Provide, throughout the entire life cycle of the facility, the necessary technical, economic and human resources with adequate qualifications and competencies, as well as an appropriate organizational structure to maintain nuclear safety and ensure adequate response capacity in emergency situations.
2. Have a nuclear safety policy that promotes continuous improvement through:
 - 2.1. The identification of any new information and analysis of anything relevant within a timeframe appropriate to its significance for nuclear safety.
 - 2.2. The systematic review of nuclear safety taking into account in-house and external operational experience, advances in nuclear safety and in science and technology.
 - 2.3. The implementation of identified nuclear safety improvements that are reasonably feasible, within the appropriate timeframes.
3. Establish, implement, evaluate and continuously improve an integrated management system, including nuclear safety, occupational risk prevention, environmental protection, physical protection, quality and economic aspects, to ensure that nuclear safety is duly taken into account with regard to all activities of the organization. This management system must give due priority

to nuclear safety above any other consideration, guaranteeing its maintenance and promoting its continuous improvement.

4. Make sure that the integrated management system incorporates all the necessary measures to promote and improve an organizational nuclear safety culture that, among other things, enhances the ability to scrutinize safety principles and practices and to report on safety issues at all levels of the organization.
5. Take into account the influence of human and organizational factors on nuclear safety throughout the entire life cycle of the facility.
6. Guarantee that the quality requirements are defined and applied in an appropriate manner to achieve the safety objective established in Article 6 of this Regulation, and that these requirements are integrated into its management system throughout the life cycle of the facility.
7. Ensure that contractors (and subcontractors under their responsibility) whose activity may affect the safety objective established in article 6 of these Regulations have the adequate human, technical and economic resources for the efficient and safe performance of assigned tasks.

7.2.6.2 Maintenance, inspection, and testing

According to article 26 of [Royal Decree 1400/2018 \[127\]](#), the licensee must prepare, document and implement maintenance, testing, surveillance and inspection programs for the structures, systems and components that are important for safety, to ensure that their availability, reliability and operability are maintained in accordance with their design bases.

7.3 Findings and Conclusions

Finding H1: In Spain there is no specific legislation for hydrogen production plant (HPP) and it is considered as chemical/industrial facility as any other inorganic gas production facility, Furthermore, there is not differentiation for the method of production of hydrogen (PEM, alkaline, reforming...), the daily amount produced, the storage capacity or the purpose of the gas.

Finding H2: “Domino effect“ should also be considered in relation to the proximity of other facility with specific hazards. In this case the nuclear power plant should be considered. The operators must exchange information and cooperate in the area of risk management, emergency response and public information. (by [Royal decree 1196/2003 \[113\]](#),)

Finding H3: [Royal decree 1196/2003 \[113\]](#) and [Royal Decree 840/2015 \[114\]](#) on Control of major accident hazards require to the plant operator of facilities which store more than 5 tonnes of Hydrogen to implement a Major Accident Prevention Policy through a Safety Management System. One of the elements required is related to planning for emergency situations.

Finding N1: The case of install a new HPP sharing resources from an existing NPP will be treated as a design modification. According to article 25 of [Royal Decree 1836 /1999 \[123\]](#), modifications to nuclear installations require analysis by the licensee to verify compliance with safety and radiological protection criteria. If modifications affect exploitation authorization criteria, the owner must obtain approval from MITECO before implementing changes. In any case, MITECO may require authorization for major design modifications.

Finding N2: It is required a **safety assessment** ([Royal Decree 1400/2018 \[127\]](#) article 12) on the facility (siting, design, and operation) to confirm that an adequate level of nuclear safety has been achieved. The safety assessment must be documented in a **Safety Study** that shall be kept up to date, so it reflects the analyses and modifications made to the facility and the site conditions. According to Article 31, the owner must ensure that no modification of the facility, individually or in conjunction

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with others, whether permanent or temporary, impairs the ability to operate the facility safely, ensuring compliance with the fundamental safety functions and the objective of facility safety.

Finding N3: Article 19 of [Royal Decree 1400/2018](#) [127] requires to the license holder to analyze the effects of external natural events and unintended man-made events. Therefore, new postulated events due to the proximity of the HPP should be included in the analysis.

Finding N4: [Safety Instruction IS-25](#) [131], from CSN (Spanish nuclear regulator) provide criteria and requirements for development of PSA (Probabilistic Safety Analysis, also called Probabilistic Risk Analysis). PSA should consider all internal and external events and must be kept updated by the licensee holder. Therefore, there is a requirement to updated probabilistic risk analysis (PSA) due to changes in the installation or sitting introduced by the HPP.

Finding N5: An acceptable method for establishing the distances beyond which no adverse effect would occur is defined in [Regulatory Guide 1.91 rev.2](#) (RG 1.91) [132]. This guide can be used in Spain as Spanish nuclear regulator (NRC) accepts guidance from the countries where the plants has been designed.

Conclusions:

C1: In Spain in addition to the permitting process associated to a HPP will be required the authorization from the Nuclear Safety Council (CSN) and the Government through Ministry for the Ecological Transition (MITECO) for a Design Modification of the nuclear facility. The documentation required for this authorization is summarized in section 7.2.1.1.

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8 Analysis for Ukraine

Ukraine operates four nuclear power plants with 15 reactors located in Volhynia and South Ukraine. The total installed nuclear power capacity is over 13 GWe, ranking 7th in the world in 2020. Energoatom, a Ukrainian state enterprise, operates all four active nuclear power stations in Ukraine. In 2019, nuclear power supplied over 20% of Ukraine's energy.

The Energy Strategy of Ukraine [136], approved in 2017, provides for the use of hydrogen as a potential opportunity to decarbonize the transport sector using hydrogen fuel cell vehicles.

On December 6, 2022, the Verkhovna Rada (the Parliament) of Ukraine registered the draft Resolution No. 8258 "On the development of hydrogen energy in order to ensure economic and energy security of Ukraine". In the explanatory note to the Resolution, it is emphasized that such a base will regulate the production and use of hydrogen in national energy needs and its export to the EU. Measures will be developed for:

- amendments to legal acts on hydrogen energy development.
- analysis of the current legislation, first in the area of hydrogen storage and transportation through gas networks.
- development and implementation of technical standards, hydrogen production and supply regulations.

Currently there are not a specific regulation for Hydrogen Production Plants.

8.1 Hydrogen Production Plant

8.1.1 General description of HPP Licensing policy

8.1.1.1 Government bodies of Ukraine related with Hydrogen production

As the head of the state, the President of Ukraine manages all spheres of society, including the economy, within the framework of the powers defined by the Constitution of Ukraine. The Verkhovna Rada (the Parliament) of Ukraine participates in the management of the economy, its individual spheres and industries indirectly, through the formation of the necessary legislative framework. The central executive power of the state is represented by the Cabinet of Ministers of Ukraine, which practically implements the socio-economic policy of the country, coordinates and directs the activities of specific branches of the national economy through the relevant central bodies of the executive power — ministries, state committees, agencies, and other institutions. The Government is headed by the Prime Minister. The Cabinet of Ministers includes the heads of all ministries, including: the Ministry of Energy, the Ministry of Health (MoE), the Ministry of Environmental Protection and Natural resources (MEPNRU) and others.

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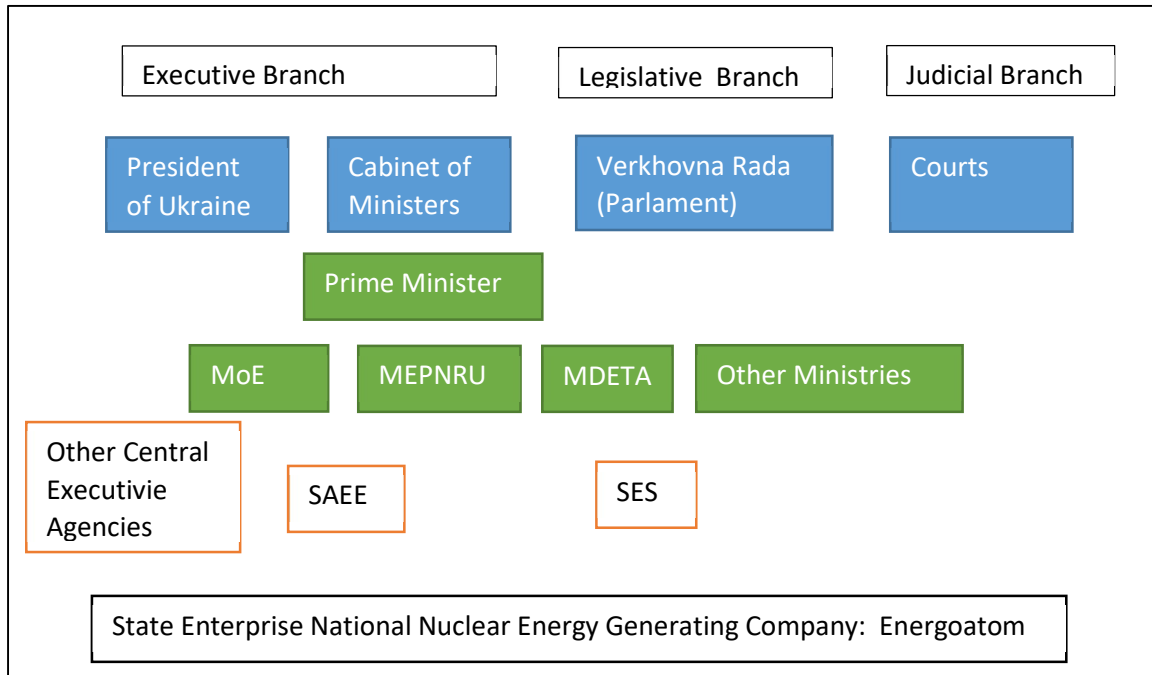


Figure 28: Main Government bodies in Ukraine

The State Emergency Service of Ukraine (SES) is a central executive body that ensures the implementation of state policy in the fields of civil protection, protection of the population and territories from emergency situations and their prevention, liquidation of emergency situations, rescue work, fire extinguishing, fire and man-made security, the activity of emergency and rescue services. SES is under the jurisdiction of the Ministry of Internal Affairs. Emergency plans of HPP and nuclear power plants should be approved by the SES.

