

ENSREG Guidelines regarding Member States
Reports 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

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I Introduction

These Guidelines were developed by the European Nuclear Safety Regulators Group (ENSREG) to assist Member States to fulfil the requirement of Article 9.1 of the Council Directive 2009/71/EURATOM of 25 June 2009 establishing a Community framework for the nuclear safety of nuclear installations (hereinafter called the Directive). Their purpose is to provide guidance to Member States regarding information and material that may be useful to include in the reports required under Article 9.1 ('National Reports'), and in this way establish a unified structure for reporting. These Guidelines are intended to be read in conjunction with the text of the Directive.

In the opinion of ENSREG, the reporting required under Article 9.1 should demonstrate how the Member States are addressing the objectives of the Directive by fulfilling their obligations under the Directive and illustrate their national approaches.

These Guidelines 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. The use of these Guidelines is voluntary and Member States have the right to submit their National Report with the form, length and structure they believe necessary to describe how they comply with the obligations under the Directive.

The Guidelines are generic in nature and drawn up to promote a mutual understanding of the structures and measures taken in individual Member States in regards to nuclear safety. To achieve this, they may extend beyond the legal obligations set out in the Directive.

The Guidelines, by providing a common structure of reporting, are also intended to enable the Commission to meet its obligations under the requirement of Article 9.2 of the Directive to submit a report to the Council and the European Parliament on progress made with the implementation of the Directive.

II General principles

A *Basic considerations*

The basic concept of the Directive is for Member States to ensure that they 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 intent of Article 9.1 of the Directive is for Member States to report, on a three yearly cycle, on how they have implemented the obligations of the Directive and to encourage the continuous improvement of nuclear safety and its regulation. This requires reporting on any changes since the last National Report while still reporting on the entirety of the obligations of the Directive.

Taking into account that:

- there is a need for the Commission to prepare its own report, based on Member States reports, which requires the National Reports to be in as similar a format as possible; and
- a flexible approach can be adopted in the writing of National Reports.

The report should:

- address in due detail all aspects of the obligations (in Articles 4 to 8 inclusive) of the Directive to enable the Commission, Council and Parliament to form a complete and comprehensive understanding of Member States' compliance;
- be both sufficiently comprehensive to permit a genuine evaluation of the extent of fulfilment of each obligation and sufficiently concise to make both writing and reviewing the National Report practicable;
- provide comprehensive information based on the actual situation;

- follow an article-by-article approach;
- clearly distinguish between the requirements stipulated in the national framework and the status of implementation of these requirements;
- clearly distinguish between implementation at the national, regulatory and licence holder levels;
- support the principle of continuous improvement by enabling other Member States and the Commission to identify any changes and achievements without losing sight of the overall context;
- be written in such a way as to make it comprehensible for an informed non-expert audience; and
- put detailed information and supporting data into annexes as appropriate.

B General suggestions on the structure and format of the National Report

The National Report should be a stand-alone report, rather than a report restricted to changes and updates only, to avoid the need for readers to reference and review earlier reports.

All information contained in the National Report should be explicitly connected to a specific Directive Article and should be structured in accordance with the subparagraphs within each Article. Detailed suggestions are contained in Section III.

The total number of pages of a National Report should not exceed a reasonable amount. For a Member State with nuclear installations in operation, it is suggested that this amount may be approximately 50 pages¹, excluding any necessary annexes. For a Member State without nuclear installations, this amount will be considerably less.

The National Report should have a table of contents and, if necessary, a list of acronyms, definitions or abbreviations should be included.

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 and ENSREG members as a single PDF format file.

C General suggestions on the content of the National Report

Each National Report should contain an Introduction and Summary as described in Section III.

The National Report should focus on describing the specific measures the Member State is implementing to address the obligations of the Directive.

Duplication within the National Report should be avoided, for example, by cross-referencing where appropriate.

If it is considered necessary to direct the reader to additional information, without undermining the stand-alone nature of the report, the National Report may make reference to other publicly available reports, including reports of national and international review missions. If feasible, any such references should be to publications available on the internet.

