

## **ENSREG Guidelines**

**Regarding Member States to submit Reports by 22 July 2020 as required under Article 9.1 of Council Directive 2009/71/Euratom of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations, as amended by the Council Directive 2014/87/Euratom of 8 July 2014 (hereafter called the Directive)**

### **I Introduction**

1. Under Article 9.1 Member States are required to submit a report to the Commission demonstrating how they are addressing their obligations under the Nuclear Safety Directive and illustrating their national approaches.
2. The Guidelines are intended to assist and ease the reporting work performed by each Member State (MS). They should assure effective and efficient reporting efforts for the MS by a balanced usage of other publications like the previous National Report for the Directive in 2014, the National Reports for the Convention on Nuclear Safety (CNS) and the Joint Convention (JC) and the reports from IAEA Integrated Regulatory Review Service (IRRS), whilst keeping the stand-alone character of the National Report.
3. They also provide guidance to MS regarding information that may be useful to include in their National Reports, and propose a common structure for reporting. The use of these Guidelines is voluntary. They have no legal status, neither do they set out to interpret, modify or extend the obligations of the Directive, the text of the Directive prevails. They are intended to be read in conjunction with the text of the Directive.
4. These Guidelines are developed from the initial ENSREG Guidelines on Member States Reports under the Directive 2009/71/Euratom (HLG\_p(2012-21)\_108), taking into account the amendments brought by the Directive 2014/87/Euratom. They also reflect, as appropriate, the MS's experience from the first 2014 reporting cycle, the Commission's findings and recommendations included in its 2015 Implementation Report (COM(2015) 573 final), as well as lessons learned from the transposition process of the Directive 2014/87/Euratom.
5. The Guidelines are also intended to support the Commission to meet its obligations under the requirement of Article 9.2 of the Directive to submit its report to the Council and European Parliament.

### **II General Principles**

#### **A Basic considerations on the content and structure of the report**

6. It is noted, that many Articles of the Directive cover similar content to the Articles under CNS or JC, even though there are differences in scope and reporting timeframes. In many respects, the Articles under the Conventions cover more details than is required under the Directive. However, in some aspects the Directive is more demanding than the Conventions.
7. The National Report should give a comprehensive, stand-alone, but concise overview to permit evaluation of the implementation of the obligations of the Directive. To achieve efficient and effective reporting MS are advised to take into account information from other existing publicly available reports (e.g. previous report under this Directive, CNS and JC – and/or IRRS-reports), make reference to specific parts of such sources for additional information, if needed and/or put (detailed) information and supporting data into annexes, as appropriate.
8. The National Report should follow an article-by-article approach and address all aspects of the obligations of the Directive, while the level of detail should be higher

for strengthened and/or new obligations and major developments in the MS since the previous report.

9. In this respect to illustrate the situation in the MS more clearly, MS should provide a number of key examples, as appropriate. The role of these examples is to highlight certain aspects of implementation of the Directive. They do not (necessarily) represent a comprehensive national approach and are not intended to be drawn upon for more general conclusions on an overall situation.
10. The National Report should provide:
  - information reflecting the status in the MS at the time of the release of the report;
  - Information about implementation at the national, regulatory and licence holder levels;
11. The total number of pages of a National Report should remain reasonable. For a Member State with nuclear installations in operation, it is suggested that this amount may be approximately 50 pages, excluding any necessary annexes. For a Member State without nuclear installations, this amount will be considerably less.
12. The National Report should have a table of contents and, if necessary, a list of acronyms, definitions or abbreviations should be included.
13. Duplication within the National Report should be avoided, for example, by cross-referencing where appropriate.
14. In order to facilitate the handling of National Reports, they should be prepared in the format A4 (297mm x 210mm), and should be submitted electronically to the Commission as a single PDF format file. In addition to submission to the Commission, Member States should send a copy to the ENSREG Secretariat.

## ***B Member States without nuclear installations***

The report to be submitted by a Member State without a nuclear installation may still follow the structure of Section III, addressing relevant articles of the Directive as appropriate considering its national arrangements.

### **III Detailed suggestions on the content of the National Report**

#### ***A Introduction***

Start with the basis and purpose of the report.

Then the National Report should provide a short overview of the Member State's civil nuclear programme. A list of all civilian nuclear installations (as defined in Article 3(1) of the Directive) within the Member State should be provided, together with a short description (such as columns with name, type of facility, capacity, status of licence):

- Nuclear power plant(s)
- enrichment plant(s)
- nuclear fuel fabrication plant(s)
- reprocessing plant(s)
- research reactor facility(ies)
- spent fuel storage facility(ies)
- storage facilities for radioactive waste that are on the same site and are directly related to nuclear installations listed above

## ***B Reporting article by article***

The following guidance provides examples of subjects that Member States might address, where appropriate, under each article of the Directive. These examples are not intended to exclude other issues that might also be relevant to demonstrate compliance with the obligations of the Directive.

The guidance provides for each article a comparison of the Articles of the Directive with the Articles of the CNS and the JC; Member States can use input from and/or refer to the latest reports prepared in the context of the review meetings of the Conventions to develop where useful their reporting under the Directive.

It is important to note that the definitions of 'nuclear installations' differ between the Directive and the Conventions. The effect of this is that both Conventions have to be considered when compiling the report for the Directive. Installations not covered by CNS/JC are fuel cycle facilities (enrichment, reprocessing, fuel fabrication). Research reactors are covered on a voluntary basis under the CNS.