The Ministry of Energy (MoE) along with the **State Agency for Energy Efficiency and Energy Saving of Ukraine (SAEE)** subordinated to it as an implementation arm should perform overall coordination of the activities provided for by hydrogen related projects. One of the main SAEE's tasks is implementation of the state policy in the field of efficient use of fuel and energy resources, energy saving, renewable energy sources and alternative fuels.

The Ministry of Environmental Protection and Natural Resources of Ukraine (MEPNRU) is responsible for:

- coordination of the activities of the national standardization body on the implementation of the national standardization program for the adoption / harmonization / actualization of standards on hydrogen technologies.
- functions of regulation and supervision the safety of nuclear power plants as part of the hydrogen production complex.
- keeping the provisions and objectives of the hydrogen related projects in Ukraine's foreign policy in negotiations, concluding international agreements and Ukraine's participation in international initiatives on climate change and environmental protection.
- keeping the provisions and objectives of the hydrogen related projects in developing of a low-carbon development strategy of Ukraine to implement the provisions of the Paris Agreement.
- ensuring the fulfilment of Ukraine's obligations in achieving the objectives of the Paris Agreement and other international agreements on climate change.

Local government authorities ensure the implementation of the hydrogen related projects within their competence, in particular:

- development and approval of plans (schemes) for the development of local energy systems and other use of hydrogen technologies.
- approval of investment plans of municipal energy and transport companies.

8.1.1.2 Ukrainian licensing process in relation to Hydrogen Production

In accordance with Ukrainian legislation, the right to produce particularly hazardous chemicals belongs to enterprises that have received the appropriate license. The decision to issue a license is taken by the MEPNRU based on the application and after reviewing the package of documents.

To start the licensing process, you need to submit an application to MEPNRU and the following package of documents:

- application for obtaining a license.
- information signed by the licensee about the availability of own or leased production space (premises) necessary for conducting business activities for the production of particularly hazardous chemicals.
- information, signed by the licensee, about the availability of the material and technical base necessary for carrying out economic activities for the production of hazardous chemicals, together with copies of supporting documents.
- information on the availability of a safety declaration and a plan for the localization and elimination of an accident at the facility.
- information on the availability of permissive documents.
- a copy of the data card of the hazardous factor.
- a copy of the technological regulations.

More complete requirements for the licensing process are given in the “Resolution on the approval of licensing conditions for conducting economic activities for the production of particularly dangerous chemical substances” [137]. It is worth highlighting the following main directions:

- documents submitted for obtaining a license for conducting/extending the conducting of economic activities to produce particularly hazardous chemicals (see above).
- personnel requirements for conducting business activities to produce the hazardous chemicals.
- organizational requirements for the implementation of economic activities to produce hazardous chemicals.
- technological requirements for the implementation of economic activities to produce the hazardous chemicals.

8.1.2 Safety concept for HPP

Currently, there is no complete concept of specialized hydrogen production in industrial volumes in Ukraine. Hydrogen production belongs to chemical enterprises. There are currently no national special standards relating specifically to the safety of hydrogen plants or hydrogen production in Ukraine, although such work is underway. Ukraine has taken the path of adopting such EU standards to local conditions.

The facility safety concept (safety declaration) is approved by the operator and provided to the SES authority.

The main part of the safety concept should reflect:

- operator's obligations to ensure safety of the plant:
 - a. assessment of the threat of accidents, considering the available hazardous substances.
 - b. taking all necessary measures to prevent accidents and eliminate their consequences.
 - c. providing information for assessing the potential danger of the plant for the population and other facilities.
 - d. ensuring proper safety policy implementation.
- safety management system:
 - a. organizational structure and personnel - definition and implementation of safety measures by establishing functions, duties of personnel, requirements for personnel training, training in actions in case of an accident.
 - b. assessment of the main threats that may appear during normal operation, as well as during an accident, assessment of their probability and severity.
 - c. operational control - introduction of procedures, instructions for the safe operation of the plant, management of the safety system.
 - d. modifications' management.
 - e. accident planning - development and implementation of plans for localization and elimination of accidents and their consequences, training of the plant personnel in the actions of the plan.
 - f. monitoring the implementation of the procedures for the current evaluation of the safety policy and safety management system.
 - g. audit and review - implementation of procedures for evaluating the effectiveness of the safety management system.

In the safety concept, the operator also reflects the measures planned by him aimed at ensuring an adequate level of protection of the plant, compliance with the requirements of the legislation on:

- civil protection,
- fire and technogenic safety,
- labor protection,
- environmental safety and environmental protection,
- sanitary and epidemic safety.

8.1.3 Environmental Protection and Industrial Emissions

The Ministry of Environmental Protection and Natural Resources of Ukraine (MEPNRU) is a state executive authority of Ukraine since 2020. The Ministry, whose activity is directed and coordinated by the Cabinet of Ministers of Ukraine, is the main body in the system of central executive authorities in the formation and implementation of state policy in the field of environmental protection.

Due to the lack of national regulations regarding the characteristics of industrial emissions from hydrogen plants, the requirements for hazardous chemical plants can currently be applied.

The main regulatory framework for Environmental Impact Assessment (EIA) is based on:

- Law of Ukraine "On environmental protection" [138];
- Law of Ukraine "On environmental audit" [139];
- "Composition and contents of materials of Environmental Impact Assessment (EIA) during construction and designing of enterprises, buildings and facilities" [140];
- Resolution "On approval of the list of activities and objects that constitute an increased environmental risk» [141];

The Law of Ukraine “On Environmental Impact Assessment” establishes the legal and organizational basis for environmental impact assessment aimed at preventing environmental damage, ensuring environmental safety, environmental protection, in the process of making decisions on the implementation of economic activities that may have a significant impact on the environment.

Environmental impact assessment is a clear procedure for determining the degree of action on the natural environment of planned economic activities. This process involves the following activities:

- development of an environmental impact assessment report by a facility.
- preparation and discussion of the results of planned activities with public involvement.
- review of the information presented in the report, as well as transferred from the public, by the authorized state body in the field of ecology.
- issuing conclusions of the environmental impact assessment by the state authority.
- if necessary, making changes in the project according to the comments and suggestions that arose as a result of the analysis and presented in the conclusion.

Assessment of environmental impact on design is developed by specialized design organizations, which have an appropriate license for this type of work. The report includes the following sections:

- description of the business activities.
- ecological condition of the territory at the moment.
- description of the environmental factors that will be affected and the types of impact.
- methods of nature protection, methods of forecasting, the degree of expected impact.
- an abstract of the environmental impact assessment of non-technical content.

8.1.4 External Hazards and Risks

Due to the lack of national regulations regarding the characteristics of industrial emissions from hydrogen plants, the requirements for hazardous chemical plants can currently be applied.

Regarding chemical facilities, “Methodology for Forecasting Consequences of Hazardous Chemicals Release (Emission) in Accidents at Industrial Facilities and Transport” was introduced by Order No. 73/82/64/122.

The methodology was developed to improve the procedure for assessing the chemical situation by predicting the extent of pollution in the event of an accident involving a release of hazardous chemicals (RHC) from process tanks at chemically hazardous facilities (CHF), including pipeline transportation. The methodology is intended for use by the facility, local and central government management bodies and civil defense forces of the unified state civil defense system that organize, implement and ensure measures to prevent accidents, eliminate accidents related to the release of RHC and their consequences. The methodology will allow for a long-term (operational) and emergency assessment of the situation in the event of accidents involving the release of RHC from CHF technological tanks and pipeline transport.

Assessment of the chemical situation involves determination of:

- extent of chemical contamination.
- level of chemical contamination hazard.
- duration of chemical contamination.