While the practice of supplementing National Reports with appropriate explanatory data in annexes is encouraged, the main body of the National Report itself should nevertheless contain all the key elements of information necessary to demonstrate how the Member State meets the obligations of the Directive.

Reports after the first National Report, while still being a stand-alone report, should highlight updated information on matters covered in the previous report(s), noting significant changes and progress relevant to the Directive. Member States are also

¹ This is an estimate which will be revised following the development of the example reports.

encouraged to address international review mission results, where applicable and appropriate, in their National Report.

D 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

The Introduction in the National Report should start by identifying which civilian nuclear installation(s), as defined in Article 3(1) of the Directive, are operating in the Member State under a licence, as defined in Article 3(4) of the Directive, at all stages covered by that licence.

This should be presented as a list of all installations, and a short description of each one (e.g. name, type of facility, capacity, under construction/operating/in decommissioning, together with information on associated radioactive waste facilities that are on the same site and are directly related to the nuclear installation):

- enrichment plant(s)
- nuclear fuel fabrication plant(s)
- nuclear power plant(s)
- reprocessing plant(s)
- research reactor facility(ies)
- spent fuel storage facility(ies)

After the first National Report this list should also identify changes since the last report.

The Introduction in the National Report should also include:

- general introductory remarks outlining the national policy towards nuclear activities;
- an overview of the national nuclear programme;
- a survey of the main safety issues addressed in the National Report; and
- an explanation on the preparation, structure and main features of the National Report (in particular if different from these guidelines).

B Summary

The Summary in the National Report should serve as a major information source by summarizing updated information on matters that have developed since the previous National Report, focussing on significant changes in national laws, regulations, administrative arrangements, and practices related to nuclear safety.

The Summary should address important issues relevant to the Directive that have been identified in the Member State's previous National Report or that have arisen since the previous National Report.

C Reporting article by article

The following lists provide useful examples of issues that Member States might address, where appropriate, under each article. The lists are structured in accordance with the given articles and sub-paragraphs 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.

Article 4 – Legislative, regulatory and organisational framework

Article 4

1. Member States shall establish and maintain a national legislative, regulatory and organisational framework (hereinafter referred to as the 'national framework') for nuclear safety of nuclear installations that allocates responsibilities and provides for coordination between relevant state bodies. The national framework shall establish responsibilities for:

(a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;

(b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;

(c) the provision of a system of nuclear safety supervision;

(d) enforcement actions, including suspension of operation and modification or revocation of a licence.

A summary statement providing:

- An overview of the national legislative, regulatory and organisational framework for nuclear safety of nuclear installations, including interfacing national legislation.
- A description of how the national framework is implemented by:
 - the regulatory body,
 - other organizations with responsibilities for nuclear safety within the Member State as applicable.
- Where these vary for different types of nuclear installation these should be identified.
- Information on how this national framework allocates responsibilities and provides for coordination between relevant state bodies.
- Ratification of relevant international conventions and legal instruments related to the scope of the Directive, e.g.:
 - Convention on Nuclear Safety
 - Joint Convention.

Article 4

1. The national framework shall establish responsibilities for:

(a) the adoption of national nuclear safety requirements. The determination on how they are adopted and through which instrument they are applied rests with the competence of the Member States;

- Identification of who is responsible for preparing and issuing national nuclear safety requirements.
- An overview of the process of establishing and revising national nuclear safety requirements, including the involvement of interested parties.

Article 4

1. *The national framework shall establish responsibilities for:*

(b) the provision of a system of licensing and prohibition of operation of nuclear installations without a licence;

- A description of the licensing process and system (e.g. responsibility for issuing, need for consent by other entities, etc.), together with the types of licensed activities (particularly where these vary for different facilities).
- The process and system for relicensing/licence renewal.
- The legal provisions to prevent the operation of a nuclear installation without a valid licence.