A table is provided at the end of this document. It summarises which chapters of the CNS, JC and other documents can be used to address the reporting on the 2014 Directive articles. It also highlights (third column) which articles are new, as compared to the 2009 Directive (2014 National Reports).

## Article 4 – Legislative, regulatory and organisational framework

### Article 4

*1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (“national framework”) for the nuclear safety of nuclear installations.*

- Include a summary statement providing:
  - An overview of the national legislative, regulatory and organisational framework for the safety of nuclear installations.
  - A description of how the national framework is implemented by the regulatory authority and other organizations with responsibilities for nuclear safety oversight within the Member State as applicable.
  - Where the framework or its implementation varies for different types of nuclear installation, this should be identified.
  - Ratification of relevant international conventions and legal instruments related to the scope of the Directive, (e.g. Convention on Nuclear Safety, Joint Convention).

#### **Note:**

In general, MS reports addressing CNS Article 4 - *Implementing Measures* and Article 7.1 - *Legislative and Regulatory Framework* and Joint Convention Article 18 - *Implementing Measures* and Article 19.1 - *Legislative and Regulatory Framework* could provide input to this article. Specific paragraphs of the CNS / JC Articles, corresponding to letters (a)-(e) of Article 4 of the Directive are identified below.

### Article 4

*The national framework shall provide in particular for:*

*1. (a) the allocation of responsibilities and coordination between relevant state bodies;*

- Summarise how the national framework allocates responsibilities and ensures coordination between relevant state bodies with responsibilities that are under the scope of the Directive.

#### **Note:**

CNS and JC refer to a “Legislative and Regulatory Framework”, as mentioned above.

However, neither CNS nor JC specifically require that the national framework (which includes ‘administrative’ or ‘organisational’ aspects) provides coordination between relevant bodies.

However, JC Article 19.2 (vi) “Legislative and Regulatory Framework” does require that the legislative and regulatory framework shall provide for a clear allocation of responsibilities of the bodies involved in the different steps of spent fuel and of radioactive waste management.

### Article 4

*1. (b) national nuclear safety requirements, covering all stages of the lifecycle of nuclear installations;*

- Describe the nuclear safety requirements and in which instruments (e.g. laws, regulations) they are set, covering all stages of the lifecycle of nuclear installations that

require a licence or a set of licences according to the national system (e.g. siting, construction, commissioning, operation, decommissioning).

**Note:**

MS reports addressing CNS Article 7.2(i) - *Legislative and Regulatory Framework* and JC Article 19.2(i) - *Legislative and Regulatory Framework* could provide input to this article.

*Article 4*

*1. (c) a system of licensing and prohibition of operation of nuclear installations without a licence;*

- Describe the licensing process and system, identify the responsible bodies (e.g. responsibilities for issuing, need for consent by other entities, etc.), together with the types of licensed activities (particularly where these vary for different facilities).
- Describe the process and system for relicensing/licence renewal, if applicable.
- Identify the legal provisions to prevent the operation of a nuclear installation without a valid licence.

**Note:**

MS reports addressing CNS Article 7.2(ii) - *Legislative and Regulatory Framework* and JC Article 19.2(ii) and (iii) - *Legislative and Regulatory Framework* could provide input to this article.

*Article 4*

*1. (d) a system of regulatory control of nuclear safety performed by the competent regulatory authority;*

- Describe the system of regulatory control (oversight, i.e. assessment, inspection and control processes) of nuclear installations.

**Note:**

MS reports addressing CNS Article 7.2(iii) - *Legislative and Regulatory Framework* and JC Article 19.2(iv) - *Legislative and Regulatory Framework* could provide input to this article.

*Article 4*

*1. (e) effective and proportionate enforcement actions, including, where appropriate, corrective action or suspension of operation and modification or revocation of a licence.*

- Describe the enforcement responsibilities of the regulatory authority.
- Describe the regulatory authority's power of enforcement (e.g. fines, suspension, cancellation or withdrawal, revocation of licence).
- Describe the policy framework, which ensures enforcement decisions are both proportionate and effective.

**Note:**

MS reports addressing CNS Article 7.2(iv) - *Legislative and Regulatory Framework* and JC Article 19.2(v) - *Legislative and Regulatory Framework* could provide input to this article. JC does not specifically address the suspension of operation and modification or revocation of a licence. However, this might not be relevant if the "national framework" applies equally to all facilities.

*Article 4*

*The determination on how national nuclear safety requirements referred to in point (b) are adopted and through which instrument they are applied remains within the competences of the Member States.*

No reporting is needed. It is just a statement.

*Article 4*

*2. Member States shall ensure that the national framework is maintained and improved when appropriate, taking into account operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research, when available and relevant.*

- Describe the process of developing, adopting and revising national nuclear safety requirements, including the actors involved.
- Describe the arrangements for the improvement of the national framework for nuclear safety when appropriate that would take into account relevant return on operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research (including international developments).
- Provide specific examples of (recent) improvements to the national framework, as appropriate.

**Note:**

MS reports addressing CNS Article 7.1 - *Legislative and Regulatory Framework* and JC Article 19.1 - *Legislative and Regulatory Framework* could provide input to this article.

Neither CNS nor JC specifically require the regulatory framework to be 'maintained and improved when appropriate'.

**Article 5 - Competent regulatory authority**

*Article 5*

*1. Member States shall establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations.*

- Identify and describe the regulatory authority or authorities and its/their legal foundations.