Based on the results of long-term forecasting of the possible scale of chemical contamination, the business facilities can be classified by the degree of chemical hazard. The criteria for classifying the

facilities by their level of chemical hazard are the share of the territory falling within the chemical contaminated area and the number of people falling into the chemical contaminated area in case of an accident at chemically hazardous facilities. These criteria are determined in the “Methodology for Forecasting Consequences of Hazardous Chemicals Release in Accidents”.

8.1.5 Emergency provisions and response organization

Since there are no large-scale hydrogen production plants in Ukraine, the regulatory framework covering the issues of emergency preparedness and emergency response for such plants is also absent. In case an HPP is constructed in Ukraine, these issues will be regulated by the general requirements of the state and local authorities.

Currently, the basic normative documents defining the requirements for development of the Site Emergency response plan (ERP) are the Law of Ukraine “on high risk objects” [142] and Safety rules [143]. In order to respond to man-made and natural emergency situations, the business entities that plan to operate at a dangerous object (as well as HPP) must develop the facility safety concept (safety declaration), and the ERP for managing accidents.

Accidents at hazardous facilities (which can include HPP), depending on their scale, can be of three levels: A, B and C:

- Level “A” - an accident within one part (department, production site) of the facility.
- Level “B” - an accident within the whole plant.
- Level “C” - an accident with a transition outside the location of the plant, the possibility of impact on the population and other facilities, as well as on the environment.

The Site Emergency Response Plan (ERP) covers all accident levels established during the hazard analysis process.

The ERP must be agreed with the local departments of supervision:

- labor protection,
- fire safety,
- Ministry of Emergency Situations,
- state sanitary service,
- and local governments, as appropriate.

The ERP is approved by the owner of the plant. Responsibilities for the development and implementation of the ERP and responsibility for its quality are assigned to the owner of the plant. The development of ERP can be carried out by the owner independently or with the involvement of specialized organizations.

The ERP is based on:

- prediction of accident scenarios.
- analysis of the stages of accidents and the extent of their consequences.
- assessment of the sufficiency of measures preventing the occurrence and development of an accident, as well as technical means of localizing an accident.
- analysis of the actions of production personnel and special units for localization of accidents.

To effectively cope with the accident, a headquarters is established with the following functions:

- collection of information on the course of the accident and the measures taken.

- ongoing assessment of information and decision making.
- coordination of actions of the personnel of the enterprise and all involved divisions and services.

The general management of the headquarters is carried out by the head of work on the localization and elimination of accidents.

The owner of a plant is obliged to:

- develop special programs for retrofitting control, automatic control, explosion prevention and explosion protection devices, systems for safe emergency shutdown of a facility, alarm, protection and rescue of people, and more.
- provide for the installation of redundant life support systems, alarm systems and emergency protection, if necessary. For example, there should be redundant communication lines, duplicates should be assigned for leading specialists, an alternative control center should be determined in case the functioning of the main center is disrupted, vital nodes should be duplicated at high-risk facilities.
- ensure prompt detection, efficient localization and manage of the accident use of technical means.
- ensure compliance with staff responsibilities by their duties.
- promptly notify authorities responsible for accident management of all incidents that involve hazardous substances and that may cause harm to human health and the environment impact.
- provide for the provision of pharmaceuticals, as well as ensure the availability supply of medical needed in case of an accident, protective equipment for personnel of emergency medical teams.
- provide the media with information about any hazards identified during the analysis.
- collaborate with government and local authorities in developing the operational part of the ERP for Levels “B”, “C” accidents.

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A State-level emergency response plan [144], developed to streamline and coordinate the actions of state authorities, local self-government bodies, management bodies and civil defense forces, business entities aimed at eliminating the consequences and providing assistance to victims in the event of a threat of occurrence or occurrence of an emergency situation. The plan is intended to:

- a) ensure prompt response of governing bodies and civil defense forces, prevent loss of life, reduce material losses, and arrange priority life support for victims.
- b) provide management, interaction and informing of governing bodies and civil defense forces, involved in the liquidation of the consequences of an emergency.
- c) determine the sequence and scope of organizational and practical measures to respond to an emergency and eliminate its consequences, determine the time, responsible persons and resources necessary for this.

8.1.6 Operation and organization

The owner of a dangerous facility (as well as HPP) is obliged [142] to:

- take measures aimed at preventing accidents, limiting and eliminating their consequences and protecting people and the environment from their effects.

- report on accidents that occurred at the dangerous facility and the measures taken to eliminate its consequences to executive authorities and local government bodies and the population.
- ensure the operation of dangerous facilities in compliance with an acceptable level of risk.
- comply with the requirements of regulatory acts that regulate the activities of dangerous facilities.
- upon request provide the central body of executive power that implements state policy in the field of civil protection with information and documents regarding:
 - a) measures provided for by the regulations for dangerous facilities,
 - b) increase in the amount or changes in the properties of dangerous substances, which leads to an increase in the risk of accidents,
 - c) modernization of production, equipment, technology changes, which leads to an increase in the risk of accidents.

8.2 Nuclear Power Plant

8.2.1 General description of NPP licensing policy

The procedure for licensing activities in the field of nuclear energy is regulated by the Law of Ukraine “On Authorizing Activity in Nuclear Energy” [145]. Authorizing activities is an integral part of state regulation of nuclear energy and provide for licensing of certain types of activities of nuclear energy.

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Ukrainian system of normative regulation in nuclear sphere



Figure 29: Legislative regulation system in Ukraine

Regulation in the field of nuclear energy in Ukraine is built on the principle of hierarchy. The highest priority for the regulatory process is the orientation towards international conventions accepted by Ukraine. The next level of influence on nuclear regulatory documentation has nuclear laws and

international agreements of Ukraine in the field of nuclear energy use. The fundamental law regulating relations in the sphere of the use of nuclear energy is the Law of Ukraine “On Authorizing Activity in Nuclear Energy” [145]. Several laws and other legal acts have also been accepted that establish norms and rules for the safe use of nuclear energy. The third level is the legal acts signed by the President of Ukraine and the Cabinet of Ministers of Ukraine. In accordance with them, normative legal acts accepted by state regulatory bodies and other central executive authorities are developed. The SINRU is the regulator in the field of nuclear energy. In addition, state regulatory bodies for nuclear and radiation safety develop documents that are not normative but advisory or explain the application of regulations.

The main principles of permitting activity in the field of nuclear energy are:

- priority of ensuring nuclear and radiation safety over other interests.
- differentiated approach to different types of activities, taking into account the potential nuclear and radiation hazards associated with them.
- objectivity of the state regulatory body for nuclear and radiation safety when assessing the level of safety and making decisions.
- validity of the established criteria, requirements and conditions for ensuring safety, taking into account the entire complex of environmental, economic and social factors.
- responsibility of the state regulatory body for nuclear and radiation safety for compliance with the established procedures for permitting activities and adequacy of the conditions and restrictions determined by them.
- inadmissibility of interference by any bodies, officials and officials, citizens and their associations in solving issues related to the responsibility of the state regulatory body for nuclear and radiation safety.
- openness and publicity of the permitting activity by the state regulatory body for nuclear and radiation safety.

Permitting activity is an integral part of state regulation and provides for:

- licensing of certain activities.
- licensing the activities of the operating organization and issuing separate permits to such an organization for performance of certain types of work or operations.

An entity that intends to carry out activities involving the use of sources of ionizing radiation must inform the state regulatory body of nuclear and radiation safety in writing form about its intention and provide complete and reliable information about the type of work and the type of sources of ionizing radiation.

The state regulatory body for nuclear and radiation safety issues an operational license to the operating organization that submitted an application, based on a comprehensive safety assessment and assessment of the ability of the specified operating organization to perform all measures to ensure safety, in particular:

- for construction and commissioning of a nuclear facility.
- for operation of a nuclear facility.

Obtaining a license by the operating organization is the basis for starting the activity, including all objects located on the site of this nuclear facility and technologically connected with it. The license establishes the conditions and limitations of the activities, implementation of works and operations,

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determines the technological complex and the boundaries of the site, which are covered by this license.

The conditions of the license, obtained by the operating company for conducting activities at a certain stage of the life cycle, determine the types of works or operations, which can be implemented during construction, commissioning and operation only with a separate written permit. The permit is issued by the state regulatory body for nuclear and radiation safety, who also establishes the conditions and procedure for its issuing.

8.2.1.1 Modifications associated with changes in NF configuration

The requirements for modifications of nuclear facilities and the procedure for assessing their safety are developed in accordance with the Law of Ukraine “On Authorizing Activity in Nuclear Energy” [145], and the law “General Provisions on Nuclear Safety” [146], developed for fulfilling IAEA Safety Standard No. NS-G-2.3 “Modifications at Nuclear Power Plants” [147]. The General Provisions define the requirements for modifications of a nuclear facility (NF), the procedure for assessing the safety of NF modifications and for approving technical solutions developed in the modification process.

The safety assessment of modifications is performed by the operating company. For modifications involving changes in the NF configuration, the assessment is performed considering the SNRIU (regulator) approved classifications of systems and elements important for safety that are part of the NF design. Any NF modification performed by the operator during the NF life cycle shall not reduce the NF safety level. To substantiate this, the operator shall assess the safety of the nuclear facility considering the proposed modification and new operating conditions [148].