Article 4

1. *The national framework shall establish responsibilities for:*

(c) the provision of a system of nuclear safety supervision;

- A description of the system of safety supervision (oversight i.e. assessment, inspection and control processes) of nuclear installations.
- Responsible bodies (e.g. regulatory body, Technical Support Organisation (TSO), other organisations) for implementing the elements of the system of nuclear safety supervision.

Article 4

1. *The national framework shall establish responsibilities for:*

d) enforcement actions, including suspension of operation and modification or revocation of a licence.

- Legal powers/responsibilities for implementing enforcement measures.
- A description of the system of enforcement for the safety of nuclear installations.
- A description of enforcement measures available (e.g. fines; suspension; cancellation or withdrawal/revocation of licence).

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.

- A description of the arrangements for ensuring that the elements of the national framework for nuclear safety, as described in Article 4(1) remain effective (i.e. fulfil the goals set) and are not negatively affected by any changes.
- A description of the arrangements for the improvement of the national framework for nuclear safety that would take into account relevant operating experience, insights gained from safety analyses for operating nuclear installations, development of technology and results of safety research (including international developments).
- Specific examples, when available, of improvements to the national framework (since the last National Report).

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.

- Legal foundations of the regulatory authority or authorities.
- Identification of authority or authorities and their responsibilities (if there is a “system of authorities”).

Article 5

2. Member States shall ensure that the competent regulatory authority is functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.

- A description of the position of the regulatory authority in the MS organisational structure / legal system.
- A description of how the regulatory authority is functionally separate from the bodies responsible for promotion or utilisation of nuclear energy, including electricity production.
- A description of how effective independence of the regulatory decision making is ensured.
- A description of the reporting arrangements of the regulatory authority (to the parliament, government, specific ministries, etc) to illustrate their effective independence.

Article 5

3. Member States shall ensure that the competent regulatory authority is given the legal powers and human and financial resources necessary to fulfil its obligations in connection with the national framework described in Article 4(1) with due priority to safety. This includes the powers and resources to:

(a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;

(b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;

(c) verify this compliance through regulatory assessments and inspections; and

(d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).

- A description of the legal powers and human and financial resources of the regulatory authority; including identification of the legislation in which the required legal powers are conferred.
- A description of the arrangements in place for the regulatory authority (including the TSOs, where relevant) with regard to the availability of qualified human resources, including an explanation on whether this resource is considered sufficient (Annex A.1. provides one of the possible approaches that might be used to conclude on the sufficiency of human resources).
- A description of the arrangements in place for the regulatory authority with regard to meeting its financial needs (fees, taxes, etc.), and an explanation on whether these financial resources are considered sufficient (Annex A.2. provides one of the possible approaches that might be used to conclude on the sufficiency of financial resources).

Article 5

3. This includes the powers and resources to:

(a) require the licence holder to comply with national nuclear safety requirements and the terms of the relevant licence;

- A description of the legal provisions in place by which the regulatory authority can require the licence holder to comply with the national nuclear safety requirements and the terms of the relevant licence.
- A description of examples of implementation of these powers, if appropriate.

Article 5

3. *This includes the powers and resources to:*

(b) require demonstration of this compliance, including the requirements under paragraphs 2 to 5 of Article 6;

- A description of the legal provisions in place by which the regulatory authority can require the licence holder to demonstrate how it meets the nuclear safety requirements under paragraphs 2 to 5 of Article 6.
- A description of examples of implementation of these powers, if appropriate.

Article 5

3. *This includes the powers and resources to:*

(c) verify this compliance through regulatory assessments and inspections; and

- A description of the legal arrangements in place for the regulatory authority to verify, by assessment and inspection, that the licence holder:
 - regularly assesses, verifies and continuously improves nuclear safety;
 - ensures that measures are in place for prevention of accidents and mitigation of consequences;
 - establishes and implements management systems, giving due priority to nuclear safety; and
- A description of examples of implementation of these powers, if appropriate.

Article 5

3. *This includes the powers and resources to:*

(d) carry out regulatory enforcement actions, including suspending the operation of nuclear installation in accordance with conditions defined by the national framework referred to in Article 4(1).