**Note:**

Alternatively refer to 4(1)(a) if the response given there already covers this item.

## Article 5

2. Member States shall ensure the effective independence from undue influence of the competent regulatory authority in its regulatory decision-making. For this purpose, Member States shall ensure that the national framework requires that the competent regulatory authority:

(a) is functionally separate from any other body or organisation concerned with the promotion or utilisation of nuclear energy, and does not seek or take instructions from any such body or organisation when carrying out its regulatory tasks;

- Describe the position of the regulatory authority (RA) in the Member States' organisational structure/legal system, its powers, responsibilities and accountability (to whom is the RA accountable / reports to).
- Describe how the regulatory authority is functionally separate from the bodies responsible for promotion or utilisation of nuclear energy, including electricity production.
- Describe the mechanisms to ensure effective independence of the regulatory decision-making.

### Note:

MS reports addressing CNS Article 8.2 – *Regulatory Body* and Joint Convention Article 20.2 – *Regulatory Body* could provide input to this article.

For Article 8.2, the Guidelines regarding National Reports under the Convention on Nuclear Safety (INFCIRC 572) require an explanation of the “means by which independence of the regulatory body in making its safety-related decisions is assured”.

The Joint Convention under Article 20.2 requires “effective independence” of the regulatory functions.

## Article 5

2. (b) takes regulatory decisions founded on robust and transparent nuclear safety-related requirements;

- Describe the process for nuclear regulatory decision-making, highlighting the regulatory framework and controls in place to ensure effective independence from undue influences.
- Describe the nuclear safety-related requirements that are the basis of the decision-making (MS may wish to refer to article 4).
- Describe the regulatory authority's policy for transparency of its safety-related requirements and its implementation.
- Provide specific examples in respect to the transparency of the nuclear safety requirements (e.g. publication on the external website of the regulator, on other websites / official journal).

### Note:

Neither CNS nor JC draw these points out specifically.

#### Article 5

2. (c) *is given dedicated and appropriate budget allocations to allow for the delivery of its regulatory tasks as defined in the national framework and is responsible for the implementation of the allocated budget;*

- Describe the arrangements in place for the regulatory authority (RA) with regard to meeting its financial needs and explain, whether these financial resources are considered as sufficient. There should be described how the budget is earmarked for the RA and the power of the RA to decide about its spending alone. Also the mechanism to require additional budgets, when circumstances make it necessary, should be described.

**Note:**

MS reports addressing CNS Article 8.1 – *Regulatory Body* and Joint Convention Article 20.1 – *Regulatory Body* could provide input to this article.

#### Article 5

2. (d) *employs an appropriate number of staff with qualifications, experience and expertise necessary to fulfil its obligations. It may use external scientific and technical resources and expertise in support of its regulatory functions;*

- Describe the arrangements in place of the regulatory authority with regard to meeting its staffing needs, and an explanation on whether these personnel resources are considered sufficient. Similarly, include information on the arrangements / programmes in place to ensure that the regulatory authority employs staff with the adequate qualification, experience and expertise.
- Provide information on the non-in-house technical expertise to support its regulatory functions.

**Note:**

MS reports addressing CNS Article 8.1 – *Regulatory Body* and Joint Convention Article 20.1 – *Regulatory Body* could provide input to this article.

#### Article 5

2. (e) *establishes procedures for the prevention and resolution of any conflicts of interest;*

- Describe the provisions and mechanisms in place to prevent and resolve any conflicts of interest.  
In this context, provide information on how the following two specific situations are addressed: (i) conflicts of interest in the case of rotation of staff between the nuclear industry and the regulators and (ii) conflicts of interest in the case of organisations that provide the competent regulatory authority with advice or services e.g. Technical Support Organisations (TSOs).

**Note:**

Neither CNS nor JC draw these points out specifically. IAEA Safety Standard GSR Part 1 (Rev. 1) addresses the subject, e.g. under par. 2.40 (used for IRRS question set) and 4.7.

*Article 5*

2. (f) *provides nuclear safety-related information without clearance from any other body or organisation, provided that this does not jeopardise other overriding interests, such as security, recognised in relevant legislation or international instruments.*

- Describe the provisions in the national framework and competences of the regulatory authority on this subject.

**Note:**

Neither CNS nor JC draw these points out specifically.

*Article 5*

3. Member States shall ensure that the competent regulatory authority is given the legal powers necessary to fulfil its obligations in connection with the national framework described in Article 4(1). For this purpose, Member States shall ensure that the national framework entrusts the competent regulatory authorities with the following main regulatory tasks, to:

(a) *propose, define or participate in the definition of national nuclear safety requirements;*

- Describe the role in the preparation of national nuclear safety requirements, as entrusted to the regulatory authority in the regulatory framework and provide some recent examples.

**Note:**

Neither CNS nor JC draw these points out specifically.

Alternatively refer to 4.1. (b) if the response given there already covers this item.

*Article 5*

3. (b) *require that the licence holder complies and demonstrates compliance with national nuclear safety requirements ;*

- Describe the legal provisions in place by which the regulatory authority can require the licence holder to comply with the national nuclear safety requirements.

**Note:**

Neither CNS nor JC draw these points out specifically.

*Article 5*

3. (c) *verify such compliance through regulatory assessments and inspections;*

- Describe the legal arrangements in place for the regulatory authority to verify, by assessment and inspection, compliance with Art. 5 (3) (b).
- Provide key examples of implementation, as appropriate.