Technical decisions on NF modifications shall be reviewed before implementation at the NF. As part of the quality manual, the operator shall develop a procedure that establishes the procedure for NF modifications. In case of changes in the design, construction of safety related systems (SRS) or their characteristics, software, buildings and structures containing SRS, the operator shall develop and agree the technical solution with the SNRIU for the established stages of the modification:

- conceptual decision on modification,
- technical decision on installation of the modification,
- technical decision on putting into trial operation,
- technical decision on putting into commercial operation.

The Safety Analysis Report (SAR) is developed to demonstrate that the implemented modification will not decrease the safety level of the NF:

- Modification is in compliance with the nuclear and radiation safety standards and regulations.
- Principle of defense-in-depth strategy is preserved.
- No increase in the probability of severe core damage.
- Redundancy, independence and diversity principle is in place.
- Protection against personnel errors and equipment failures is foreseen.
- Single failure principle is preserved.
- Protection against internal and external hazards is foreseen.
- No impacts of the modification on the NF as a whole, as well as on other SRS, which could cause a malfunction and/or change in the characteristics of these systems under any operating conditions.

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- No increase of radiation impact on NPP personnel or the public, accident consequences and negative impact on the environment.
- No hazardous consequences in case of single failures of the modified SRS.
- Fire and technical safety are ensured.
- No hazardous consequences as a result of erroneous actions of personnel during the implementation and operation of the modified SRS.
- Functioning and regulatory characteristics of the modified SRS in case of failures in adjacent equipment are preserved.

The analysis should include an assessment of the impact of the proposed modification on NF safety and the environment during all stages of its implementation. The SAR considers the results of the trial operation of the modification object. The operator should use a conservative approach when performing the safety analysis. The impact of implemented system modification on the results of the entire NF should be considered [148].

8.2.1.2 Permit for the use of land and water bodies located at Sanitary Protection Zone

The document NP 306.4.181-2012 [149] establishes the conditions and procedure for issuing permits for the use of land and water bodies located in the sanitary protection zone (SPZ) of a nuclear facility (NPP) by the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU).

A permit for the use of land and water bodies located in the SPZ of a nuclear facility is issued to legal entities and individuals, who intend to use land, water bodies located in the sanitary protection zone of a nuclear facility. Such rules also apply to accommodating industrial enterprises, auxiliary and other facilities related to the activities of a nuclear power plants. Entrepreneurial activity in the sanitary zone of nuclear power plants without permission is prohibited. To obtain a permit, a legal or private person applies for a permit to the Regulatory Authority of Ukraine. The list of documents that must be attached to the application is given in NP 306.4.181-2012 [149].

8.2.2 Safety Concept

The Law of Ukraine “On Use of Nuclear Energy and Radiation Safety” [150] defines that nuclear safety is the observance of norms, rules, standards and conditions of use of nuclear materials ensuring radiation safety.

The NPP meets the safety requirements if, as a result of the technical and organizational measures taken in the project, the basic safety goal is achieved. The safety criteria for operating NPP power units are:

- not exceeding the estimated frequency of severe core damage equal to 10^{-4} per reactor per year;
- non-exceeding of the frequency of the maximum emergency release of radioactive substances into the environment for operating NPPs is set at a level of no more than 10^{-5} per reactor per year.

The defense-in-depth strategy is implemented at 5 levels.

- Level 1: Prevention of abnormal operation.
- Level 2. Ensuring safety in case of violations of normal operation and prevention of emergency situations.
- Level 3. Prevention and elimination of accidents.
- Level 4. Management of beyond design basis accidents.

- Level 5: Emergency preparedness and response.

Attention was paid to correct choice of site, its distance from large settlements, emergency preparedness. The NPP should be designed considering extreme natural events, it was desirable to use “passive” devices for protection. It is required to present the quantitative analysis of reliability, and the quantitative analysis of probability of emergency situations in the project. High reliability of emergency protection systems should be achieved through high quality, multi-channel, checks and tests, as well as availability of backup power sources. The damage limits of fuel elements and the associated radioactivity levels must be determined in the design.

In 2008, a new version of the “General Safety Provisions of Nuclear Power Plants” OPBU-2008 [151] was issued. This document introduced additions to the content of the requirements for NPP safety, set out the basic principles and criteria for NPP safety based on the IAEA publications outlined in the “Basic Safety Principles for Nuclear Power Plants” (INSAG-12) [152].

There are two methods for evaluating accidents in the design. In the deterministic method, design basis events are chosen to encompass a range of related possible initiating events that could challenge the safety of the plant. The second is a probabilistic principle, according to which it is necessary to strive for the probability of a large accidental release not exceeding 10^{-7} per reactor per year. If this requirement is not met, additional technical measures to manage the accident to mitigate its consequences must be taken. The agreed position is to strive to ensure that in any possible accident the release of radioactive substances outside the nuclear power plant does not exceed values that could lead to the need for urgent interventions and limited intervention measures to a short period of time and only in a limited area.

Other important additions to previous regulations include the decision to consider possible changes in the natural conditions of the site, which is supposed to be realized by increasing the margins of NPP characteristics in relation to external impacts, such as earthquakes.

Documentation related to the modifications of system structures and safety-related elements is subject to SNRIU review. The procedure for implementing measures to modify these systems and components is determined by the regulatory documents. Before starting the modification, a preliminary assessment of its safety impact is performed. Based on the results of the preliminary assessment, the need and scope of additional safety justifications are determined. All modifications are considered during the periodic safety reassessment and are reflected in the periodic safety assessment report (PSAR) [153].

8.2.3 Environmental Protection and Industrial Emissions

The requirements for the content of the report on the safety analysis of Ukraine NPPs with VVER-type reactors include the Environmental Impact Assessment (EIA) [153]. The section Environmental Impact Assessment must contain brief information reflecting the issues of environmental impact of the NPP during its operation. Materials of the chapter are formed based on the EIA materials. If there is no EIA, the materials of the chapter are formed based on the materials of the NPP Technical Safety Justification.

The following data shall be provided on: chemical discharges, thermal discharges, radioactive discharges and releases, radiation exposure, groundwater contamination.

The dynamics of the values for the considered period in comparison with the design data should be shown and the corresponding analysis of the state should be made. For NPPs, for which the EIA is

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done, the summary data should be provided for the complex environmental impact on the environment considering the risk assessment for the population. Also, a summary table must be included with the measures to reduce the impact on the environment, which are implemented at the NPP and/or will be implemented soon [153].

Each nuclear power plant in Ukraine has subdivisions in its structure that control the impact on the environment. The external dosimetry laboratory, the department of environmental protection, and specialized chemical laboratories perform monitoring and generate information on the compliance of the current state with the established criteria. All emissions and discharges of gas and liquid media into the environment are monitored. The main document that establishes the criteria for the impact on the environment, emission standards and the scope of monitoring is the industry standard "SOU NAEK 076:2015 [154].

8.2.4 External hazards and Risks

The document "Requirements for safety assessment of nuclear power plants in terms of external natural effects" [155] states that the safety justification of nuclear power plants in terms of external natural effects is performed for design based natural effects and beyond-designed external hazards, which should be considered during the analysis of extended design conditions. The list of natural effects for safety analysis covers all possible natural events with an average annual probability more of 10⁻⁷, as well as their possible combinations.

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The requirements for content of the safety analysis report for NPP power units with VVER-type reactors operated in Ukraine are defined in [153]. According to the requirements to the annex "Additional safety analysis basis", the section "Characteristics of the site and area of NPP location" should be developed. The following information must be included:

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- Technogenic conditions of NPP site location, including:
 - a) Explosions,
 - b) Fires,
 - c) Emission of toxic and corrosive substances,
 - d) Mechanical effects from aircraft,
 - e) Failures of hydraulic structures and other flooding of the site.
 - Meteorological conditions
 - Geological and hydrological conditions
 - Changes in the power system
 - Source data for additional assessment of external impacts.

If a power unit is in the proximity of another power unit, the probability of its possible impact on the safety as one of the external factors should be additionally estimated.

The NPP design is based on the defense-in-depth strategy, which prevents:

- violations of the integrity of physical barriers,
- damage of the physical barriers in case of initial events,
- damage of the physical barriers because of other physical barriers damages,
- damage of the physical barriers due to common causes.

Particular attention is paid to initiating events that may lead to a damage of multiple physical barriers. Such events are fire, flooding, earthquakes, explosions, aircraft crashes. The NPP design must include protection measures against external fire [153].

8.2.5 Emergency provisions and response organization

The NPP administration shall constantly maintain the level of emergency preparedness required to ensure effective response to accidents and other hazardous events to:

- regain control of the situation,
- prevent and/or minimize consequences,
- interact with organizations involved in emergency response to protect personnel, public and environment.

The NPP site emergency response plan (Site ERP) and the Energoatom Head Office emergency response plan (EA ERP) are developed, agreed, and approved in accordance with the regulations [153]. The plans are developed based on the initial data presented in the NPP design and in the SAR.