- A description of the legal arrangements in place for the regulatory authority to ensure the enforcement process.
- A description of examples of implementation of these powers, if appropriate.

Article 6 - Licence holders

Article 6

1. Member States shall ensure that the prime responsibility for nuclear safety of a nuclear installation rests with the licence holder. This responsibility cannot be delegated.

A description of the legislation which assigns the responsibility for safety to the license holder and which stipulates that this responsibility cannot be delegated.

Article 6

2. Member States shall ensure that the national framework in place requires licence holders, under the supervision of the competent regulatory authority, to regularly assess and verify, and continuously improve, as far as reasonably achievable, the nuclear safety of their nuclear installations in a systematic and verifiable manner.

Note - Article 6.2 requires Member States to have a legal framework for licence holders to carry out certain activities. In ENSREG's view, the National Report on Article 6.2 need not provide a complete description of the implementation of the requirements for all licence holders. Nevertheless, providing some examples would illustrate the actual practices.

A description of:

- the regulatory requirements to perform systematic safety assessments within the licensing process for different stages in the lifetime of the nuclear installation;
- the regulatory requirements to perform regular verification of nuclear safety (e.g. in-service inspection, surveillance, functional testing of systems, etc.); and
- the regulatory requirements for continuous improvement in nuclear safety of the installation as far as reasonably achievable.

The National Report should give examples of how the licence holders address the following:

- the arrangements by the licence holder to perform systematic safety assessments on their installations;
- the arrangements by the licence holder for continuous improvement in nuclear safety (both hardware and operation), as far as reasonably achievable, taking account of operation experience, new safety insights and the results of safety assessments;
- the main elements of programmes for verification of safety including programmes to implement corrective actions; and
- the periodic safety assessments performed on nuclear installations (using deterministic and/or probabilistic methods of analysis, as appropriate).

Article 6

3. The assessments referred to in paragraph 2 shall include verification that measures are in place for prevention of accidents and mitigation of consequences of accidents, including verification of the physical barriers and licence holder's administrative procedures of protection that would have to fail before workers and the general public would be significantly affected by ionizing radiations.

A description of the regulatory requirements that establish the basis for the verification of the measures for the prevention of accidents and mitigation of the consequences as well as their implementation. Including:

- requirements for the measures for preventions of accidents during the design stage (e.g. general design criteria if present in national legislation);
- requirements for the measures for prevention of accidents during the operation (e.g. operation manuals and guidelines, operational limits and conditions); and
- requirements for mitigation of consequences of accidents (e.g. emergency planning and preparedness).

The National Report should give examples of how the licence holders address the following:

- measures to prevent incidents becoming accidents and minimising their consequences (e.g. redundant safety systems, physical barriers, emergency management procedures, severe accident guidelines etc.); and
- measures for the mitigation of the consequences (e.g. emergency preparedness).

The National Report should also include a description of methods and approaches undertaken by the regulatory authority in verifying the status of the measures implemented by the licence holder (of both the physical barriers and the administrative limits/procedures) to protect the workers and the public from effects of ionising radiation.

Article 6

4. Member States shall ensure that the national framework in place requires licence holders to establish and implement management systems which give due priority to nuclear safety and are regularly verified by the competent regulatory authority.

Note - Article 6.4 requires Member States to have a legal framework for licence holders to establish and implement specific management systems. In ENSREG's view, the National Report on Article 6.4 need not provide a complete description of the implementation of the requirement for all licence holders. Nevertheless, providing some examples would illustrate the actual practices.

A description of the requirements of the national framework for the licence holders to have (a) management system(s) that gives due priority to nuclear safety in all stages in the lifetime of the nuclear installation.

This description should include examples of main features of the management system implemented by licence holders.

The National Report should also include a description of the arrangements for regular verification by the regulatory authority of the existence and adequacy of such management system(s).

Article 6

5. Member States shall ensure that the national framework in place requires licence holders to provide for and maintain adequate financial and human resources to fulfil their obligations with respect to nuclear safety of a nuclear installation, laid down in paragraphs 1 to 4.