**Note:**

Alternatively refer to 4.1(d) if the response given there already covers this item.

Neither CNS nor JC draw these points out specifically.

## Article 5

### 3. (d) propose or carry out effective and proportionate enforcement actions.

- Describe the role of the regulatory authority to propose or carry out enforcement measures (e.g. fines, suspension, cancellation or withdrawal, revocation of licence).

#### **Note:**

Alternatively refer to 4.1(e) if the response given there already covers this item.  
Neither CNS nor JC draw these points out specifically.

## Article 6 – Licence holders

### Article 6

#### 1. (a) *the prime responsibility for the nuclear safety of a nuclear installation rests with the licence holder. That responsibility cannot be delegated and includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of a nuclear installation;*

- Describe how the national framework assign the responsibility for safety to the license holder, which includes the responsibility for the activities of contractors and sub-contractors that might affect the nuclear safety and which stipulates that this responsibility cannot be delegated.
- Provide succinct information on the practical implementation in respect to the contractors and subcontractors' activity.

#### **Note:**

MS reports addressing CNS Article 9 - *Responsibility of the Licence Holder* and JC Article 21.1 and 21.2 - *Responsibility of the Licence Holder* could provide input to this article.

Neither CNS nor JC explicitly require that the responsibility cannot be delegated. However, ensuring that “each such licence holder meets its responsibilities” (Art. 9 CNS) might be interpreted as ensuring that responsibility cannot be delegated.

Neither CNS nor JC specifically require that the responsibility includes responsibility for the activities of contractors and sub-contractors whose activities might affect the nuclear safety of nuclear installations.

### Article 6

#### 1. (b) *when applying for a licence, the applicant is required to submit a demonstration of nuclear safety. Its scope and level of detail shall be commensurate with the potential magnitude and nature of the hazard relevant for the nuclear installation and its site;*

- Describe the regulatory requirements for safety assessments and documentation that is required to be submitted when applying for a licence.
- Provide an overview on how the requirements for safety assessments and documentation are graded according to the potential magnitude and nature of the hazard relevant for the nuclear installation and its site.

**Note:**

The licencing process was already provided under 4.1.(c). Refer as appropriate. MS reports addressing CNS Article 14 – *Assessment and verification of safety* and JC Article 8/Article 15 – *Assessment of Safety of Facilities* could provide input to this article.

*Article 6*

*1. (c) licence holders are to regularly assess, verify, and continuously improve, as far as reasonably practicable, the nuclear safety of their nuclear installations in a systematic and verifiable manner. That shall include verification that measures are in place for the prevention of accidents and mitigation of the consequences of accidents, including the verification of the application of defence-in-depth provisions;*

- Describe the regulatory requirements for licensees to:
  - Perform a comprehensive and systematic safety assessment to demonstrate that hazards posed by a site are adequately controlled.
  - Periodically review, assess and verify safety assessments.
  - Demonstrate continuous improvement in nuclear safety as far as reasonably practicable.
- Describe the regulatory requirements that establish the basis for the verification of the measures for the prevention of accidents and mitigation of the consequences (including of defence-in-depth provisions).
- Describe the methods and approaches undertaken by the regulatory authority to verify the status of the implementation of the requirements by the licence holder.
- Provide examples of implementation, as appropriate.

**Note:**

Add reference to Art 8b as appropriate.

MS reports addressing CNS Articles 14.1 and 14.2 - *Assessment and Verification of Safety* together with JC Articles 8/15(i) and (ii) - *Assessment of Safety of Facilities* and 9/16(ii) - *Operation of Facilities* could provide input to this article.

MS reports addressing CNS Article 18(i) – *Design and Construction* together with JC Article 7/14(i) – *Design and Construction* could provide input from which reporting under this Article of the Directive can be developed although only aspects may apply.

Although continuous improvement is not explicitly mentioned in the CNS, MS were expected to report on the implementation of the Vienna Declaration on Nuclear Safety.

*Article 6*

*1. (d) licence holders establish and implement management systems which give due priority to nuclear safety;*

- Describe the requirements of the national framework for the licence holders to have management systems that give due priority to nuclear safety in all stages in the lifetime of the nuclear installation.
- Indicate which are the arrangements for the regular verification by the regulatory authority of the existence and adequacy of such management systems.

**Note:**

MS reports addressing CNS Article 10 – *Priority to Safety* and 23 – *Quality Assurance* could provide input from which reporting under Article 6(1)(d) of the Directive can be developed. JC does not address management systems.

*Article 6*

1. (e) *licence holders provide for appropriate 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. Those shall in particular:*

*(i) be consistent with other operational procedures and periodically exercised to verify their practicability;*

*(ii) address accidents and severe accidents that could occur in all operational modes and those that simultaneously involve or affect several units;*

*(iii) provide arrangements to receive external assistance;*

*(iv) be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents;*

- Describe the requirements of the national framework for the licence holders to provide for appropriate 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.
- Provide an overview of how the national framework requires the licence holders for their on-site emergency arrangements :
  - to be consistent with other operational procedures and periodically exercised to verify their practicability.
  - to address accidents and severe accidents that could occur in all operational modes and those that simultaneously involve or affect several units.
  - to provide arrangements to receive external assistance.
  - to be periodically reviewed and regularly updated, taking account of experience from exercises and lessons learned from accidents.
- Describe the methods and approaches undertaken by the regulatory authority to verify the status of the implementation of the requirements by the licence holder.
- Provide examples of implementation, as appropriate.