The emergency response system of “Energoatom” is an integral organizational component of the functional “Safety Subsystem of Electric Power and Nuclear Industrial Complexes” of the Ministry of Energy of Ukraine. Considering the recommendations of the IAEA (GSR Part 7) and the requirements from [156], the following classes of accidents are established:

- alert,
- facility emergency,
- site area emergency,
- general emergency.

If the NPP declares a general emergency, the following shall be applied immediately:

- a) NPP site emergency plan (Site ERP),
- b) emergency plan of “Energoatom” (EA ERP),
- c) response plans of local and regional territorial subsystems of the unified state system of civil protection, the territory of which belongs to the NPP surveillance zone,
- d) response plans of relevant functional subsystems,
- e) National Emergency Response Plan, which provides for the establishment of an interagency headquarters that analyzes the situation and determines actions for further emergency response at the national level and liquidation of the consequences of the emergency.

The NPP site emergency plan is developed and approved by the NPP. The Site ERP is coordinated with the emergency response plans of the organizations with which the EA interacts during the emergency response.

The EA ERP shall be developed and approved by “Energoatom” and shall establish the procedure for:

- coordination of actions of the NPP administration and “Energoatom”,
- mobilization of the “Energoatom” resources and provision of assistance to the NPP,
- interaction of “Energoatom” with the state authority in the field of nuclear energy use, emergency response authority, SNRIU and other central executive authorities.

To maintain constant readiness in case of an accident and other emergencies, the Site ERP and EA ERP are maintained and reviewed in the specified period. “Energoatom” and the NPP develop and implement emergency training programs to practice personnel actions in emergency conditions.

The NPP design provides for internal (on the NPP site) and external (in the observation area) crisis centers. The design of crisis centers and technical support centers should ensure reliable receipt and storage of reliable information on the status of NPP power units, communication with the control

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room and other control panels. The NPP design shall provide for protective structures to shelter personnel and other persons present at the NPP site at the time of an accident.

The Emergency Preparedness and Response System of “Energoatom” is a part of the unified state civil protection system established to implement the state policy in the field of civil protection.

The NPP emergency plan defines the emergency organizational structure of the NPP, distribution of responsibilities and duties for emergency response, composition of emergency response equipment, and external organizations involved in emergency response. The NPP emergency plan establishes the procedure for implementing emergency response measures and maintaining NPP emergency preparedness and is intended to ensure implementation of the Level 5 measures of the defense-in-depth strategy, defined as Emergency Preparedness and Response.

The NPP emergency plan contains a reference to the NPP physical protection document (with a restricted access). In accordance with the IAEA recommendations and requirements of the current legislation in the field of safety of nuclear facilities, contains the main organizational and technical measures to strengthen the security of the protected zone of an emergency NPP, as well as actions of reserve forces and security units in the event of an accident or sabotage at the NPP.

The Emergency Response Plan of “Energoatom” Directorate (HO ERP) establishes the procedure for:

- coordination of actions of the emergency NPP administration, Directorate and separate divisions of the company,
- mobilization of resources of the operating organization and provision of assistance to NPPs,
- interaction of the Directorate of NNEGC “Energoatom” with the Ministry, SNRIU, medical and other central executive authorities.

Thus, if potentially hazardous production is located in the zone of possible impact on NPPs, both the Site Emergency Plans and the “Energoatom” (EA ERP) should be revised. In addition, appropriate adjustments should be made to the programs for training personnel for accident response.

8.2.6 Operation and organization

Each of the Ukrainian NPPs is a separate subdivision of the State Enterprise “National Nuclear Energy Generating Company: “Energoatom” (NNEGC “Energoatom”). NPPs have the production and functional structural units in accordance with the organizational structure.

A separate subdivision (each NPPs) do not have the status of a legal entities. NPPs carries out its activities on behalf of the Company based on the current legislation of Ukraine and perform part of the Company’s functions.

The Company delegates the rights to the Head of the Separate Subdivision (SS) to represent its interests in relations with legal entities and individuals within the scope of the NPP.

The safe and efficient production of electricity and heat is the main purpose each of the Separate Subdivision. The head of the Separate Subdivision is the Director General of the NPP. The Director General is administratively subordinated to the President and operationally managed by the First Vice President, Technical Director of NNEGC “Energoatom”.

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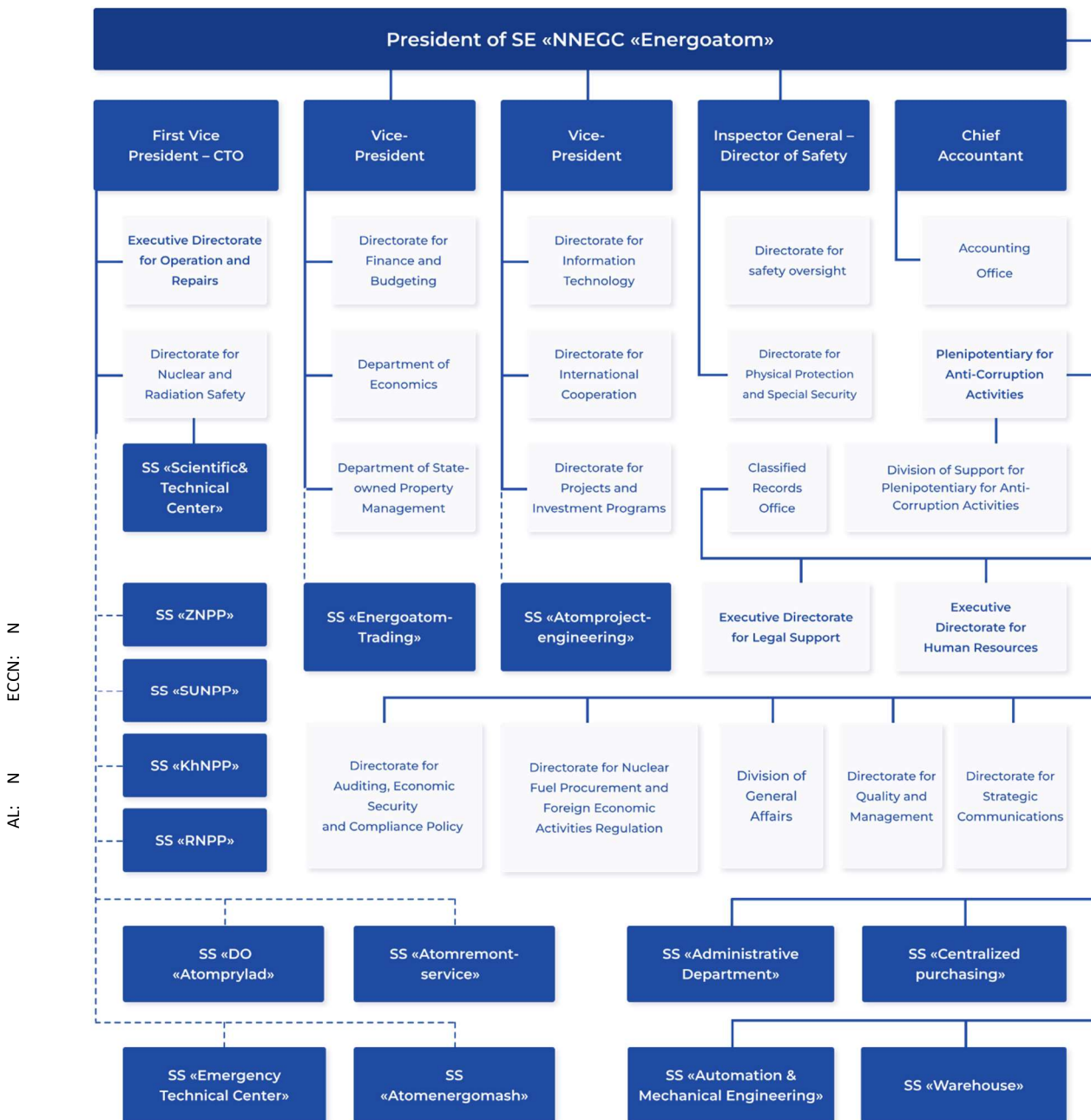


Figure 30: Energoatom main structure

Each NPP has operational staff, repair, engineering, and support staff. The functions of the units and personnel are defined in the organizational documents of the NPP. The typical NPP structure includes the following main departments:

- Reactor Department operates the nuclear power plant with the main and auxiliary systems, diesel power plant equipment.
- Turbine Department operates the main and auxiliary turbine equipment, as well as equipment for steam generators feeding, fire and service water supply facilities.