Financial resources

A description of the requirements of the national framework for the licence holder to provide for and maintain adequate financial resources in order to fulfil their obligations with respect to nuclear safety of the nuclear installation throughout its lifetime

Note - In ENSREG's opinion, the licence holder should be able to demonstrate to the appropriate national authorities that it has adequate financial resources available for all phases of the lifetime of the nuclear installation. That should also include adequate financial resources for systematic safety assessments and safety improvements.

Therefore, the description should include the process for confirming the adequacy of licence holders financial resources.

Human resources

A description of the requirements of the national framework for the licence holder to provide for and maintain adequate human resources in order to assure nuclear safety of the nuclear installation throughout its lifetime.

Note - In ENSREG's opinion, the licence holder should be able to demonstrate to the regulatory authority that it has adequate human resources, with the expertise and skills required under Art. 7, available for each phase of the lifetime of the nuclear installation. These human resources may be permanent or temporary staff as well as contractors.

Therefore, the description should include the process for confirming the adequacy of licence holders human resources.

Article 7 – Expertise and skills in nuclear safety

Article 7

Member States shall ensure that the national framework in place requires arrangements for education and training to be made by all parties for their staff having responsibilities relating to the nuclear safety of nuclear installation in order to maintain and to further develop expertise and skills in nuclear safety.

Note - In the context of Article 7, in ENSREG's view, whilst responsibilities related to nuclear safety of nuclear installations lie primarily with the licence holder, the regulatory authority nonetheless has some responsibilities related to nuclear safety. These two bodies should be considered in the National Report.

Licence holders

A description of the legal requirements concerning education, training and retraining the staff of licence holders having responsibilities for the nuclear safety of nuclear installations.

A description of the system established by the licence holder to implement the requirements of Article 7. For example, this may include:

- Methods used for the analysis of competence requirements and training needs for all safety related activities in nuclear installations.
- Arrangements for initial training and retraining of operations staff, including simulator training.
- Capabilities of plant simulators used for training with regard to fidelity to the plant and scope of simulation.
- Arrangements for training of maintenance and technical support staff within the licensee.
- Arrangements for the improvement of training programmes as a result of new insights from safety analyses, operational experience, development of training methods and practices, etc.

Regulatory authority

A description of the national arrangements for the education, training and retraining of the staff of the regulatory authority having responsibilities relating to the nuclear safety of nuclear installations.

A description of the system established by the regulatory authority to implement the requirements of Article 7. For example, this may include:

- Methods used for the analysis of competence requirements and training needs for all safety related activities.
- Arrangements for initial training and retraining of staff.
- Arrangements for the improvement of training programmes as a result of new insights from safety analyses, operational experience, development of training methods and practices, etc.

Additional information

Further guidance on training for the regulatory authority might be found in the following IAEA document: *GS-G-1.1 "Organisation and staffing of the Regulatory Body for Nuclear Facilities"*.

Article 8: Information to the public

Article 8

Member States shall ensure that information in relation to the regulation of nuclear safety is made available to the workers and the general public. This obligation includes ensuring that the competent regulatory authority informs the public in the fields of its competence. Information shall be made available to the public in accordance with national legislation and international obligations, provided that this does not jeopardise other interests such as, inter alia, security, recognised in national legislation or international obligations.

Description of the legal requirements for making information available to the public and workers on the regulation of nuclear safety.

Details of the regulatory authority's communications strategy to include descriptions of:

- how the regulatory authority provides 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);
- the frequency of information provision including arrangements for ensuring that the information provided is up to date and easily accessible;
- particular arrangements for providing information in emergency situations;
- the categories of information that are not being provided and the legal basis that is limiting the access to information and appeal mechanisms;

Additional information:

ENSREG has adopted "Principles for Openness and Transparency" in 2011 (document number HLG_p(2011-14)_57) which provide general guidance to National Regulatory Organisations in their communications activities. The principles are challenging and go beyond the legal obligations set out in Article 8. They are generic in nature and may need to be adapted to the organisational structures in individual Member States.