**Note:**

CNS Article 19 (iv) – *Operation* addresses procedures for responding to accidents, CNS Article 16.1 – *Emergency Preparedness* addresses on on-site emergency plans. JC does not cover the subject of procedures in relation to accidents.

*Article 6*

1. f) *licence holders provide for and maintain financial and human resources with appropriate qualifications and competences, necessary to fulfil their obligations with respect to the nuclear safety of a nuclear installation. Licence holders shall also ensure that contractors and subcontractors under their responsibility and whose activities might affect the nuclear safety of a nuclear installation have the necessary human resources with appropriate qualifications and competences to fulfil their obligations.*

Financial resources:

- Describe the requirements of the national framework for the licence holders to provide for and maintain adequate financial resources in order to fulfil their obligations with respect to nuclear safety of the nuclear installations.
- Describe the regulatory process for confirming the adequacy of the licence holder's financial resources.

Human resources:

- Describe the requirements for the licence holder to provide and maintain adequate human resources to assure nuclear safety.
- Describe the regulatory process for confirming the adequacy of the licence holder's human resources.

Contractors and Sub-Contractors:

- Describe the requirements of the national framework for the licence holders to ensure that contractors and subcontractors whose activities might affect the nuclear safety of their nuclear installations
  - Are appropriately qualified and competent.
  - Are subject to adequate oversight by the licensee.
- Describe the regulatory process for confirming the adequacy of the contractors and subcontractors' human resources and the oversight by the licensee.

**Note:**

MS reports addressing CNS Article 11.1 and 11.2 – *Financial and Human Resources* together with JC Article 22(i),(ii) and (iii) – *Financial and Human Resources* could provide input to this article.

Neither CNS nor JC specifically provide for a direct requirement on licence holders to provide these resources. Also neither CNS nor JC address contractors and sub-contractors.

**Article 7 – Expertise and skills in nuclear safety**

*Article 7*

*Member States shall ensure that the national framework requires all parties to make arrangements for the education and training for their staff having responsibilities related to the nuclear safety of nuclear installations so as to obtain, maintain and to further develop expertise and skills in nuclear safety and on-site emergency preparedness.*

Licence holders:

- Describe the legal requirements concerning education, training and retraining the staff of licence holders having responsibilities for the nuclear safety of nuclear installations. This description should explicitly include the requirements for obtaining, maintaining and further developing expertise and skills on nuclear safety and on-site emergency preparedness.

Regulatory authority:

- Describe the legal requirements for the education, training and retraining of the staff of the regulatory authority having responsibilities relating to the nuclear safety of nuclear installations. This description should explicitly include the requirements for obtaining, maintaining and further developing expertise and skills on nuclear safety and on-site emergency preparedness.

**Note:**

In the context of Article 7 both the licence holder and the regulatory authority should be considered in the National Report. In case there are other relevant entities at national level, this should be indicated.

MS reports addressing CNS Article 11.2 – *Financial and Human Resources* together with JC Article 22(i) – *Financial and Human Resources* could provide input to this article.

For CNS, this Article relates to skills etc. for licensee staff at nuclear power plants and for JC, this Article relates to skills etc. for licensee staff at spent fuel and radioactive waste management facilities.

As skills and expertise can be considered as a subset of competence, then CNS Article 8.1 together with JC Article 20.1 address the requirement of competence and human resources for the regulatory body.

**Article 8: Transparency**

*Article 8*

**Note:**

ENSREG has adopted “Principles for Openness and Transparency” in 2011 (document number HLG\_p(2011-14)\_57 which provides general guidance to National Regulatory Organisations in their communications activities.

ENSREG has also published a working paper on “Current Community and International Law with Relevance to Transparency” in 2009 (document number HLG\_p(2009-09)\_31), this working paper has been updated in 2016 (document number HLG\_r(2015-31)\_319).

These documents can be taken as a support to developing responses to Article 8.1 to 8.4 of this directive.

*Article 8*

*1. Member States shall ensure that necessary information in relation to the nuclear safety of nuclear installations and its regulation is made available to workers and the general public, with specific consideration to local authorities, population and stakeholders in the vicinity of a nuclear installation. That obligation includes ensuring that the competent regulatory authority and the licence holders, within their fields of responsibility, provide in the framework of their communication policy:*

*(a) information on normal operating conditions of nuclear installations to workers and the general public; and*

- Describe the legal requirements to licensees and regulatory authorities for making information available to workers and the general public during normal operation.

- Provide details of the regulatory authority's and licensee's communications policy and strategy to include descriptions of:
  - how the regulatory authority and the licensee provide information and communicates in its fields of competence to the general public and to workers (e.g. via website reports, workshops, conferences, interaction with the media etc.);
  - the type of information provided and the language used (e.g. translation into English);
  - examples of the involvement of local authorities, population and stakeholders in the vicinity of a nuclear installation;
  - the frequency of information provision including arrangements for ensuring that the information provided is up to date and easily accessible;
  - the categories of information that are not being provided and the legal basis that is limiting the access to information and appeal mechanisms.