- Electrical Department carries out operation, repair, control, debugging and testing of electrical equipment, relay protection, electrical automation and electrical measurements, dispatching and technological control.
- Instrumentation and Control Department (I&C) carries out departmental supervision, maintenance, repair, control, adjustment and testing of technological, chemical and radiation control devices, technological protection and signaling, remote control of valves.
- Chemical Department operates equipment for water treatment, special water treatment and special gas cleaning, chemical and radiochemical control, development and implementation of technology for decontamination of equipment, premises and overalls, as well as methods for processing and disposal of liquid and solid radioactive waste.
- Department of Radiation Protection provides dosimetry control, repair and operation of dosimetry equipment. At the same time, it is a functional department and is responsible for ensuring radiation and general safety, reducing the level of occupational exposure of personnel, personal hygiene of workers during the operation and repair of NPP equipment, and also monitors compliance with current environmental protection standards.
- Department of Nuclear Safety and Reliability provides control over compliance with the requirements, measures the parameters of the reactor core, performs calculations regarding the justification of refueling and permissible modes of operation of nuclear power plants, and analyzes the reliability of equipment.
- Hydrotechnical Department supervises and operates hydraulic structures and their mechanical equipment.
- Decontamination Department carries out periodic and pre-repair decontamination of equipment and production facilities, processing and disposal of radioactive waste, implements the rules of the sanitary access regime, and also provides personnel with overalls and personal protective equipment with their subsequent decontamination.
- Maintenance Equipment Department carries out repairs of thermal and mechanical equipment of the reactor and turbine shops, chemical equipment, special water treatment equipment, external structures, including hydrotechnical systems of ventilation, heat supply and underground communications, other equipment.
- Heat Supply and Underground Communications Department is engaged in the maintenance and repair of external heating networks.

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Each technical department is managed by its head. Heads of all technical departments report to the Chief Engineer and his deputies.

Operational management of multi-unit NPPs (all Ukrainian NPPs) is carried out by the NPP Shift Supervisor. Operational control of power units is carried out by the Unit Shift Supervisor of the related power unit. In addition, the management of equipment located on the NPP site outside the power units is carried out by the personnel of the relevant departments (electrical, chemical, radiation safety, hydro and other).

Normal operation is performed in accordance with the relevant procedures. Abnormal operation modes and accidents management is performed by the power unit personnel and the NPP Shift Supervisor in accordance with emergency procedures.

8.3 Findings and Conclusions

Finding H1: There is no special legislation for a hydrogen production plant (HPP) in Ukraine. To assess the requirements for HPP, the requirements for industrial chemical facilities can be used as for any other inorganic gas production facility and as Dangerous Production facility.

Finding H2: In accordance with the Ukrainian legislation, the production of hydrogen in the amount more than 50 tons belongs to enterprises of the 1st hazard group. The procedure for obtaining a permit for hazardous production is described in the legislation of Ukraine [142].

Finding H3: The process of standardization continues in Ukraine, along the path of adopting EU standards to the conditions of the production, technological and legal base of Ukraine. Relevant organizations have been created and are working on this issue.

Finding N1: It should be to consider the potential danger of the facility (HPP) in terms of the impact on the nuclear power plant in the case of a close location of the HPP. When reassessing NPP safety, HPP should be considered as an additional source of external hazard on NPP safety.

Finding N2: A nuclear power plant safety reassessment is required to confirm that an appropriate level of safety is maintained in case of design modification. The safety assessment should be documented in a safety study, which should be updated to reflect the analyses and modifications made to the facility and site conditions. The plant owner must ensure that no modification of the plant, alone or in combination with others, whether permanent or temporary, does not impair the ability of the plant to operate safely, while ensuring that the essential safety functions and safety objectives of the plant are met. This should be considered when using NPP resources for HPP.

Finding N3: In the sanitary protection zone it is prohibited to place industrial enterprises, auxiliary and other structures not related to the activities of a nuclear installation, in accordance with article 45 of the Law of Ukraine ("On the Use of Nuclear Energy and Radiation Safety"). To meet this requirement, the HPP must be either considered as a NPP auxiliary facility or located no closer than the boundary of the NPP sanitary zone (2.7 km for KhNPP). However, Ukrainian legislation establishes the procedure for obtaining permission to locate industrial facilities not associated with nuclear power plants on the territory of the nuclear power plant sanitary zone (See 8.2.1.2). Relevant documents should be reviewed by the National Regulatory Authority. Regulator is authorized to approve the submitted application.

Finding N4: State normative document GND 34.09.205-2004 does not contain information that confirms the possibility of using the NPP's own needs to supply HPP with electricity. The State normative document GND 34.09.205-2004 regulates the consumption of electricity for own and economic needs of power plants and networks. It does not contain information that confirms the possibility of using the NPP's own needs to supply HPP with electricity.

Conclusions:

In Ukraine, in addition to the permitting process associated with the HPP, the authorization will be required from the State Nuclear Regulatory Inspectorate of Ukraine (SNRIU) and the Government through the Ministry of Protection of Environment and the Ministry of Fuel and Energy of Ukraine for a Design Modification of the nuclear facility.

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9 Findings and Conclusions

In this chapter the major findings from the various country analyses are summarized. Subsequently in section 9.2 these findings are restructured into more general conclusions.

9.1 Findings

From the Ukraine analysis the following findings were identified:

In the Ukraine there is no special legislation for a hydrogen production plant (HPP). To assess the requirements for HPP, the requirements for industrial chemical facilities can be used as for any other inorganic gas production facility and as Dangerous Production facility. In accordance with the Ukrainian legislation, the production of hydrogen in the amount more than 50 tons belongs to enterprises of the 1st hazard group. The procedure for obtaining a permit for hazardous production is described in the legislation of Ukraine. The process of standardization continues in Ukraine, along the path of adopting EU standards to the conditions of the production, technological and legal base of Ukraine. Relevant organizations have been created and are working on this issue.

The potential danger of the facility (HPP) in terms of the impact on the nuclear power plant in the case of a close location of the HPP should be considered. When reassessing NPP safety, HPP should be considered as an additional source of external hazard on NPP safety. A nuclear power plant safety reassessment is required to confirm that an appropriate level of safety is maintained in case of design modification. The safety assessment should be documented in a safety study, which should be updated to reflect the analyses and modifications made to the facility and site conditions. The plant owner must ensure that no modification of the plant, alone or in combination with others, whether permanent or temporary, does not impair the ability of the plant to operate safely, while ensuring that the essential safety functions and safety objectives of the plant are met. This should be considered when using NPP resources for HPP. Different scenarios of HPP location, can be require of modifications of NPPs of different significance.

In the sanitary protection zone, it is prohibited to place industrial enterprises, auxiliary and other structures not related to the activities of a nuclear installation, in accordance with article 45 of the Law of Ukraine ("On the Use of Nuclear Energy and Radiation Safety"). To meet this requirement, the HPP must be either as NPP auxiliary facility or located no closer than the boundary of the NPP sanitary zone (2.7 km for KhNPP). However, Ukrainian legislation establishes the procedure for obtaining permission to locate industrial facilities not associated with nuclear power plants on the territory of the nuclear power plant sanitary zone. Relevant documents should be reviewed by the National Regulatory Authority. Regulator is authorized to approve the submitted application.

The state normative document GND 34.09.205-2004 does not contain information that confirms the possibility of using the NPP's own needs to supply HPP with electricity. The State normative document GND 34.09.205-2004 regulates the consumption of electricity for own and economic needs of power plants and networks. It does not contain information that confirms the possibility of using the NPP's own needs to supply HPP with electricity.

Concerning the Spain country analysis, the following most important findings were summarized:

In Spain there is no specific legislation for hydrogen production plant (HPP) and it is considered as chemical/industrial facility as any other inorganic gas production facility. Furthermore, there is no differentiation for the method of production of hydrogen (PEM, alkaline, reforming...), or the purpose of the gas. "Domino effect" should also be considered in relation to the proximity of other facility with

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specific hazards. In this case the nuclear power plant should be considered. The operators must exchange information and cooperate in risk management, emergency response and public information (Royal decree 1196/2003).

In the Royal decree 1196/2003 and Royal Decree 840/2015 on Control of major accident hazards require of the plant operator of facilities which store more than 5 tonnes of Hydrogen to implement a Major Accident Prevention Policy through a Safety Management System. One of the elements required is related to planning for emergency situations.

The case of installing a new HPP sharing resources from an existing NPP will be treated as a design modification. According to article 25 of Royal Decree 1836 /1999, modifications to nuclear installations require analysis by the licensee to verify compliance with safety and radiological protection criteria. If modifications affect exploitation authorization criteria, the owner must obtain approval from MITECO before implementing changes. In any case, MITECO may require authorization for major design modifications. A safety assessment (Royal Decree 1400/2018 article 12) of the facility (siting, design, and operation) is required to confirm that an adequate level of nuclear safety has been achieved. The safety assessment must be documented in a Safety Study that shall be kept up to date, so it reflects the analyses and modifications made to the facility and the site conditions. According to Article 31, the owner must ensure that no modification of the facility, individually or in conjunction with others, whether permanent or temporary, impairs the ability to operate the facility safely, ensuring compliance with the fundamental safety functions and the objective of facility safety.

In Article 19 of Royal Decree 1400/2018 requires of the license holder to analyze the effects of external natural events and unintended man-made events. Therefore, new postulated events due to the proximity of the HPP should be included in the analysis.