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).

Annex A

Potential approaches to the assessment of resources of the regulatory authority - Article 5(3)

A.1. Human resources

The assessment of the adequacy of human resources (staffing, qualifications, training etc.) of the regulatory authority would ideally be based on a systematic approach². This should consider all the duties of the regulatory authority, as required by the applicable national legal framework, which address the obligations of Article 5(3) of the Directive, including the obligations of Article 4(1).

The systematic approach should include an estimate of the resources needs as related to each element of Article 5(3) of the Directive.

The systematic approach should, as applicable, take account of, but need not be limited to:

- National legal framework and regulatory infrastructure.
- Various types and the number of nuclear installations.
- Number of licence holders.
- Regulatory framework (prescriptive, goal-setting etc.) adopted.
- Regular or continuous, as well as ad-hoc tasks within each element of Article 5(3) of the Directive.
- Regulatory authority staffing structure, whether permanent, dedicated contract staff or support from adequate TSOs (when the availability of resources to pay for those should be taken into account).

² The systematic approach may be a task analysis.

A.2. Financial resources

Similarly, the assessment of the adequacy of financial resources of the regulatory authority would ideally be based on a systematic approach.

Consideration should, as applicable, be given to, but need not be limited to:

- Funding being available for all staff resources as determined by the systematic approach under point 1.
- Adequacy of salaries to attract and retain staff with necessary qualifications (e.g. competitive with the industry).
- Funding for:
 - operating budgets;
 - financial resources to engage TSOs;
 - offices and equipment;
 - communications and transport;
 - training.

Additional information

Further guidance on resources might be found in the following IAEA document: *GS-G-11 "Organisation and staffing of the Regulatory Body for Nuclear Facilities"*

Appendix – Relevant Articles of the CNS and Joint Convention

The objective of this Appendix is to assist Member States (MS) developing their National Report in compliance with Article 9.1 of the Council Directive 2009/71/Euratom, establishing a Community framework for the nuclear safety of nuclear installations ('the Directive'), by providing a comparison of the Articles and Obligations of the Directive with the Articles of the Convention on Nuclear Safety (CNS) and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management (JC or 'Joint Convention').

The Appendix identifies which aspects of their CNS and JC reports could be used to assist MS and to identify where MS may need to provide information in addition to that currently required by the Convention obligations.

It should be borne in mind that the CNS and JC reports are out of phase in time with the Directive report and therefore data may need updating.

General

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 and that, where appropriate, installations covered by neither Convention (e.g. research reactors) may need additional information.

Article 4.1

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* should provide text from which a response to this Article of the Directive can be developed.

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 - *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 (a)

MS reports addressing CNS Article 7.2(i) - *Legislative and Regulatory Framework* and JC Article 19.2(i) - *Legislative and Regulatory Framework* should provide text from which a response to this Article of the Directive can be developed.

Article 4.1 (b)

MS reports addressing CNS Article 7.2(ii) - *Legislative and Regulatory Framework* and JC Article 19.2(ii) and (iii) - *Legislative and Regulatory Framework* should provide text from which a response to this Article of the Directive can be developed.

Article 4.1 (c)

MS reports addressing CNS Article 7.2(iii) - *Legislative and Regulatory Framework* and JC Article 19.2(iv) - *Legislative and Regulatory Framework* should provide text from which a response to this Article of the Directive can be developed.

Article 4.1 (d)

MS reports addressing CNS Article 7.2(iv) - *Legislative and Regulatory Framework* and JC Article 19.2(v) - *Legislative and Regulatory Framework* should provide text from which a response to this Article of the Directive can be developed.

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 4.2

MS reports addressing CNS Article 7.1 - *Legislative and Regulatory Framework* and JC Article 19.1 - *Legislative and Regulatory Framework* should provide some text from which a response to this Article of the Directive can be developed.

Neither CNS or JC specifically refer to a ‘national framework’ or that it be maintained and improved when appropriate.