#### Article 8

##### *1. (b) prompt information in case of incidents and accidents to workers and the general public and to the competent regulatory authorities of other Member States in the vicinity of a nuclear installation.*

- Describe the legal requirements to licensees and regulatory authorities for making information available to the public and workers in case of incidents and accidents.
- Describe how the licence holders and the competent regulatory authority, within their fields of responsibility, provide in the framework of their communication policy prompt information in case of incidents (system of reportable events) and accidents to workers and the general public.
- Describe the particular arrangements for providing information in emergency situations (national crisis communication arrangements).
- Describe the arrangements with and the kind of information provided to the competent regulatory authorities of other MS in the vicinity of a nuclear installation. Provide the name(s) of these MS countries.

#### Article 8

##### *2. Information shall be made available to the public in accordance with relevant legislation and international instruments, provided that this does not jeopardise other overriding interests, such as security, which are recognised in relevant legislation or international instruments.*

- Describe how the regulatory authority's and the licence holders' communication policies take into account and are consistent with other overriding interests, such as security if relevant, which are recognised in related legislation or international instruments.

#### Article 8

##### *3. Member States shall, without prejudice to Article 5(2), ensure that the competent regulatory authority engages, as appropriate, in cooperation activities on the nuclear safety of nuclear installations with competent regulatory authorities of other Member States in the vicinity of a nuclear installation, inter alia, via the exchange and/or sharing of information.*

- Describe the cooperation activities on information exchanges with competent regulatory authorities of other MS with regard to the nuclear safety of nuclear installations in the vicinity of the borders. Provide the name(s) of the countries to illustrate.

#### *Article 8*

*4. Member States shall ensure that the general public is given the appropriate opportunities to participate effectively in the decision-making process relating to the licensing of nuclear installations, in accordance with relevant legislation and international instruments.*

- Describe how the general public is given appropriate opportunities to participate effectively in the decision-making process relating to the main licensing stages of a nuclear installation (e.g. construction, operation, decommissioning...).
- In particular, Member States should include, if available, key examples of public participation activities and how the views of the public are taken into account.

#### **Article 8a: Nuclear safety objective for nuclear installations**

##### *Article 8a*

*1. Member States shall ensure that the national nuclear safety framework requires that nuclear installations are designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents and, should an accident occur, mitigating its consequences and avoiding:*

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

- Provide an overview of the legislation that requires nuclear installations to be designed, sited, constructed, commissioned, operated and decommissioned with the objective of preventing accidents.
- Provide an overview of the legislation and regulation that requires that an accident's consequences – should it occur – are mitigated. This should include:
  - the requirements that are put in place to avoid early radioactive releases which would require off-site emergency measures but with insufficient time to implement them;
  - the requirements that are put in place to avoid large radioactive releases which would require protective measures that could not be limited in area or time.

#### **Note:**

In the 7th National Report under the CNS MS were required to report on the Vienna Declaration on Nuclear Safety. JC Article 24.1(iii) addresses prevention of uncontrolled releases and Article 24.3 addresses appropriate corrective measures are implemented to control the release and mitigate its effects. This might help to develop a response to this Article under the Directive with a focus on the regulatory framework.

*Article 8a*

*2. Member States shall ensure that the national framework requires that the objective set out in paragraph 1:*

*(a) applies to nuclear installations for which a construction licence is granted for the first time after 14 August 2014;*

- Include a statement whether any construction license has been granted for the first time after 14 August 2014.
- In the affirmative case, describe the underlying concrete regulatory requirements through which the objective is to be achieved.
- Provide specific examples of practical implementation, as appropriate.

**Note:**

Details on initial assessment are provided under Article 8c (a).

*Article 8a*

*2. (b) is used as a reference for the timely implementation of reasonably practicable safety improvements to existing nuclear installations, including in the framework of the periodic safety reviews as defined in Article 8c(b).*

- Describe how this article is implemented through regulatory requirements and practices, covering the methodology, processes and criteria required for the identification and timely implementation of reasonably practicable safety improvements to existing installations.
- Provide examples of implementation of reasonably practicable safety improvements at existing nuclear installations according to objective Art. 8 a para 1, as appropriate.

**Note:**

ENSREG has adopted “WENRA Guidance Article 8a of the EU Nuclear Safety Directive: Timely Implementation of Reasonably Practicable Safety Improvements to Existing Nuclear Power Plants” 2017 (document number HLG\_M(2017-34)\_372 which provide general guidance to National Regulatory Organisations in their communications activities.

This documents can be taken as a basis to developing responses to Article 8a 2.(b) of this directive.

**Article 8b: Implementation of the nuclear safety objective for nuclear installations**

*Article 8b*

*1. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that where defence-in-depth applies, it shall be applied to ensure that:*

- (a) the impact of extreme external natural and unintended man-made hazards is minimised;*
- (b) abnormal operation and failures are prevented;*
- (c) abnormal operation is controlled and failures are detected;*
- (d) accidents within the design basis are controlled;*
- (e) severe conditions are controlled, including prevention of accidents progression and mitigation of the consequences of severe accidents;*

*(f) organisational structures according to Article 8d(1) are in place.*

- Provide an overview of the national or regulatory requirements with regard to the application of the defence-in-depth concept, covering point a) through f) whereby multiple independent barriers are provided as barriers to fault progression, for all nuclear installations.
- Describe requirements for provision of additional measures intended to mitigate the radiological consequences of accidents, especially severe accidents.
- Provide specific examples of practical implementation, as appropriate.

**Note:**

The content of Article 8b 1. (a)-(f) corresponds to the text required under CNS Article 18(1) as described in INFCIRC /572 Article 18(1), which could provide input to this article.  
8b 1. (f) is also covered by the answer to 8d (1).