Safety Instruction IS-25, from CSN (Spanish nuclear regulator) provides criteria and requirements for development of PSA (Probabilistic Safety Analysis, also called Probabilistic Risk Analysis). PSA should consider all internal and external events and must be kept updated by the license holder. Therefore, there is a requirement to update the probabilistic risk analysis (PSA) due to changes in the installation or siting introduced by the HPP.

An acceptable method for establishing the distances beyond which no adverse effect would occur is defined in Regulatory Guide 1.91 rev.2 (RG 1.91). This guide can be used in Spain as Spanish nuclear regulator (NRC) accepts guidance from the countries where the plants has been designed.

The most important findings from the Netherland country analysis are listed in the following:

In the Netherlands there is no specific HPP regulation. Hydrogen production is considered as chemical industry, inorganic gas production. There is no differentiation for the method of hydrogen production, only for the amount of hydrogen stored. Requirements, standards and (threshold) values are based on EU legislation (e. g. Seveso Directive). The difficulty in the licensing framework lies in the many different variations, caused by regional differences (e. g. water authorities, safety region), that are possible. For each application, a different set of requirements and extra applications for additional licenses can be needed. These variations can be caused by different configurations or plant characteristics, but also by a unique set of communal, regional, provincial, or national requirements.

The main legislation relevant for HPP licensing is:

- WABO: General Provisions Act
- BRZO: Major Accidents Risks Decree



- BEVI: External Safety of Establishments Decree

The requirements stemming from the BRZO and BEVI can be incorporated into the license that is used to prove compliance with the WABO. In this way, one license is used to cover multiple laws. The entire process is coordinated by the Regional Service authority.

The BRZO integrates laws and regulations (also Directive 2012/18/EU) in the field of occupational safety, external safety, and disaster relief. Important aspects to consider are “Domino effects”. These are related to the proximity of other facilities (e. g. NPP) with specific hazards.

The BEVI stipulates that the risks and effects of a company in which hazardous substances are present must comply with safety standards and guideline values. The intention is to keep or create sufficient distance between the danger objects and civilians/vulnerable objects. Key parameters in this context are the Local Risk (PR) and the Group Risk (GR). Determination and application of the safety standards are further elaborated in the accompanying Regulation on External Safety Establishments (REVI). For so-called 'categorical establishments', the REVI provides tables with fixed safety distances which dictate the minimum distances between the establishment and a vulnerable object.

For the situation in which the heat sink (surface water) of both facilities can be shared: When assessing heat discharges, a balance is made between the characteristics of the discharge and the effects on the surface water to which the discharge is carried out. Heat discharges smaller than 50 MW are regulated by the Activities Decree. Discharges of cooling water with a higher heat load are subjected to a permit.

The Nuclear Energy Act is the most prominent law governing nuclear activities. It is a framework law, which sets out the basic rules on the application of nuclear technology and materials, makes provision for radiation protection, designates the competent authorities and outlines their responsibilities. Subordinate to this act are a number of decrees containing additional regulations related to the use of nuclear technology and materials. These decrees and the ministerial regulations are continuously updated in the light of ongoing developments, partly owing to the mandatory implementation of amended EU directives on nuclear safety (Directive 2009/71/Euratom, as amended by Directive 2014/87/Euratom) and radiation protection (Basic Safety Standards: Directive 2013/59/Euratom).

The ANVS has drawn up the Safety Guidelines on the Safe Design and Operation of Nuclear Reactors. The specific requirements (called Dutch Safety Requirements or DSR) defined in the Safety Guidelines are aligned with the latest insights, particularly those disseminated by the IAEA and WENRA, and may, where applicable and necessary, serve as a basis for formulating the conditions attached to licenses for new reactors. The ANVS is the competent authority for nuclear facilities for all environmental aspects, so also conventional activities are part of the nuclear license of the facility. Therefore, when integrating an HPP in a licensed NPP establishment, the permit application is to be submitted to the ANVS.

The nuclear license for an NPP can be refused based on Article 18 of the Bkse. This article contains the maximum allowable radiological effective doses for individuals, specified per frequency of occurrence, and maximum allowable risk of dying for an individual and for groups. These risks can change after implementation of an HPP.

The National Plan for Nuclear and Radiological Emergencies (NPNRE) describes the national crisis management for radiation accidents. It refers to national regulations and guidelines and is based on international regulations and guidelines. Regional authorities (like Safety Regions) have an important role in this. New scenarios concerning HPP will have to be implemented in the NPNRE and to be aligned with the Safety Regions.

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The relevant outcome of the country analysis of France is summarized in the following:

The Nuclear Safety Authority (Autorité de sûreté nucléaire) ASN is the independent authority that provides a legislative framework for basic nuclear installations (INB) integrated with HPP. HPP is considered as Installation Classified for the Protection of the Environment (ICPE). Hydrogen and hydrogen production are respectively substance and activities ICPE classified. Inside INB/BNIs (basic nuclear installations also including NPP), the French nuclear regulator ASN manages the ICPE. Outside the INB/BNI, DREAL manages ICPE.

The integration of HPP in a NPP is not mentioned in TSN Act. According to Article 29 of TSN ACT, this integration could imply a change in the licensee boundary and a significant change in the installation.

The integration of HPP in a NPP is not mentioned in French Environment Code. In case that the HPP is integrated into a new installation, according to article L 593-7, the creation of the installation is subject to authorization. To obtain this authorization, the operator is requested to demonstrate that the technical or organizational measures adopted or conceived at the design, construction and operation stages, as well as the general principles proposed for decommissioning, are suitable to prevent or limit the risks or drawbacks that the facility presents for the protection of interests mentioned in Article L. 593-1 (public security, health and safety, protection of nature and the environment). The applicant is requested to provide a "dossier" that includes a preliminary version of the safety report, which specifies the risks to which the planned installation may expose the interests mentioned in Article L. 593-1, as well as an analysis of the measures taken to prevent these risks and a description of the measures to limit the probability of accidents and their effects.

The integration of HPP into an existing basic nuclear facility implies a significant modification of the basic nuclear facility. In accordance with Article L593-15 significant modifications to a basic nuclear installation are subject to declaration to the Nuclear Safety Authority, or to the authorization by this authority.

Although the integration of HPP into a NPP is not mentioned in the French Decree 2007-1557, from regulatory point of view the integration of HPP within a perimeter of an existing NBI/INB installation could be configured as significant modification of the NBI/INB and a change of its nature as per article 31 of French Decree 2007-1557 of 2 November 2007. In fact, the integration of HPP within a perimeter of INB/NBI implies a modification of the elements essential for protection of the interests mentioned in I of article 28 of the Act of 13 June 2006 (public security, health and safety, protection of nature and environment), which appear in the authorization decree pursuant to article 16 of the French Decree 2007-1557.

In case of integration of HPP in a new installation NPP, to build a basic nuclear installation, according to article 8 of Decree 2007-1557 of 2 November 2007, the documents to be prepared include the impact assessment and the preliminary safety case. Meaning, that the operator of the HPP integrated in a NPP in France shall be required to carry out regular safety assessments to identify potential hazards and risks and to ensure that appropriate measures are in place to control these risks.

With reference to HPP integrated into a NPP, the preliminary safety report should include a description of facilities, a description of safety functions applicable and preliminary list of elements important for the protection of interests, the analysis of operating situations. This analysis aims to identify potential incident-accident events, causes of postulated events, potential consequences, and the levels of defense in depth implemented in the integrated plant in terms of prevention, controls/detection and mitigative measures. For the events that cause potential release of hazardous

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(i.e. hydrogen)/radioactive substances into the environment specific evaluation of the release need to be carried out and quantified. Furthermore, this analysis leads to identify the bounding events and to evaluate the impact on operators, public and environment. The lines of defense in depth implemented include prevention means as well as control/detection and mitigation provisions including zonings. Typically, the zonings concern the following fire zoning, contamination zoning, ATEX zoning, The preliminary safety reports should provide safety and seismic classification of the systems, structures and components and identification of detailed defined safety requirement.

The integration of HPP with a NPP implies the introduction of an IED (Industrial Emissions Directives) activity as hydrogen production and a hazardous substance and mixture (Directive 2012/18/UE Seveso 3) as hydrogen; these represent, respectively, an activity/substance classified according ICPE regulation with nomenclature 3420 and 4715.

The authorization, known as an environmental authorization or environmental permit, is issued under the conditions provided for in the single chapter of Title VIII of Book I.

The installations classified for the protection of the environment subject to declaration under heading "4715" are subject to the provisions of Annex I of the Arrêté du 12/02/98. The provisions concern the declaration dossier documents and specific rules impacting layout, safety and security and environmental impact of the HPP.

Furthermore, the hydrogen storage and hydrogen distribution are regulated. The applicable rules depend on the quantities of hydrogen being stored.

The production of hydrogen in industrial quantities activity, ICPE classified (3420), is subject to authorization. This authorization is released after having demonstrated that the risks to the environment are mitigated, specific measures to prevent pollution of, and protect, water are implemented, and greenhouse gas emission are limited.