Other articles of CNS that cover this subject: include Article 14 – ‘*Assessment*’ which refers to “*comprehensive and systematic safety assessments... throughout its life. Such assessments shall be well documented, subsequently updated in the light of operating experience and significant new safety information*” and Article 19 – ‘*Operation*’ which refers to “*programmes to collect and analyse operating experience are established, the results obtained and the conclusions drawn are acted upon and that existing mechanisms are used to share important experience with international bodies and with other operating organizations and regulatory bodies*”.

Additionally, some reference is made in JC Article 9/16(vi) – ‘*Operation of Facilities*’ which requires that “*programmes to collect and analyse relevant operating experience are established and that the results are acted upon, where appropriate*”.

Article 5.1

MS reports addressing CNS Article 8.1 – *Regulatory Body* and JC Article 20.1 – *Regulatory Body* should provide text from which a response to this Article of the Directive can be developed.

Article 5.2

MS reports addressing CNS Article 8.2 – *Regulatory Body* and Joint Convention Article 20.2 – *Regulatory Body* should provide text from which a response to this Article of the Directive can be developed.

CNS does not specifically require functional separation from another organisation or body concerned with the utilisation of nuclear energy, including electricity production.

Article 5.3

MS reports addressing CNS Article 8.1 – *Regulatory Body* and Joint Convention Article 20.1 – *Regulatory Body* should provide text from which a response to this Article of the Directive can be developed.

Whilst the CNS and JC nominally cover this Article, the Directive requires more substantiation, as discussed in Annex A.

Article 5.3(a) – (d)

Neither CNS or JC draw these points out specifically. MS will have to provide additional information on powers and resources of regulatory authorities.

Article 6.1

MS reports addressing CNS Article 9 - *Responsibility of the Licence Holder* and JC Article 21.1 and 21.2 - *Responsibility of the Licence Holder* should provide text from which a response to this Article of the Directive can be developed.

Neither CNS or JC specifically require that the responsibility cannot be delegated. However, ensuring that “each licence holder meets its responsibilities” might be interpreted as ensuring that responsibility cannot be delegated.

Article 6.2

MS reports addressing CNS Articles 13 - *Quality Assurance* and 14.1 and 14.2 - *Assessment and Verification of Safety* together with JC Articles 23 - *Quality Assurance*, 8/15(i) and (ii) - *Assessment of Safety of Facilities* and 9/16(ii) - *Operation of Facilities* should provide text from which a response to this Article of the Directive can be developed.

CNS requires assessment to be updated but not continuous improvement. JC does not require the regular assessment and verification, and continuous improvement, as far as reasonably achievable, of the nuclear safety of nuclear installations in a systematic and verifiable manner.

Installations not covered by CNS/JC: Fuel cycle facilities (enrichment, reprocessing, fuel fabrication, research reactors (covered on a voluntary basis)).

Article 6.3

MS reports addressing CNS Articles 15 – *Radiation Protection* and 18(i) – *Design and Construction* together with JC Articles 24.1(i),(ii) and (iii) – *Operational Radiation Protection* and 7/14(i) – *Design and Construction* should provide text from which a response to this Article of the Directive can be developed.

Neither CNS or JC specifically detail what the assessment should contain, but aspects of the reports noted above may apply.

Article 6.4

MS reports addressing CNS Article 10 – *Priority to Safety* may provide text from which a response to this Article of the Directive can be developed.

CNS does not specifically require regular verification and ‘management systems’ might be seen as more specific than the requirements of the CNS. JC does not address management systems.

Article 6.5

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* may provide text from which a response to this Article of the Directive can be developed.

Neither CNS or JC specifically provide for a requirement on licence holders to provide the resources.

Article 7

MS reports addressing CNS Article 11.2 – *Financial and Human Resources* together with JC Article 22(i) – *Financial and Human Resources* may provide text from which a response to this Article of the Directive can be developed.

CNS relates only to skill etc. for licensee staff at nuclear power plants and JC relates only for skills etc. for licensee staff at spent fuel and radioactive waste management facilities.

Article 8

Not specifically required by either CNS or JC.