*Article 8b*

*Implementation of the nuclear safety objective for nuclear installations*

*2. In order to achieve the nuclear safety objective set out in Article 8a, Member States shall ensure that the national framework requires that the competent regulatory authority and the licence holder take measures to promote and enhance an effective nuclear safety culture. Those measures include in particular:*

- Describe how the national regulatory framework requires the competent regulatory authority and the license holder to promote and enhance an effective nuclear safety culture.
- Provide practical examples of the application of this article at all levels in the organization of the regulator and licensee.

*(a) management systems which give due priority to nuclear safety and promote, at all levels of staff and management, the ability to question the effective delivery of relevant safety principles and practices, and to report in a timely manner on safety issues, in accordance with Article 6(d);*

- Describe how the national framework requires the licence holder to implement management systems and take measures to promote and enhance an effective nuclear safety culture, including the questioning of effective delivery of relevant safety principles and practices and the reporting in a timely manner on safety issues.

**Note:**

Refer, as appropriate, to text under Article 6 (d) which already describes the requirements of the national framework for a licence holder's management system that gives due priority to safety. Expand the information to include the regulatory authority.

*Article 8b*

*2. (b) arrangements by the licence holder to register, evaluate and document internal and external safety significant operating experience;*

- Describe the requirements to have arrangements to register, evaluate and document internal and external safety significant operating experience.

**Note:**

The content of Article 8b 2.(b) corresponds to the text required under CNS Article 19(7), which could provide input to this article. It also corresponds to JC Article 9 (ii) to (iv) as well as 16 (ii) and (iii).

*Article 8b*

*2. (c) the obligation of the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority; and,*

- Describe the requirements of the national framework for the licence holder to report events with a potential impact on nuclear safety to the competent regulatory authority.

**Note:**

The content of Article 8b 2.(c) corresponds to the text required under CNS Article 19(6), which could provide input to this article. It also corresponds to JC Article 9(v) and 16(vi).

*Article 8b*

*2. (d) arrangements for education and training, in accordance with Article 7.*

**Note:**

The description to Article 7 already gives extensive information on training and education for both the staff of the regulatory authority and the licence holder(s). Refer to this description in Article 7 to avoid duplication.

**Article 8c: Initial assessment and periodic safety reviews**

*Article 8c*

*Member States shall ensure that the national framework requires that:*

*(a) any grant of a licence to construct a nuclear installation or operate a nuclear installation, is based upon an appropriate site and installation-specific assessment, comprising a nuclear safety demonstration with respect to the national nuclear safety requirements based on the objective set in Article 8a;*

**Siting:**

- Provide an overview of the national framework's requirements relating to the siting and evaluation of sites of nuclear installations, including:
  - An overview of assessments made and criteria applied for evaluation of all site-related factors affecting the safety of the nuclear installation, with particular regard to the safety objective set in Article 8a.

**Design and Construction:**

- Provide an overview of the national framework's requirements relating to the design and construction of a nuclear installation, including:
  - An overview of regulatory requirements and regulations for new nuclear installations addressing the principles and safety objectives set out in Article 8a.
  - Incorporation of related technical criteria and standards for the design of new nuclear installations.

Initial assessment:

- Provide a description of safety assessments within the licensing process and of safety analysis reports for different stages in the lifetime of nuclear installations (siting, design, construction) including:
  - Evaluation of hazard assumptions (e.g. according to international best practice, using deterministic and probabilistic methods of analysis).

Provide succinct information on the practical implementation of the requirements of this Article, where appropriate.

**Note:**

This Article only applies to a construction licence that has been granted after 14 August 2014. Details on the licencing system in general are already provided under Article 1 (c).

**Note:**

The content of Article 8c (a) corresponds to the text required under CNS Articles 14(1), 17 and 18 which could provide input to this article.

*Article 8c*

*Member States shall ensure that the national framework requires that:*

*(b) the licence holder under the regulatory control of the competent regulatory authority, re-assesses systematically and regularly, at least every 10 years, the safety of the nuclear installation as laid down in Article 6(c). That safety reassessment aims at ensuring compliance with the current design basis and identifies further safety improvements by taking into account ageing issues, operational experience, most recent research results and developments in international standards, using as a reference the objective set in Article 8a.*

- Provide an overview of the national framework's requirements to perform periodic safety reviews in a systematic manner.
- Describe the role of the regulatory authority in periodic safety reviews.
- Indicate the date when the most recent PSR was performed. If publicly available, links to the PSR reports can be included.
- Please indicate how ageing issues, operational experience, most recent research results and developments in international standards are taken into account in the PSRs to identify further safety improvements. Provide recent examples of practical safety improvements identified during PSR.

**Note:**

MS National Report under the CNS Article 14(1) - *Assessment and verification for safety* could provide input to this article.

## Article 8d: On-site emergency preparedness and response

### Article 8d

*1. Without prejudice to the provisions of the Directive 2013/59/Euratom, Member States shall ensure that the national framework requires that an organisational structure for on-site emergency preparedness and response is established with a clear allocation of responsibilities and coordination between the licence holder, and competent authorities and organisations, taking into account all phases of an emergency.*

- Provide an overview of the national framework's requirements for an organizational structure for on-site emergency preparedness and response.
- Describe the requirements for a clear allocation of responsibilities and coordination between the licence holder, competent authorities and organisations. This description should take into account all phases of an emergency.
- Provide specific examples of practical implementation, as appropriate.