The Transportation of Hydrogen is subject to different regulations according to the modality adopted. Two different modalities of transportation have been identified: transportation via the pipelines of a dedicated transportation network or through the existing natural gas transportation network. In case of use of a dedicated pipeline, specific regulations need to be developed by the government. If the pipeline used for hydrogen transportation is part of the existing natural gas transportation network (this applies only to renewable hydrogen), the hydrogen transportation is regulated by the same regulations applied for natural gas.

Hydrogen storage is regulated. The relevant rules depend on the quantities of hydrogen being stored. The hydrogen storage is ICPE classified (4715).

Hydrogen-specific laws and regulations shall be introduced in France over the next months, one of these, the Law-Decree No 2021-167 of 17 February 2021 relating to hydrogen, has been introduced in 2021 and the implementing regulations shall be enacted in the coming months. The Law-Decree No 2021-167 of 17 February 2021 relating to hydrogen added the Book VIII in the Energy Code, related to "Provisions relating to hydrogen". The Law-Decree provides several clarifications on the legal framework for hydrogen, the implementing regulations shall be enacted in the coming months. Hydrogen produced from nuclear energy is defined as "low-carbon hydrogen". The Law-Decree introduces also a section dedicated to the self-consumption of hydrogen in the Energy Code (hydrogen produced and consumed on the same site). Furthermore, according to the Law-Decree No 2021-167 of 17 February 2021, the traceability system for the production of renewable and low-carbon hydrogen is introduced: the "guarantee of origin" (garanzia di origine) is issued for each megawatt-

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hour of energy. This guarantee certifies the origin of the renewable or low-carbon hydrogen. The Law-Decree No 2021-167 of 17 February 2021 relating to hydrogen, the produced hydrogen can be transported via new pipeline dedicated to the transport and storage of hydrogen or via the existing natural gas networks. Furthermore, the operators have the responsibility to ensure the safety conditions of goods and people, in addition to the proper functioning and balancing of the networks.

For Romania the following most important findings were concluded:

The integration of HPP in a NPP is not mentioned in the current Romanian legislation framework. Currently in Romania hydrogen is produced by steam methane reforming and by-product in chlor-alkali plants and is mostly used at the place of production. The Romanian Ministry of Energy is going to issue a national hydrogen strategy (expected date by 2023); this plan includes measures to develop the hydrogen supply chain in Romania, particularly for electrolyzer manufacturing. According to this strategy, clean hydrogen from renewable electricity shall be supported, involving public and private stakeholders, to outline a strategic roadmap with targets and potential funding sources.

It is expected that for the integration of HPP-NPP the actors involved could be those involved in the nuclear programme, together with the following authorities:

- Romanian Energy Regulatory Authority (ANRE) that is involved in the development, licensing and operation of new installations for hydrogen generation.
- Local Authority / Town and Country Planning Authority that is involved in issuing regulation for the use of land, in Environmental Impact Assessment and is also the competent hazardous substance authority in relation to storage.

The relevant regulations and guidance published by CNCAN that could support the licensing of the integrated plant NPP-HPP are the following:

- NSN-22 - Regulation on the licensing of nuclear installations (2019)
- NSN-14 (rev.1) - Regulation on the licensing of operating personnel, management personnel and personnel in charge of specific training, applicable to nuclear power plants, research reactors and other nuclear installations
- GSN-03 - Guide on fulfilling the overall nuclear safety objective set in the fundamental nuclear safety requirements for nuclear installations (2018)
- GSN-04 - Guide on the format and content of the final safety analysis report for nuclear power plants (2015)

The integration of HPP in a NPP is not mentioned in Law no.111/1996. If the HPP is integrated into a new installation, according to Article 8 of the Law no 111/1996, the design, placement, siting, construction, and commissioning of the installation is subject to authorization. To obtain this authorization, the operator is requested to demonstrate that the safety of the facility or proposed activity is ensured in normal, incidental, and accidental conditions and to give evidence of compliance with regulatory requirements. Any new technical solutions adopted need to be proven or qualified by experience or testing or both and is capable of achieving the required level of safety.

The integration of HPP into an existing NPP implies a modification of the basis licensing documents. The licensee is obliged to notify the Regulatory Body of any modifications impacts the safety of the facility.

The HPP integrated within a NPP is to be considered as part of the nuclear installation. A detailed nuclear safety analysis should be required of all nuclear and conventional (industrial) systems in order

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to ensure that the nuclear safety functions are ensured and all the potential impacts due to potential missiles, security issues, flooding events, or any other incident/accident that may influence a component involved in the safety function are assessed.

In general, there is the need to better consolidate of the legal framework, intensifying dedication to research and innovation (in both state-owned and private companies), increasing and diversifying funding sources and developing educational resources, as well as supporting projects that promote the increased use of hydrogen. For hydrogen production facilities in Romania, relevant guides, regulations, codes, and standards may be established by the Romanian Ministry of Energy. It is important to note that the specific codes, standards, and regulations applicable to a given hydrogen production facility in Romania depend on the location and operating conditions. Hydrogen production plants in Romania need to comply with the country's regulatory framework for environmental protection and industrial emissions, as well as with EU regulations. Environmental monitoring and reporting would be critical components of compliance with these regulations, and hydrogen power plant operators would need to work to minimize the impact of their operations on the environment.

9.2 Conclusions

In this chapter the findings from the various countries are summarized and combined into more global findings and conclusions.

HPP regulations in general

The technical installations of Hydrogen Production Plants (HPPs) do not have a specific hydrogen related regulatory regime to comply with. The requirements to fulfil are covered by various acts dealing with chemical and/or industrial installations with generic safety and risk requirements. The regulatory regime is determined by a number of national acts that are derived from the relevant EU-directives. For the design and construction of a HPP's the relevant EU-directives are:

- Seveso directive
- ATEX directive
- Pressure Equipment Directive (PED)
- Industrial Emissions Directives (IED)

The size of the facility and the amount and conditions under which hydrogen is stored are important factors for the safety distances that have to be taken into account. Smaller facilities are often so-called Categorical Facilities with standardized safety distances and a limited number of specific requirements.

Generally, the larger the facilities, the more requirements have to be fulfilled and the more calculations for determination of specific safety distances have to be performed. Overall, it has to be shown that the facility is safe and complies with all safety and risk-related regulations, technically, organization-wise and with respect to the environmental impact. The licensing process for a HPP is comparable to a chemical facility or storage facility for dangerous substances of equivalent size as the HPP.

NPP regulations in general

NPP's are highly regulated and all changes to the plant itself, to the direct environment or any additional hazard introduced that may cause damage to the plant, need to be justified from a safety point of view and may require a license modification.



Constructing an HPP near the NPP will most likely have influence on the NPP safety case and on the license, depending upon the distance and the utilities and systems shared. Various cases are described below:

- An HPP in the vicinity of the NPP but not on the NPP-site, may have impact on the NPP license. This will depend on the distance of the HPP to the NPP. The HPP should be outside the sanitary zone and/or risk contour of the NPP (where specific activities are prohibited) and the safety distance of the HPP should be smaller than the distance to the NPP. If those restrictions are fulfilled the HPP needs its own license and no impact on the NPP license is to be expected.
- In the case of an HPP on the NPP site, without any coupling or integration, the hydrogen activities need to be incorporated into the NPP license, which requires a license update. The license update consists of a description of the additional buildings, installations and an update of the licensed activities to include hydrogen production. In most countries the NPP license specifically mentions the activities that the NPP operator is allowed to perform: in this case the activities related to the generation of hydrogen need to be authorised in a license update.

A license update is also required because the NPP safety case also has to be updated, since the HPP is a potential additional hazard to the NPP. It has to be shown that this hazard does not in any case jeopardize the safety of the NPP. This can be shown by demonstrating that the HPP will not have any significant impact on the NPP installations and operation or that the necessary measures are taken to prevent an increase of the NPP-risk to the public and environment.

- When coupling a nuclear power plant to an HPP, safety reassessment is required to confirm that an appropriate level of safety is maintained in case of design modification. The safety assessment should be documented in a safety study, which should be updated to reflect the analyses and modifications made to the facility and site conditions. Depending upon the number of systems shared and the kind of modifications required, the safety case and license update can require significant effort, time and costs.
- Direct sharing of the electricity produced by the NPP, while having the HPP off-site at a significant distance would impose minimal licensing changes. The HPP would simply be seen as a consumer of electricity.

The preferred overall approach for co-generation of hydrogen is to look for shared systems that do not (or minimally) affect the nuclear safety of the NPP (for instance only sharing the electricity produced by the NPP).

The more the shared systems interfere with the safety (systems) of the NPP, the higher the economic benefit of sharing should be. The benefits should outweigh the cost of the technical modifications, the additional cost for a license update and the possible extra long time period required!

When the HPP and NPP share systems, the HPP becomes part of NPP and falls under the NPP license. This will impose all kind of limitations also on future modifications of the HPP. A separate license for HPP and NPP will give much more freedom and flexibility for future modifications.

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