#### **Note:**

MS National Report under the CNS Article 16(1) - *Emergency preparedness* could provide input to this article.

### Article 8d

*2. Member States shall ensure that there is consistency and continuity between the on-site emergency preparedness and response arrangements required by the national framework and other emergency preparedness and response arrangements required under Directive 2013/59/Euratom*

- Describe which measures are taken to ensure that the national policy for emergency preparedness and response is consistent with EURATOM requirements (Directive 2013/59/Euratom).

Note: Member States had the obligation to bring into force the laws, regulations and administrative provisions necessary to comply with Directive 2013/59/Euratom by 6 February 2018.

## Article 8e: Peer reviews

### Article 8e

*1. Member States shall, at least once every 10 years, arrange for periodic self-assessments of their national framework and competent regulatory authorities and invite an international peer review of relevant segments of their national framework and competent regulatory authorities with the aim of continuously improving nuclear safety. Outcomes of such peer reviews shall be reported to the Member States and the Commission, when available.*

- Indicate the date of the last IRRS-Mission/Follow-Up-Mission, as well as, if available, of the next planned IRRS mission. A link to the latest IRRS and IRRS-FU report can be given.
- Provide information on the status of reporting of the IRRS mission reports to the Member States and the Commission.

*2. Member States shall ensure that, on a coordinated basis:*

- (a) a national assessment is performed, based on a specific topic related to nuclear safety of the relevant nuclear installations on their territory;*
- (b) all other Member States, and the Commission as observer, are invited to peer review the national assessment referred to in point (a);*
- (c) appropriate follow-up measures are taken of relevant findings resulting from the peer review process;*
- (d) relevant reports are published on the above mentioned process and its main outcome when results are available.*

- Provide a statement on MS participation in the TPR.
- MS may wish to make a link to the National information on the ENSREG website.

*3. Member States shall ensure that arrangements are in place to allow for the first topical peer review to start in 2017, and for subsequent topical peer reviews to take place at least every six years thereafter.*

*No reporting required.*

*4. In case of an accident leading to situations that would require off-site emergency measures or protective measures for the general public, the Member State concerned shall ensure that an international peer review is invited without undue delay.*

*Reporting required only if such an accident occurred.*

**Annex: list of potential input resources article by article**

NSD 2014 / key words	covered by articles of CNS-JC/other source	new vs. NR2014 for NSD 20
Article 4-summary	CNS 4/7.1 - JC 18/19.1	no
Article 4.1 a-respond and coordinate	Partially - JC 19.2	no
Article 4.1 b-requirements	CNS 7.2(i) - JC 19.2(i)	no
Article 4.1 c-licensing	CNS 7.2(ii) - JC 19.2(ii/iii)	no
Article 4.1 d-competency	CNS 7.2(iii) - JC 19.2(iv)	no
Article 4.1 e-enforcement	CNS 7.2(iv) - JC 19.2(v)	no
Article 4.2-maintain and improve	CNS 7.1 - JC 19.1	no
Article 5.1-competent		no
Article 5.2 a-separated	CNS 8.2 - JC 20.2	no
Article 5.2 b-robust and transparent		yes
Article 5.2 c-budget	CNNS 8.1 -JC 20.1	yes
Article 5.2 d-staff	CNNS 8.1 -JC 20.1	yes
Article 5.2 e-conflict of interest	IRRS	yes
Article 5.2 f-no clearance	IRRS	yes
Article 5.3 a-requirements definition		yes
Article 5.3 b-compliance		no
Article 5.3 c		no
Article 5.3d		no
Article 6.1 a-prime responsibility	CNS 9 - JC 21.1/21.2	no
Article 6.1 b-demonstration of NS	CNS 14 - JC 8/15	yes
Article 6.1 c-defence-in-depth	CNS 14.1/14.2/18 - JC 8/15/9/16/7/14	yes
Article 6.1 d-management	CNS 10/23	no
Article 6.1 e-emergency	CNS 19(iv)/16.1	yes
Article 6.1 f-HR	CNS 11.1/11.2 - JC 22 (i,ii,iii)	yes
Article 7-education	CNS 11.2 & 8.1- JC 22(i)&20.1	no
Article 8.1 a-information normal	ENSREG paper	yes
Article 8.1 b-information accident	ENSREG paper	yes
Article 8.2-overriding interests	ENSREG paper	yes
Article 8.3 neighboring MS	ENSREG paper	yes
Article 8.4-public participation	ENSREG paper	yes
Article 8a.1-prevent and mitigate	CNS/VD - JC24,1(iii)/24.3	yes
Article 8a.2 a-new NI		yes
Article 8a.2 b-existing NI	ENSREG/WENRA paper	yes
Article 8b.1-defence-in-depth	CNS 18(i)	no
Article 8b.2 a-NS culture		yes
Article 8b.2 b-document	CNS 19(vii) - JC 9(ii-iv)/16(ii/iii)	yes
Article 8b.2 c-report events	CNS 19(vi) - JC 9(v)/16(vi)	yes
Article 8b.2 d-arrangements for education	refere to article 7	no
Article 8c a-siting	CNS 14.1/17/18	no
Article 8c b-10 years visit	CNS 14.1	no
Article 8d 1-emergency preparedness	CNS 16.1	yes
Article 8d 2-consistency		yes
Article 8e.1- 10 year peer review	IRRS	no
Article 8e.2-TPR	TPR	yes